COMMITTEE ON OVERSIGHT AND REFORM

SELECT SUBCOMMITTEE ON THE CORONAVIRUS CRISIS

U.S. HOUSE OF REPRESENTATIVES

WASHINGTON, D.C.

INTERVIEW OF: STEPHEN M. HAHN, M.D.

Friday, January 28, 2022

The Interview Commenced at 8:16 a.m.

Appearances:

For the DEMOCRATIC STAFF (MAJORITY):
[Redacted]

For the REPUBLICAN STAFF (MINORITY):
[Redacted]

For the CDC and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES:
KEVIN BARSTOW, Senior Counsel

-- Continued --

Appearances:

For the WITNESS:
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Exhibits

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P R O C E E D I N G S

[Majority Counsel]. Good morning. This is a transcribed interview of Dr. Stephen Hahn conducted by the House Select Subcommittee on the Coronavirus Crisis. This interview was requested by Chairman James Clyburn as part of the Committee's oversight of the federal government's response to coronavirus.

I'd like to ask the witness to state his full name and spell his last name for the record.

The Witness. Stephen Michael Hahn, H-A-H-N.

[Majority Counsel]. Thank you.

BY [Majority Counsel].

Q Dr. Hahn, my name is [Redacted]. I am [Redacted] for the Select Subcommittee Majority staff. I want to thank you for coming in today for this interview. We recognize that you are here voluntarily and we appreciate that.

Under the Committee's rules you are allowed to have an attorney present to advise you during this interview. Do you have an attorney representing you today?

A I do.

[Majority Counsel]. Would counsel for Dr. Hahn please identify themselves for the record.

Mr. Armstrong. Chris Armstrong with Holland & Knight.

Ms. Klock. Sara Klock at Holland & Knight.

[Majority Counsel]. Thank you. Can the additional staff in the room please identify themselves for the record.

Mr. Barstow. Kevin Barstow, HHS.

[Redacted]. [Redacted] with the Republican staff.

[Redacted]. [Redacted] with the Republican staff.

[Redacted]. [Redacted] with the Republican staff.

[Redacted]. [Redacted], Majority counsel.

[Redacted]. [Redacted], Majority counsel.

[Redacted]. [Redacted] with the Majority.

[Majority Counsel]. Before we begin, I would like to go over the ground rules for this interview. The way this interview will proceed is as follows:

The Majority and Minority staffs will alternate asking you questions, one hour per side per round, until each side is finished with questioning. The Majority staff will begin and proceed for an hour and then the Minority staff will have an hour to ask questions. We'll alternate back and forth in this manner until both sides have no more questions.

We have agreed that if we're in the middle of a line of questioning, we may end a few minutes before or go a few minutes past an hour just to wrap up a particular topic. In this interview, while one member of the staff may lead

the questioning, additional staff may ask questions from time to time.

There is a court reporter taking down everything I say and everything you say to make a written record. For the record to be clear, please wait until I finish each question before you begin your answer and I will wait until you finish your response before asking you the next question. The court reporter cannot record nonverbal answers such as shaking your head, so it's important that you answer each question with an audible verbal answer.

Do you understand?

A Yes.

Q We want you to answer questions in the most complete and truthful manner possible, so we're going to take our time today. If you have any questions or do not understand any of the questions, please let us know. We will be happy to clarify or rephrase the question.

Do you understand?

A Yes.

Q If I ask you about conversations or events in the past and you're unable to recall the exact words or details, you should testify to the substance of those conversations or events to the best of your recollection. If you recall only a part of a conversation or event, you should give us your best recollection of those events or

parts of conversations that you do recall.

Do you understand?

A Yes.

Q If you need to take a break, please let us know. We're happy to accommodate you. Ordinarily we take an approximately five-minute break at the end of each hour of questioning, but if you need a break before then, just let us know. To the extent that there is a pending question, however, I would just ask that you finish answering the question before you take a break.

Do you understand?

A Yes.

Q Although you are here voluntarily and we will not swear you in, you're required by law to answer questions from Congress truthfully. This also applies to questions posed by congressional staff in an interview.

Do you understand?

A Yes.

Q If at any time you knowingly make false statements, you could be subject to criminal prosecution.

Do you understand?

A Yes.

Q Is there any reason that you are unable to provide truthful answers in today's interview?

A No.

Q The Select Subcommittee follows the rules of the Committee on Oversight and Reform. Please note that if you wish to assert a privilege over any statement today, that assertion must comply with the rules of the Committee on Oversight and Reform.

Committee Rule 16(c)(1) states: "For the chair to consider assertions of privilege over testimony or statements, witnesses or entities must clearly state the specific privilege being asserted and the reason for the assertion on or before the scheduled date of testimony or appearance."

Do you understand?

A Yes.

Q Do you have any questions before we begin?

A No.

Q To start off, I would like to ask you about your background.

Where did you attend school and what degrees did you obtain?

A I received a Bachelor of Arts from Rice University in Houston, Texas, an M.D. at Temple University in Philadelphia, a residency in internal medicine, University of California, San Francisco, a medical oncology fellowship at the National Cancer Institute in Bethesda, Maryland, and a radiation oncology residency at the

National Cancer Institute in Bethesda.

Q Thank you. Can you briefly describe your professional experience?

A I am a physician, lung cancer and sarcoma specialist, as well as a cancer researcher. I spent 18 years at the University of Pennsylvania, and then went to the MD Anderson Cancer Center at the University of Texas.

Q I understand that you were nominated by the former President to serve as FDA Commissioner on November 1, 2019 and were confirmed on December 12, 2019. When did you ultimately start at the FDA?

A Toward the end of December 2019. I don't remember the exact date.

Q What were you focused on in your first few weeks at FDA?

A Getting to know the agency, understanding the culture, building trust, and really understanding how the agency ran. A big complicated place.

Q At FDA, how many people directly reported to you?

A I don't know the exact number. There are approximately 18,000 employees at FDA.

Q I assume some of those had a dotted line and some were direct reports; is that correct?

A Correct. Most of the directors in the

Commissioner's office were direct reports, as well as the center directors at the seven centers.

Q At FDA, who did you work most closely with on issues related to the coronavirus pandemic response?

A I worked closely with all of the center directors of the seven centers, and ORA, which is the center that's related to inspections, and to the staff within the Commissioner's office. So, for example, Office of Chief Counsel and chief of staff.

Q Did that also include Dr. Amy Abernethy?

A Yes.

Q What was her role?

A She was principal deputy commissioner.

Q Did she -- strike that.

Was she responsible for particular issues or aspects of the response?

A Yes.

Q What were they?

A She was responsible for helping us collect real-world evidence during the response, as well as our tech modernization and other data modernization, for example.

Q Did you have a chief of staff?

A I did.

Q What was their name?

A Keagan Lenihan.

Q And what was Ms. Lenihan's role and responsibility with respect to COVID response specifically?

A So she was responsible in the Commissioner's office for coordinating across the different centers for the Commissioner's office. The Commissioner's office does not have direct responsibility typically for decisionmaking, so coordination among the individual centers where that decisionmaking takes place is required.

Q So how would that work in practice? Would a center or a division head make a decision and you would just be notified of it?

A Typically, that's what would happen. It really depends upon the level of significance of the decision. COVID was, of course, very different, but at normal times for routine decisions regarding products, they're made at the center level. The center director may bring it up to the chief of staff and the Commissioner, but may not.

Q You mentioned that there were some differences during the pandemic as well as perhaps some differences in how significant issues would have been handled. What would be the protocol in those instances?

A Just to clarify. Protocol during COVID of the differences?

Q That's right.

A Okay. So early on in the pandemic, we set up an emergency response team very similar to what you would do in a healthcare setting if there was a natural disaster or something like that. And comms was at the table, all the senior leadership, typical sort of thing you'd see in an emergency response.

And we set that up from the beginning because we wanted to coordinate our response, understand what our steps to our responsibilities were, and also allocate resources appropriately.

Q When was the emergency response team set up?

A I believe the end of January. I can't give you the exact date. It was either end of January or early February, one of the two.

Q You mentioned that the emergency response team included senior leadership. Who specifically?

A Center directors as well as members of the Commissioner's office.

Q In the Commissioner's office, who would that have included?

A I know that there was representation of OCC, so Office of Chief Counsel, Keagan Lenihan, the chief of staff was involved. I can't recall everybody who was on there from the office.

Q Outside of FDA, who did you work most closely with on issues related to the pandemic response?

A Typically, that would involve the other doctors on the task force. So Dr. Birx, Dr. Redfield, and Dr. Fauci.

Q How often did you communicate with the doctors on the task force?

A Regularly. It depended on the intensity, of course, of what we were seeing around the country, but of course daily, including weekends.

Q Generally speaking, what issues were you focused on in those communications with the doctors on the task force?

A They were typically related to medical issues and public health issues. So testing, for example, PPE shortages, the development of diagnostics, therapeutics. We spent a lot of time talking about the development of diagnostics, for example.

Q Apart from the doctors on the task force, were there others in the White House or at agencies that you also worked very closely with on the pandemic response?

A [Majority Counsel], I guess it depends on what you mean by "closely." Typically on that White House task force, there would be close relationships, you know, Secretary of Transportation, you know, occasionally

Secretary of State, et cetera, I had occasion to communicate with. But, in general, it was the doctors that I worked the most closely with.

Q Thank you. Who were your main points of contact in the White House specifically?

A That changed as, number one, the course of the pandemic went on and, number two, was staff changed. So initially it was Joe Grogan, and then in the White House itself the Vice President's office because he was in charge of the White House task force, Marc Short and Mark Meadows, chief of staff for the President, sorry.

Q Of course. Was there anyone else in the White House -- strike that.

Were there support staff for the White House Coronavirus Task Force that you communicated with regularly?

A Yes.

Q Who were they?

A Olivia Troye in the Vice President's office. And I'm sure there were others. But that's just who I remember.

Q On January 29, 2020, President Trump announced the formation of the coronavirus task force, which was originally chaired by Secretary of Health and Human Services Alex Azar, and had 12 total members including

Dr. Redfield and Dr. Fauci. You were not originally named as a member of the task force; is that right?

A That's correct.

Q When were you ultimately named to the task force?

A I was named at the end of February when Vice President Pence took over.

Q Did you have any role in advising the task force during that period, from its formation through the end of February?

A Not directly me personally. FDA was involved in the groups at the White House that were at the staff level.

Q Prior to joining the task force, are you aware whether there were any discussions about having you join?

A I am not aware of any discussions that took place within the task force.

Q What about outside the task force?

A Well, I was called by Joe Grogan. And he didn't refer to specific discussions that I can remember, just his opinion that I should be included in the task force.

Q Are you aware why he was of the opinion that you should be added to the task force?

A He thought it would be appropriate to have FDA

input. That was my understanding.

Q Did anyone advocate for you to be a member of the task force?

A I don't know.

Q Are you aware if anyone advocated against having you join the task force?

A I'm not aware of that.

Q Why was there a delay in making you a member of the task force?

A I don't know the reason. I think the decision-makers would have to be able to address that.

Q Did you have any discussions about it?

A There was one conversation with Secretary Azar about it at one of my first meetings regarding the formation of the task force.

Q What did you discuss with Secretary Azar?

A Secretary Azar approached me and said that he realized that I was new, getting to know the agency, and that HHS could adequately represent at that time, but that the circumstances had changed.

Q When, approximately, did you have that conversation?

A End of February.

Q Did he express what circumstances had changed that led to it being appropriate to have you join the task

force?

A Not that I remember.

Q In your opinion, would it have been helpful if you had been a member of the task force earlier on?

A In retrospect, [Majority Counsel], yes, I think it would have been.

Q Why?

A Just the urgency of the situation. The fact that emergency use authorizations are a critical part of the public health emergency, and getting medical products into the hands of providers and patients is really important.

Q Do you believe that the fact that you weren't a member of the task force in those early months impacted the pandemic response in any way?

A I don't know.

Q Do you believe that you were not receiving regular updates on information that would have been helpful in your role as commissioner of the FDA?

A I was receiving regular updates from the staff who were involved at the White House meetings and it was very helpful. And I was also listening in on several calls that happened at HHS.

Q Do you believe that if you had been involved in the task force, that it would have allowed you to

coordinate on issues such as testing more effectively?

A I do believe that.

Q Did you raise concerns about this to anyone?

A I did not.

Q You mentioned the phone call with Mr. Grogan. How did you ultimately come to join the task force?

A I was invited. I assume, I don't know, that it was coordinated through the Vice President's office.

Q Who contacted you?

A I don't remember.

Q Do you recall what you were told about why they were inviting you to join the task force at that time?

A I don't recall.

(Exhibit No. 1 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to show you a copy of some text messages. This is a compilation of text messages that appear to be between you and Mr. Grogan. And for the record, it's Bates numbered SSCC-0036553.

I'd like to direct your attention to the bottom of the third page which ends in page 557. Do you have that in front of you?

A Got it.

Q This appears to be text messages that you and

Mr. Grogan were exchanging on February 28, 2020. There are many text messages that are redacted, but at 6:58 a.m., you write, "Glad to speak and communicate with anyone about this. I am personally involved as is Shuren."

You subsequently wrote, "I just asked Shuren to do another round of touching base with companies today to ask if they need anything else from us."

Who is Shuren?

A Jeff Shuren is the center director for the devices and diagnostics center, CDRH.

Q Do you recall what you were discussing of what Dr. Shuren was doing with respect to touching base with companies?

A I do not recall.

Q Does it appear -- could it be a reference to testing, reaching out to diagnostic test manufacturers?

A I'd have to speculate, [Majority Counsel], but, yes, that would appear to be the case.

Q If you continue down the page, at 7:01 p.m. Mr. Grogan wrote, "We're adding you to the task force. Finally. Let me know if you don't get notified."

You responded, "I really appreciate your support. I received the invitation and Marc Short called me. He asked me where the issue was. Thank you Joe."

Mr. Grogan responded, "Insanity. That you weren't on

sooner."

First, do you recall the conversation that you had with Mr. Short?

A I don't.

Q Did you have any additional discussions with Mr. Grogan about joining the task force?

A [Majority Counsel], just to clarify, do you mean after this exchange?

Q Yes.

A I don't remember that. I don't believe so, but, again, it's a guess.

Q What was your understanding of why Mr. Grogan said, "Insanity. That you weren't on sooner"?

A In our conversations, Mr. Grogan had expressed his, I would say, frustration that FDA wasn't represented at a senior level on the task force.

Q Did others share the view that it was insane that you weren't on the task force?

A Not specifically using the term "insane." But my doctor colleagues had expressed that they thought it was important.

Q Who specifically?

A Dr. Redfield.

Q Dr. Redfield. When you joined the task force, how did you expect to contribute?

A My expectation was that I would give advice regarding -- and also receive input -- regarding the variety of medical products that FDA would be responsible for that would be really important to use during the pandemic.

There was a lot of incoming information about medical products, and we at the agency were prioritizing based upon science. If I were to hear about medical products or about situations that would require other prioritization within the agency, coordination at the task force level would seem to be important.

Q What did it mean to be a member of the task force?

A I'm not exactly sure what you mean by "what did it mean."

Q What responsibilities would you have had as a member?

A To represent the FDA; to communicate about the FDA's response; to answer questions around what FDA's responsibilities were in terms of authorizing with EUA for medical products.

Q Were there other member responsibilities beyond attending meetings and providing advice during those meetings?

A They weren't explicitly stated, [Majority

Counsel]. But as time went on, it became clear that we were to be responsible for communication as well.

Q What type of communication?

A So being present when asked at press conferences, speaking with the media when asked, those sorts of things.

Q Did all members attend all meetings?

A I don't remember if all members attended all meetings.

Q Were some members more engaged than others?

A I think so. I mean, again, it's a guess. It was a pretty engaged group to begin with.

Q You said I think so. Were there some members that appeared to be less engaged or less active at the task force than others?

A [Majority Counsel], if the definition of engagement involved -- not necessarily speaking -- but involved paying attention, et cetera, I would say almost everyone that I can remember was engaged. Not everyone spoke.

Q Was there a group that you would consider core members or that had responsibility for core medical issues perhaps?

A Again, it was not explicitly stated, [Majority Counsel], that there were core members. But clearly, the

docs on the task force and those are the four -- I mean, myself, Dr. Redfield, Dr. Fauci, and Dr. Birx were involved in a lot of different issues.

Q Apart from task force meetings, were there specific subject meetings that you participated in at the White House, regular meetings?

A Yes.

Q What were they?

A I don't remember exactly the names of those meetings, [Majority Counsel], but they involved coordination of responses to certain situations.

For example, we would sit down and talk about diagnostic tests and what the future would look like and what tests might be needed. Dr. Birx typically coordinated that. Sometimes Joe Grogan did. And then on a regular basis the four docs got together and had conversations.

Q For the testing discussions, how frequently were those scheduled?

A Well, in the beginning, fairly frequently. I believe -- and, again, I don't have my official schedule in front of me -- but several times a week.

Q Did that change over time?

A It did.

Q In what way?

A Less in frequency. And then when Mr. Grogan

left the White House, even more of a decrease.

Q Was there a reason why the meetings decreased?

A I can't speculate as to why the White House changed the cadence of meetings. What I can tell you is the docs met regularly to discuss these issues. So from my personal perspective, I felt that these topics were being discussed and that we had reasonable medical coordination among CDC, the White House task force, with Dr. Birx, myself, and Dr. Fauci.

Q You mentioned that the White House changed the cadence of the meetings. Was someone in charge of scheduling them and deciding when it was necessary to hold those meetings?

A I don't know exactly. Olivia was involved in a lot of that, but I don't remember if she was specifically involved in the meetings that I just described.

Q For those testing meetings specifically, when did the decrease in frequency appear to happen?

A I do not remember.

Q Did it appear to be spring, summer, fall?

A I'm guessing, [Majority Counsel], but I'm thinking spring, in late spring.

Q Late spring?

A Before Memorial Day. But, again, I'm guessing.

Q You mentioned that you regularly had meetings with the doctors on the task force. How frequently were those meetings?

A The formal meetings were frequent, several times per week. The informal conversations literally occurred daily. I mean, especially during the height of the pandemic. And then even throughout, they were very frequent, at least three or four times a week, the informal meetings.

Q On the task force, how were decisions made? Was there a formal structure? Did someone have the ultimate say?

A The Vice President had the ultimate say, and then we discussed with the President as needed.

Q I'd like to move on to discuss FDA's role in the development and approval of diagnostic tests in the early months of 2020. I'm going to hand you a document.

(Exhibit No. 2 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I am marking this as Exhibit 2. It is an undated document entitled FDA's Role in the SARS-Co-V-2 Diagnostic Development, and it is Bates numbered SSCC-0037750.

Do you recognize this document?

A I do.
Q What is it?
A It's a timeline that was constructed to provide a historical recap of our response to the increased need for diagnostic tests for SARS-CoV-2.
Q Do you recall why it was created?
A Yes, I do.
Q Why?
A We were asked by Senator Alexander in the HELP Committee to put this together.
Q Who prepared it?
A Dr. Shuren and his team at CDRH.
Q The first entry reads, "Jan 9, 2020: Initial call with CDC for an update on the novel coronavirus situation and CDC testing plans."
Were you on that call?
A I was not.
Q Do you know who participated from FDA?
A I do not.
Q It mentions CDC testing plans. Are you aware what those plans were at that time?
A I cannot give you a detailed recap of those. I spent a lot of time speaking to Dr. Redfield about the approach that they were using.
Q Had you been informed about the novel

coronavirus situation at this time?

A I don't remember exactly when. I believe so, but I don't remember the exact date, [Majority Counsel].

Q How did you learn about the coronavirus?

A It was brought up at an internal meeting at the FDA, because our staff had been asked to participate in some meetings with the White House and HHS.

Q Who asked the staff to participate in those meetings?

A Again, I'm speculating here. I would not have been involved in that conversation, but I believe it was HHS.

Q Are you aware of which FDA staff attended the meetings?

A Anna Abram.

Q As of January 9, 2020, had FDA taken any action with respect to testing?

A Other than what you see here, I'm not aware of actions that were taken.

Q Okay. Chinese officials posted the genetic sequence for SARS-CoV-2 on January 10, 2020, and by January 20th, CDC had developed a test to detect the novel coronavirus crisis.

Does that sound correct?

A That sounds correct, yes.

Q Apart from CDC, were you aware of whether other diagnostic test manufacturers were developing their own tests at that time?

A I don't know about precisely on January 20th or about then. I do know -- and this is outlined in this and other documents that I believe that you received from HHS -- that there were a number of developers who were in the process of developing tests and had contacted the agency.

Q Did FDA engage directly with those manufacturers?

A Typically we would, yes.

Q You said typically. What do you mean by that?

A In general, during the COVID response, we would directly engage with developers. What I can't tell you is if all of them that did occur.

Q Who led this effort at FDA?

A Jeff Shuren did at his center. And then an individual by the name of Tim Stenzel, who was one of Jeff's deputies and was in charge of the testing group.

Q When did Jeff Shuren and others at FDA start engaging with those test manufacturers?

A At least -- and I'm saying at least just because I cannot tell you exactly when that occurred. But at least by the end of January.

Q Did you have any involvement in that effort?
A I was informed by Dr. Shuren particularly around the EUA template that had been created to make it easier for people to apply for EUAs.
Q Were you calling companies at all?
A Not at that time, no.
Q Did you start calling diagnostic test companies later in time?
A We did later in time, yes.
Q When?
A Mid-February. Approximately, mid-February. Mid to end, I would say.
Q Why did FDA start contacting the diagnostic test manufacturing companies in January and continue doing so into February?
A It became clear to us, and I think you can certainly see in the timeline development, that the development of diagnostic tests at a commercial level was going to be really important. And I think, in retrospect, when we see how it played out, that that obviously was true.
But in this country, because of the distributive model that we have, commercial development of tests rather than centralized development of tests is typically how it could be scaled up, and we clearly needed it to be scaled

up.

Q What was discussed on those initial calls with the testing companies in the January timeframe?

A I don't know because I did not participate in those.

Q Are you aware whether FDA was seeking commitments from the test companies? Any type of commitments?

A I'm not aware.

Q Are you aware of whether FDA was asking them to develop their own tests or to scale up manufacturing capacity, for instance?

A I am aware of discussions that occurred through February, March, April with diagnostic test companies. I had quite a few of those calls myself. And it involved the subjects you described. So what kind of tests were being developed? How did that fit in with the public health response? What kind of capacity -- that was really the issue -- did they have?

Because at the end of the day, as much scaleup as possible we thought was important. And of course there were limits on reagents and pipettes, for goodness sake, and swabs. So we really wanted to get a sense of what they thought their scaleup capabilities were.

Q You just mentioned pipettes and swabs. What

were the roadblocks that needed to be worked through to enable the companies to develop the tests, manufacture them and/or increase lab capacity?

A So in terms of development, [Majority Counsel], the development early on occurred of what we call contrived samples, meaning you would take a sample of, say, saliva or a nasal swab of a noninfected person and you'd add SARS-CoV-2 to it. So you needed to have access to the virus.

Typically when a test is developed, it's done with someone who has the disease and who doesn't have the disease. So it's a real setting in this. And you can sometimes introduce biases into the test development if you're using contrived samples as opposed to real samples. So that was one issue.

Access to reagents. You may have seen in here some references to UTMB in Galveston and access, I think it was to primers, and I'm guessing on that one. But there was a general lack of a lot of these things that were needed for the development of tests.

And then, of course, to speed tests to the market, you want to try to use whatever data you have available. And with contrived samples, there's a limit to that, which means that on the back end, you have to collect real-world evidence on its use in people who have the disease.

So those were the sort of discussions that we had. And then, ultimately, do you need swabs for your test? Where are you getting your swabs? And then that's a situation where we would take it to the task force, because the task force generally was coordinating the response for PPE, swabs, et cetera. So there was a relationship between what did the companies need, which companies need what, and where could we get those.

Q And I apologize that I have very little scientific background. What is a contrived sample?

A So I know it sounds -- [Majority Counsel], it sounds awful, contrived sample. But as I mentioned, if you're developing a flu or a strep test, what you'd want to do is you'd want to take people who don't have flu and people who do have flu, and then you'd want to test them.

When you don't -- when it's a novel virus, you have a situation where you don't have people who are actually infected. So what you do is you take samples from, say, someone who's not infected, take saliva or spit or whatever and add the virus from a test tube into it. That's a contrived sample.

Now, it's a good way of saying my test can detect the virus in a human sample, but it's not the same, as you know, of having someone take a swab and do a measurement.

So when you use contrived samples, it's a different

dataset. It introduces biases into that dataset. That doesn't mean it's not a good test. It just means that you have to be cognizant of it, and it means then to make sure it's accurate, you have to look at it on the back end in a real-world setting.

So understanding -- and I don't believe that was completely understood in the world at large that these were the issues related to it. And it's just one issue.

Q Thank you. You mentioned that once you had these conversations and discussed reagents and swabs and other things that might be in short supply, you took it to the task force. Who on the task force was dealing with the supply chain issues?

A Well, there were a lot of people. Ultimately, it became FEMA who we would go to. But early on there were just a number of people who were involved. I don't remember all the people, but give you an example.

There was -- of course, the pandemic really took hold in northern Italy, and ironically and disturbingly enough, a lot of the manufacturers for swabs were in the Piemonte region of Italy. So there was a supply chain issue because that's where people were getting sick, and so that disruption was significant. So it required, of course, probably State Department and other people to be involved to make sure that we had adequate communication with other

governments. So it was a multidisciplinary approach.

Q Got it. Prior to FEMA taking over, was there a particular person who appeared to be in charge of the supply chain issues at the task force level?

A [Majority Counsel], I can't recall.

Q Do you recall who you were communicating with specifically?

A It would usually be at the task force meeting. So, in general. Sometimes I would communicate with Joe Grogan.

Q And what was Mr. Grogan's role with respect to pandemic issues?

A I don't know his formal role, but he was the head of the Domestic Policy Council.

Q It has been reported that White House officials pressed you in late January to contact diagnostic test manufacturers and begin coordinating the development of coronavirus testing options, including potentially convening a roundtable discussion at which industry leaders would make public commitments.

Do you remember that?

A I do not.

Q But just to be clear, FDA had contacted diagnostic test manufacturers and began doing some coordinating around the development of coronavirus test

options prior to late January; is that correct?

A So that's what I understand from the center. I did not participate in those.

Q Did FDA ultimately convene a roundtable discussion with industry leaders?

A We did throughout the pandemic. And not just in diagnostics, but in biologicals and therapeutics as well. So yes.

And [Majority Counsel], just -- I'm not sure what you mean by the definition of roundtable, but a discussion with diagnostic companies, whether alone or together, occurred.

Q A Politico article dated October 22, 2022 reported that you balked at convening with manufacturers themselves, telling officials that HHS had instructed you not to personally speak with companies that your agency regulated.

Do you remember that?

A I do not remember making that statement. I do remember the circumstances that are described.

Q What do you remember?

A So internally we had a discussion at FDA in late January about meeting with companies, and I was in favor of that.

One of the complicating features is that there are very specific rules at the agency about meeting with

industry. And in fact, to the point that the number of industry leaders that are at a meeting has to be restricted to a certain number. And I don't remember the exact details of the rule, but very cautious about that.

So I convened a group of folks in the Commissioner's office, and I don't remember who was there, but I do remember that both Stacy Amin, OCC, Anna Abram, and Keagan Lenihan were there. And we discussed the possibility of doing this because I thought it was a good idea.

It was then taken to HHS, and it was relayed back to me that HHS was not in favor of it. And then two weeks later, approximately -- and I'm not sure exactly of the date, but I'm thinking mid February -- I had my one-on-one meeting with Alex Azar. And there were lots of folks, it wasn't just a one person/one person meeting. And I brought it up at the end of the meeting, and Secretary Azar, yeah, said go ahead.

Q You said that it was communicated to you that HHS was not in favor. Were you told why?

A No, I wasn't.

Q Who communicated that to you?

A Keagan Lenihan.

Q You mentioned that in mid-February you had this meeting with Secretary Azar and that he said to go ahead. Was that specifically with respect to you reaching

out to the manufacturers themselves or some other action?

A Me or our staff reaching out and convening groups to talk about it. Or in general, discussing it.

And, [Majority Counsel], again I want to just provide that context that the agency is very careful from an ethics point of view about its appearance of its relationship with industry. And, of course, this was an extraordinary situation, so, you know, those were important issues that we had to discuss.

Q I just want to make sure that I'm clear. So was it specifically that having a group discussion with the test companies seemed to be potentially problematic from an ethics or other perspective, or was it any communications directly with the test companies themselves?

A So, [Majority Counsel], broadly, any communication with industry was carefully scrutinized.

Q And what or how was it scrutinized?

A There is a process in the Commissioner's office. And what I can't tell you because I don't remember, but I believe it was also reviewed at HHS, requests to meet with industry, something that went on my calendar, it would be viewed through a variety of lenses. The legal lens for sure, but also ethics lens.

Q And was the same scrutiny applied to FDA officials below your level?

A Yes.
Q And so --
A That I'm aware of. I wasn't involved in those reviews, but yes.
Q The timeline states that at the end of January, FDA made an EUA template available for diagnostic test developers. And that happened on January 22nd, and then that FDA posted a notice on its website on January 27th regarding the availability of that template upon request.
Why was there a five-day delay in posting it to the website?
A I don't know.
Q The timeline states that on January 28th, 2020, FDA kept CDC and BARDA apprised of entities that had requested the EUA review template.
How many entities had requested the template as of the end of January?
A I can't tell you that right now. I just don't remember. I believe there's documentation in some of these emails regarding those numbers.
Q I'll direct your attention to January 31st. At the end of that entry, it says that, "FDA has engaged with and shared the EUA template with 22 different test developers."

Does that sound about right?

A I'd have to base that upon the accuracy of this, but I believe that's accurate.

Q Were there prominent diagnostic test manufacturers that had not requested the EUA template at that time, at the end of January?

A I don't know.

Q Were efforts made to proactively reach out to companies and labs to encourage them to develop tests and apply for an EUA?

A Yes.

Q When did that start?

A [Majority Counsel], I can speak to when I started doing that. I can't tell you exactly when Jeff and his team -- Jeff Shuren and his team did. But end of February and into March and April, May. Actually, it continued throughout the pandemic.

Q You said end of February. Why was there a delay in doing that proactive outreach?

A I just don't remember the exact circumstances. But I was involved in giving a talk to the American -- I think it's -- ACLI. I believe that's it. And we had had a number of communications about this. We'd also been aware of agency complaints that had been made, particularly from some academic centers, about the regulatory burden that

they felt was present in terms of developing tests.

So that had occurred in February. I was involved in some of those, had received some messages and communications about it, but I can't give you the exact date.

Q What were the nature of those complaints? What regulatory burdens were they raising in the letters?

A Difficulty in terms of putting together the data and submitting an application. Typically there's a Listserv -- you probably saw it -- a Listserv of folks who develop tests, and they talked about this. And it lists here a number of different comments that had been made, which we typically were hearing in terms of the difficulty of doing the application and getting the data submitted and then the review process.

Q And so is it fair to say they were complaining that it was too complicated, took too long, and other similar considerations with respect to putting together the package to apply for the EUA?

A I think it's fair to say that that was a component of their complaints. There also was a lot of misconception about FDA's role versus CDC's role and those type of things.

Q What were those misconceptions?

A May I?

Q Of course. Just for the record, what document are you reviewing?

A It's in 37765.

Q I'm not sure that we have a copy of that with us. If you wouldn't mind just providing just your recollection of --

A You bet.

Q Or it can be refreshed by virtue of the document in front of you.

A Okay.

Q But what was the misconception about FDA's role versus CDC's?

A You know, we had heard circumstances where folks who were developing laboratory-developed tests said, "the FDA told us to stop developing," and that just wasn't true. In fact, we were trying to encourage people to develop.

There was a claim that we had assumed authority and chose to work solely with CDC and no other laboratory test developers. That's also not true. In fact, the very fact that we had an EUA template would suggest otherwise.

FDA chose to give the CDC sole responsibility for developing a test. It's really a fundamental misunderstanding of what the agency does, and probably is a lot of blame for that fundamental misunderstanding. But

FDA doesn't tell product developers who can or cannot develop a test. That's not our role. Our role is to accept the data and to review the data.

Q You mentioned that there was a misconception that FDA told companies to stop developing tests. Did you ever learn that someone else gave that instruction to the companies?

A Not that I am aware of.

Q Secretary Azar declared a public health emergency on January 31, 2020. Were you involved in any discussions about whether that public health emergency should be declared?

A No.

Q Are you aware whether anyone raised any concerns about doing so?

A Not that I'm aware of.

Q Did the declaration of a public health emergency have any impact on FDA regulatory requirements related to testing?

A Yes, [Majority Counsel]. In general, my understanding was that with the declaration of a public health emergency, that invokes our ability to issue emergency use authorizations. And the statute behind that allows us for any medical product may be effective, risk/benefit ratios in favor of the authorization, and no

alternative product available.

Q How did that impact your ability to authorize tests? Did it make it faster, easier, streamline the process, or did it make it perhaps harder?

A [Majority Counsel], do you mean "it" as in the public health declaration?

Q The fact that you had the ability to use the EUA framework.

A So if I understand the question, sorry; the fact that we had that, did it make it easier for us to conduct the reviews of data?

Q Yes.

A Yes, it did. So under an EUA, the agency has quite a bit of flexibility. Typically what would happen for -- and I'm going to make the distinction between authorization, which is what an EUA is, versus approval, which would be a typical 510(k) or PMA, or in the case of drugs or biological license applications.

So an EUA allows us -- so under normal circumstances, it would be a similar sort of first in/first out. Whoever gets their application in, we would review it then and there'd be a timeline with that.

With EUAs, there's not that specific timeline. We compare those applications depending on a number of different factors. So, actually, it enables the ability to

perform the review of all medical products.

Q So before January 31st, if a test company wanted to go through the process of creating a test, would they have to go through an approval process?

A Typically, that's what would take place. And if there was no predicate device, it would be a more laborious sort of circumstance. I think we all anticipated that this would occur; thus, the creation of the EUA template before the public health declaration.

Q Was any action contemplated to -- let me strike that.

Was there any consideration of removing an EUA requirement altogether and allowing tests to go to market without submitting the data package and the FDA reviewing and authorizing it under the EUA?

A [Majority Counsel], I don't remember specific discussions. But internally we did discuss what had happened historically with laboratory -- and typically that was around laboratory-developed tests. Let me just be clear. The question that you're asking seems most relevant in my mind to laboratory-developed tests. And that history of review of laboratory-developed tests is somewhat complicated and, of course, has led to technical assistance to Congress over the VALID Act.

We typically, during public health emergencies, would

assert regulatory oversight over laboratory-developed tests. In general, in nonpublic health emergency times, we used a risk-based approach. So the more complicated tests that might cause harm if not performed exactly right, typically those were ones that we would recommend review. And of the spectrum -- and you've probably seen the documents of LDTs. In the normal setting, that was about 10 percent of them. So 90 percent we gave enforcement discretion.

But during the SARS-CoV-2 pandemic, because it was new and because of the issues related to what I spoke about with respect to contrived samples, lack of reagents, et cetera, we really did feel it was necessary to review those.

We also internally did a review of the first hundred EUAs that were submitted to us. And I think this is really important data, these are really important data, and it was published in the New England Journal. Sixty-two of the 100 had significant problems that required oversight and intervention.

And that's nobody's fault. This is not to blame people. Just that in a fast-moving situation with a novel virus, lack of reagents, contrived samples, there are issues. And I'll tell you from a doctor's perspective, maybe, maybe -- and I'm saying maybe -- having a bad test

is worse than having no test, because you might make decisions that affect people's lives on the basis of inaccurate data.

Q You mentioned that a study showed that 62 of the 100 had significant problems. Does that mean that they weren't accurate?

A Accuracy problems typically.

Q You said that, in some cases, having no test is -- let me strike that.

You said that having a bad test can be worse than having no test because you might make decisions that affect people's lives. Was that your view of the COVID situation specifically?

A No. That was an expression of a general sort of -- I'm giving a doctor's perspective on that. But it provided me reassurance to our approach that making sure that these tests were as accurate as possible was really important.

Q Why was that really important?

A It was the early part of the pandemic. We had a lot of -- early in the pandemic, nobody really -- and I'm going to give you a specific example because it relates to this issue. Nobody really understood that there were a lot of younger people who were asymptomatic carriers of it.

And that's really important, because if you're not

symptomatic but your test is for someone who's symptomatic, you don't actually know how it performs in that study population. And so having some oversight -- and what FDA does is it looks at data from a broad number of developers. And if, for example, someone is developing a test specifically, say, for that setting, they would have data that's relevant that you could use to advise other developers because it was really important in some cases to do screening.

And what we know about diagnostic tests is if you screen in a low incidence environment, so if the probability is low of the disease, if you have a test, even if it's a great test, the false positives are likely to be greater than the true positives. And you don't know that until you do population or at least larger group testing.

So it was a really complicated sphere. There was also a mis -- not a misunderstanding, but a lack of understanding about some of the characteristics of COVID. And all those contributed, I think, to our really feeling strongly that there needed to be oversight.

Q In hindsight, with what we know now that there were significant asymptomatic carriers and that perhaps the prevalence of the coronavirus in the community was higher in February and into March than was perhaps appreciated at that time, do you still have the same assessment that doing

that oversight and potentially slowing down the availability of test authorization and manufacturing was the right decision?

A So in general, yes. I'll give you the specifics around that, though, [Majority Counsel].

I think, because there was not a whole lot known about the disease and because of our concerns around accuracy, that oversight was necessary. You'll notice that at the end of February we revised our guidance. And I think this is a characteristic of the agency, which is that we will make decisions based upon the data we have. As we gather more information and get feedback from stakeholders and others, we will revise those decisions.

So in late February, as you probably know, is we revised our guidance to say if you're developing a laboratory-developed test, you still have to bring us the data, but it can be three weeks after you institute it clinically and then we'll look on the back end of the data.

The negative of that is if your test doesn't work well, you've done a lot of tests that are probably inaccurate. But the positive is, it gets more of the laboratory-developed tests out there.

So it was a compromise that I believe was pragmatic at the time and the right thing to do.

Q Were you referring to the February 29th, 2020

policy that helped expedite availability of diagnostics?

A Yes. And the other important component of that was allowing state laboratories to be the gatekeeper. That was another important component and I think a really important lesson learned from the pandemic. And there are some terrific state laboratories that can do this well.

Q How did the decision come about to issue that policy change?

A We had a discussion at the HHS level. We -- I believe -- and my recollection is not completely known right now -- but I believe there were discussions with CDC as well, and certainly internally we discussed it, because it was a significant change from previous public health emergencies.

Q Who did you discuss it with at HHS?

A I believe it involved the chief of staff for the Secretary, I believe. Again, I'm trying to remember the conversations.

Q Was the chief of staff for the Secretary Brian Harrison?

A Yes.

Q Was anyone else involved at HHS, to your recollection?

A I believe so, but I don't know exactly who.

Q What about at CDC?

A At one conversation, Director Redfield was on the line.

Q Anyone else that you can remember from CDC?

A No, I'm sorry, I can't remember. I believe that would be the case, but I just don't remember.

Q What about at FDA. Who was actively involved on this issue?

A Dr. Shuren.

Q Who made the ultimate decision to change the policy?

A Dr. Shuren. So, again, just for context -- and this may come up in other issues -- almost all medical -- no. All medical product decisions are made at the center level by the center director based upon the reviews at the center. It is a very high bar and a very unusual circumstance for a commissioner to reverse those decisions.

Q Did you agree with the policy change?

A I did.

Q Did you have any discussions about doing it sooner?

A Yes. [Majority Counsel], we did have discussions about providing additional flexibility. Not about this specific outcome, that I can recall at least, but we did have discussions around the flexibility that we

could potentially provide.

Q When were those discussions?

A In February.

Q Early February?

A I don't believe early February. But, again, I'd be guessing.

Q Do you recall if there was a significant delay before the decision was made or if it was perhaps short?

A This is not meant to be other than just a clarification. It depends on what you mean by short and long. And having been in the federal government, I kind of felt that it was pretty short in terms of when we initiated the discussion and when it happened.

You probably know, [Majority Counsel], that when these guidances are put out, there has to be multiple reviews, including by Office of the Chief Counsel. These people were working day and night, and I considered this a pretty short turnaround time from when the decision was made, maybe not in the setting by some judgments in a public health setting.

Q Why was the decision made at this juncture?

A Feedback from stakeholders was really the big -- you know. I believe that, plus the urgency of the situation. This was a public health emergency.

Q In hindsight, do you think that the decision

should have been made sooner?

A Sorry, could you repeat the question? Sorry, [Majority Counsel].

Q In hindsight, do you believe that the decision to change that policy should have been made sooner?

A I believe it would have been ideal had it been made sooner. The "should" part of the conditional tense is -- that's the problem here, because it would have depended upon a lot of information coming together.

Q What impact would it have had if that policy had been changed earlier?

A If it had been changed earlier, there are potential different outcomes. One is we would have had some inaccurate tests out there that we would have then had to reassess, and there would have been decisions potentially clinically made that were incorrect. It is also possible that really good tests would have been put on the market and we would have seen that after the fact, and that would have expedited testing.

Q What were the consequences of not having as many tests on the market in that period?

A Certainly -- and I don't know, [Majority Counsel], how many tests that would have involved because, again, it's a distributive model and it occurs typically at the academic center level to develop a laboratory-developed

test.

But clearly, having more testing available early on in a pandemic is important so that public health officials and doctors know what they're dealing with.

Q The CDC test was the only test authorized for use in the United States for all of February; is that correct?

A I don't know exactly when the first non-CDC test was authorized.

Q Let me direct your attention -- do you still have the timeline in front of you?

A I sure do.

Q On the first page -- the second page ending 751, on February 4th it mentions that FDA issued the Emergency Use Authorization for the CDC test.

Do you see that?

A I'm sorry, which one?

Q The very first bullet at the top of the page.

A Okay. Yes.

Q I'd like to direct your attention to page 4, ending 753.

A Yes.

Q The very first bullet at the top says, "February 29, 2020: FDA issues an EUA to New York State Department of Health's Wadsworth Laboratory."

Do you see that?

A I do.

Q Now skipping ahead to March 12th, it's on page 5 ending 754. "March 12th: FDA receives EUA application from Roche Molecular Diagnostics, reviewed, and authorized it the same day. This is the third EUA granted for a diagnostic test."

A Yes.

Q So is it fair to say that the second test that was authorized was the New York State Department of Health's Wadsworth Laboratory test that was authorized on February 29th?

A Yes.

Q So prior to this time, was the CDC test the only test available for use in the United States?

A Yes.

Q And all the lab tests, whether by Wadsworth Labs or Roche, they were being developed, they were being reviewed, but they weren't actually being deployed; is that right?

A That would be the assumption I would make, [Majority Counsel], yes.

[Majority Counsel]. We are just about at time, so this is a good place to take a break.

(Recess.)

BY [MINORITY COUNSEL].

Q Dr. Hahn, my name is [Redacted]. I'm on the Republican staff of the Select Subcommittee on the Coronavirus Crisis. I promise I do not have an hour of questions. Just a couple of them.

So you said that you were named to the COVID task force late February-ish.

A Yes.

Q Who were the doctors that you most usually spoke to on the task force? Was it Dr. Birx, Dr. Fauci, and Dr. Redfield?

A Yes.

Q Did you speak to Dr. Birx often between December 31st, 2019 and when you were named to the task force?

A Yes. Dr. Birx was named at the same time I was. And so from that point on.

Q Okay. Would it be common for you to speak to Dr. Fauci outside of task force meetings between December 31st and February?

A Occasionally. Certainly not as much as Dr. Redfield or Dr. Birx.

Q So it would have been very common to talk to Dr. Redfield prior to joining the task force?

A Oh, prior to.

Q Yes.

A I apologize, [Minority Counsel]. So I spoke to Dr. Redfield prior to joining the task force particularly around test development with the CDC. We spent a lot of time speaking to each other.

Q So I'll clarify my previous questions then.

Would you have talked to Dr. Birx prior to joining the task force about COVID or anything?

A No.

Q No?

A No.

Q What about Dr. Fauci?

A I was at a few meetings with Dr. Fauci at HHS, I believe, and that's when I -- we would have had that discussion. But it was very uncommon.

Q Okay. So primarily Dr. Redfield?

A Before, yes.

[Minority Counsel]. Dr. Birx was in Africa at the time; is that correct?

The Witness. That's correct.

[Minority Counsel]. Okay.

The Witness. I didn't meet Dr. Birx until she joined the task force.

[Minority Counsel]. Okay.

BY [MINORITY COUNSEL].

Q And then you were asked a lot about the declaration of the public health declaration on January 31st. I want to put it in a little context.

By that day, there were under ten COVID cases in the United States, the first one was detected ten days prior, and there were no deaths. There were around 7,000 cases in China and Asia, but still none here. On that date also they had instituted a travel ban to try to keep those cases from coming over to the United States.

On January 21st, Dr. Fauci was saying a major threat to the people of the United States -- COVID was not a major threat to the people of the United States and it's not something that people should be worried about.

On January 26th, he said the American people should not be worried or frightened by this.

On February 29th, he said, "Right at this moment, there is no need to change anything you're doing."

Would it have made sense to declare a public health emergency prior to January 31st?

A That, [Minority Counsel], would not be something that I would have expertise around. As you describe it, it'd be pure speculation on my part regarding whether it would have been appropriate or not.

Q But by that point in time, there wasn't a whole lot of COVID in the United States. Declaring a

public health emergency has requirements.

A That's correct.

Q Okay.

[Minority Counsel]. That's all I have for now.

[Minority Counsel]. I have one quick question.

BY [MINORITY COUNSEL].

Q You talked about needing access to the virus to develop a test. Can you explain why we didn't have access to the virus and -- do you have any knowledge of the sort of process or anything behind the scenes related to the United States getting access to the virus?

A I don't have specific knowledge about having access. I do know that both for reagents to perform the PCR test as well as the virus -- I discussed with [Majority Counsel] the fact that the contrived samples were so important to the development of tests because there were so few cases in the United States, that that was a major impediment to developing tests was actually getting access to it.

And I think there's some mention in here of, for example, UTMB -- I mentioned that before, the Texas Medical Branch in Galveston -- releasing limited samples. At some point they decided they were no longer going to give samples out. So there were supply chain issues related to that that made the development difficult as well as these

contrived samples issues.

[Minority Counsel]. Thank you. I think that's all I have.

[Minority Counsel]. We're good.

(Brief discussion held.)

[Majority Counsel]. We can go back on the record.

(Exhibit No. 3 was identified for the record.)

BY [MAJORITY COUNSEL].

Q Dr. Hahn, I just handed you what has been marked as Exhibit 3. This is an April 18th, 2020 email from Jeff Shuren to you and other individuals. It is Bates numbered SSCC-0037764.

Before we took a break, I believe you referenced a document. Just to be clear, is this the document that you were referring to?

A Yes, it is.

Q Okay. On February 3rd, 2020, CDC submitted their EUA request for their test to FDA, and the following day FDA authorized it for emergency use; is that correct?

A Yes.

Q The test was developed, though, by January 20th; is that right?

A I believe that's correct.

Q Are you aware why it took until February 3rd

for CDC to submit the EUA request package?

A I can give you some general aspects to that, [Majority Counsel].

What we did during the pandemic in the review was not wait for the data to be submitted at a final application, but to work with the developer during. It's why you see in the timeline authorization a day or so after the data are completely submitted.

So we spent time with CDC in terms of helping them develop their test and giving them some clarity around what would be the data that would be needed for that authorization. That was part of it as well as their own internal processes for putting it together.

Q Were you just referring to pre-EUA reviews?

A Yes. We -- I assume that that's what you mean. We refer to it as rolling reviews. Someone would say we want to submit an application, we deemed it a priority, and we would go back and forth with the developer and say we need these data. They would send preliminary data. We would review that before a final package was submitted.

Q Could anything have been done to speed up that process so that FDA could have granted the EUA sooner?

A [Majority Counsel], I think it's always important to think about things that could have been done

that would have sped things up. Really, it's dependent upon the gathering of the data that are needed. What we didn't want to do was create or insert processes or requests for data that did not lead to an accurate test.

So that was our primary motive at that point, was let's make sure that we get the data that we need to make an assessment because, again, these are not normal circumstances of developing a test and it was contrived samples. So understanding how that influenced our regulatory decisions, but also the performance characteristic test was very important, and that, unfortunately, does take time.

Q It's been widely reported that the tests developed by the CDC were faulty. We don't need to get into all the reasons for that, but my question is just when was the concern first raised that the CDC test kits were not giving reliable results?

A [Majority Counsel], I believe -- and, again, I'm recalling here -- I believe it occurred when -- after authorization when the test kits, if you will, but the tests were rolled out to the public health agencies around the country, that some of the states had tried to implement, had done what you normally would do, which is to validate a test in your own laboratory, and found that there were problems.

One thing I want to highlight here is that's a very important quality assurance system and it demonstrates that the system worked. It picked up potential problems that then had to go back to the developer to correct.

Q So how were the faults discovered?

A Again, recollection, [Majority Counsel]. But as I remember it, these tests -- the validation of the test at the public health laboratories in individual states was being performed. It was during the performance of that validation that they noticed some inaccuracies with the tests. And I don't know the details, I apologize for that. But that was, I believe, reported to CDC or CDC reported that to us and then we helped them address the issue.

Q What is your recollection of when that was first reported to CDC and then on to FDA?

A I believe that was -- and, again, I'm guessing dates here -- the beginning of February.

Q Are you aware of why those issues were not uncovered during the EUA review and authorization process?

A Well, [Majority Counsel], I would make the assumption, and it could be incorrect. I'll just say that if data had been submitted to the FDA that showed there were these problems, the EUA typically would not have been issued.

And it gets to the point I made before, which is the

speed with which these tests are developed leads to the fact that in a laboratory setting, the development of that test can lead to one set of results. When you then deploy it into the real world, if you will, there can be situations where these problems arise, and that's why this validation QA is so important.

Q I just want to clear up some ambiguity that potentially may be in the record.

I had asked, "Are you aware of why those issues were not uncovered during the EUA review and authorization process?"

And you said, "Well, [Majority Counsel], I would make the assumption, and it could be incorrect. I'll just say that if data had been submitted to the FDA that showed there were these problems, the EUA typically would not have been issued."

So is it fair to say that that was not part of the data package and FDA did not uncover it during that process?

A I think that's fair to say, yes.

Q Okay.

[Majority Counsel]. I'd like to mark as Exhibit 4 a February 16th, 2020 email from Jeff Shuren to you and some other individuals. Just for the record, it's Bates numbered SSCC-0038049.

(Exhibit No. 4 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct your attention to the last page, which is Bates numbered 052.

On February 15th, Dr. Shuren reported, "We have become aware of two new issues regarding the CDC's test as well as a request by the Secretary for expanded use of the test. As you know, approximately 26 out of the approximately 100 public health labs to have received the CDC test reported false positive results."

The email continues, "CDC informed us that the test they validated for purposes of the EUA used a different lot of components than the test that was manufactured for the public health labs, i.e., they were made by two different entities (and they clearly performed differently). First, they shouldn't have done that and, second, they should have told us at the outset. It's just one more reason why CDC tests need to stay under an EUA (under FDA oversight)."

Do you see that?

A Yes.

Q Prior to the discovery of these faulty tests, were there concerns as to CDC's involvement or expertise with respect to developing tests?

A [Majority Counsel], I don't remember

conversations where that was the case.

Q Do you know what Dr. Shuren was referring to when he said "it's just one more reason why CDC tests need to stay under an EUA"?

A This, [Majority Counsel], goes back to the issue of the difficulties with developing a test in general under emergency circumstances. The processes that go into it, the contrived samples and things we spoke about and the potential for inaccuracies, all of those were things that we found in, as I mentioned, our first hundred EUAs.

And I believe that Jeff is referring to the fact that all of those issues come together, CDC being the first test, to make it really important that there be that oversight.

Q Did you understand that this was not a specific criticism of CDC's test as opposed to just a general view that these tests needed to be validated and authorized by FDA?

A I believe this was a specific criticism about CDC at the time. I believe it also is generalizable.

Q What discussions did you have about -- that may have expressed criticisms about the CDC's tests?

A I don't remember. And I don't remember the timing of this, [Majority Counsel], but ultimately it was found that there was a contaminant in one of the components

of the test. And I'm not sure if we knew that before this conversation or after, but that certainly was part of the discussion that we had throughout the course of this review.

Q Had anyone been advocating for FDA to not provide authorization for CDC's tests at that time?

A I can't name specific individuals, [Majority Counsel]. Not because I can't. I just don't remember. But there was -- and this occurred throughout the pandemic. There was always this tension between speed and accuracy. Accuracy in terms of the product, but speed with respect to getting the product out into the hands of people who could use those.

And so I believe your question relates to that tension that inherently existed throughout the pandemic, but really started with this.

Q So on the previous page, which ends in the number 51, Anna Abram responded to Dr. Shuren's email and said, "Do you have an idea of how long it would take to work through these issues you've identified below? And do you think the Commissioner needs to call Redfield? I agree that this situation underscores why CDC tests should be subject to FDA oversight."

Moving up the chain, in response Dr. Shuren wrote, "The Commissioner and Redfield have already spoke."

Is that correct?

A That's correct.

Q What did you discuss with Dr. Redfield?

A At that time, the CDC had requested the ability -- and I think you see it referenced in Dr. Shuren's email at 2:53 p.m. -- regarding, I believe, someone requesting that asymptomatic individuals be tested.

So, [Majority Counsel], this gets back to the issue -- and CDC had asked that the tests be allowed to be performed on asymptomatic individuals. And this gets back to the issue of, in what study population do you have data that gives you assurance that the test is accurate?

It's a pretty -- and it continued to be throughout the pandemic, a pretty significant leap in terms of asymptomatic individuals. One, because that typically wasn't the test situation the tests were developed in. And again, as I said, false positives in an asymptomatic population with low incidence. But the other part of this was that it shifted with time. It really depended upon who the population was.

So, for example, elderly people typically weren't asymptomatic from COVID. So, again, low incidence in an elderly population. Younger people, it would be. And a lot of that wasn't known at the time. So there were a lot of things that weren't understood at the time that led to

some concern about the request.

Q Did you discuss anything else with Dr. Redfield on that call?

A I don't remember, that call, specifically what else we discussed. But typically, [Majority Counsel], we would.

Q Do you recall if there was any contemplated action that came out of that call apart from the asymptomatic test authorization?

A I don't.

Q What happened next? Did FDA play any further role in trying to resolve the issues with CDC's tests?

A Yes.

Q What?

A So I don't remember the exact timeline and circumstances, but we did send Dr. Stenzel down to Atlanta to help in realtime at the laboratory and we provided ongoing technical assistance, as we would with any developer for the tests, including issues around manufacturers and the reagents they supply. Because that's all part of the EUA, is who are you going to buy them from? Because, as Dr. Shuren points out, sometimes there can be variabilities that affect test performance.

Q Thank you.

[Majority Counsel]. I'd like to mark Exhibit 5.

(Exhibit No. 5 was identified for the record.)

BY [MAJORITY COUNSEL].

Q This is a February 25th, 2020 email exchange from Ms. Lenihan to you, Dr. Hahn, bates numbered SSCC-0038055. I'd like to direct your attention to the second email from the top, an email from Dr. Shuren to Ms. Lenihan at 1:30 p.m.

Do you see that?

A Yes.

Q It says, "CDC wants to have a broad EUA for both diagnosis and 'prospective surveillance' (namely, screening) which we would be fine with, but right now CDC hasn't settled on what they want to do with their test (eg., use test using N1 and N2 or also use N3) and may have changed the primers/probes they are making, and may want to make other changes. My folks can't get a straight answer and CDC doesn't seem to know what they want to do. Tim is trying to sort it out."

Just first, who is the Tim that's referenced in this email?

A Dr. Tim Stenzel. I'm not completely sure what his title is, but broadly in charge of the testing review group within CDRH.

Q What was CDC advocating for with respect

to -- what does broad EUA for both diagnosis and "prospective surveillance" refer to?

A So any time we receive an application, we as in FDA, either for EUA or for an approval, there is intended use. It's called intended use. That might even be a statutory term. I'm not sure. But we take that very seriously because it has to be specifically on the label.

So in this case, typically for EUAs, for COVID it was a test to be performed in someone who healthcare providers suspected of having COVID. And, of course, suspected typically means having symptoms. That would be what a provider would do. So, again, that's a different circumstance than screening individuals who are asymptomatic, a different patient population, a different population in general.

So what Jeff's communicating here is that they -- CDC wanted to have the label changed to allow for broad use, both in asymptomatic screening, for example, as well as in symptomatic individuals.

Q The reference that CDC hasn't settled on what they want to do with their test, using N1 and N2 or also N3, is this a reference to the three different components of the test, with N3 referring to the one that was later found to be contaminated and faulty?

A Yes.

Q It said that they may have changed the primers and probes that they're making, and want to make other changes.

What do you recall was happening right now with the CDC tests, and what ended up happening? What decision did they make?

A They were trying to sort out whether, for example, the tests could be performed adequately with just N1 and N2, or did they have to get another supply or source of N3. And of course that takes time to figure out. You have to repeat some of the tests that you do.

So this is something that happens pretty regularly at the agency. A sponsor would find a problem, hopefully they would identify it and bring it to your attention, and then you would work with them and say get technical assistance. That's pretty much what we do. So that was the circumstance we were in.

Q Dr. Shuren had written, "My folks can't get a straight answer and CDC doesn't seem to know what they want to do."

Was that a frustration that you had heard previously about CDC with respect to the tests?

A Yes.

Q Who expressed that frustration?

A Jeff Shuren.

Q Do you know why he was frustrated?

A I think this email is illustrative of some of the concerns that he had, but I can't give you specific details of all the aspects that led to his frustration.

Q Do you know who Dr. Shuren was working with at CDC on these issues?

A I think his review team, including Dr. Stenzel, was working directly with the CDC. I am not aware of who Dr. Shuren would have contacted directly at CDC.

Q Dr. Shuren's email continues. "There is a commercial developer who has made primers/probes for the CDC test. We are reaching out to see if their kits are available now. If so, we would have the public health labs use those primers/probes with the CDC test and verify with the material provided in the CDC kit. We'll check with CDC to see if they're on board. That could resolve the test issue but it's a moving target and still more to come."

Does this reflect that FDA was taking an increasing role in trying to address the problems with CDC's tests, or was this consistent with the working relationship throughout the month of February?

A I don't know the specific answer to this circumstance. But what this illustrates is the fact that in a normal situation, non-public health emergency, the level of involvement, we would provide technical

assistance. But to the point of doing this, it was told to me that this was highly unusual, but it continued throughout the pandemic as we realized we had a broader view of things and could potentially intervene to help test developers.

I had always in my mind -- and I don't know this to be true historically -- but in my mind had seen this as a time that really indicated to us that many developers would need more active assistance from the FDA.

Q You just said that it was told to you that this was highly unusual. What did you mean by that? What specifically?

A That typically developers develop a test. There may be a communication with the FDA ahead of time about what's needed, may not. The data are put together, and then that's submitted to the FDA. The FDA would review it and give feedback. So the iteration would occur after the data is completely submitted.

In this circumstance, what we started doing is before the submission of the add/drop application, the give-and-take occurred.

Q And why was that highly unusual action needed in this situation?

A In a public health emergency, particularly one of this magnitude, I think everyone felt that -- and I'm

going to refer to it broadly, [Majority Counsel], as rolling review, was a really good best practice, if you will, to try to expedite medical products and do it with the best oversight possible.

Q What ended up happening with respect to CDC's tests? Were they able to fix the problem?

A Yes.

Q When did that occur, roughly?

A I'm not exactly sure of the timing. Late February, early March.

Q It has been widely reported that South Korea approved test kits from several private companies in early February, and that the World Health Organization also developed their own tests by that time; is that right?

A That was my understanding as well.

Q Did FDA review these tests for possible use in the United States?

A To my knowledge, no.

Q Why not?

A So I did understand that the World Health Organization test was restricted and relatively -- well, restricted in that. Because we had contacted the WHO about the tests at some point, I don't remember when that occurred, but that it had been developed for underserved countries, so developing countries, and wasn't going to be

widely available.

With respect to the South Korea tests, I don't know what communications had occurred, but later on in the pandemic I did receive communications from Dr. Shuren about the South Korea tests and problems associated with it. And I believe -- and, again, I'm remembering as best I can -- that we had reached out to them at some point about the possibility of submitting EUAs.

Q Let's unpack that a little bit.

You mentioned that someone contacted the World Health Organization. Who was that?

A I believe someone on Jeff Shuren's staff did.

Q What were they told?

A Well, I mentioned that the test was for limited distribution to developing countries.

Q Are you aware if that person specifically asked if they could access the technology perhaps to be manufactured in the United States?

A I'm not aware of the specific components of the conversation.

Q Do you know who that staffer on Dr. Shuren's team was?

A I don't.

Q Are you aware if the World Health Organization declined to make the test available specifically to the

United States?

A I don't remember that conversation at all, [Majority Counsel].

Q Do you know when that would have happened?

A I don't.

Q With respect to the South Korea test, who contacted -- let's back up a moment.

Were those developed by private companies?

A I don't know.

Q Do you know who at FDA looked into potentially getting access to those tests?

A I don't remember that. My communication about these tests was with Jeff Shuren.

Q Are you aware what was discussed during those communications with South Korea, either private companies or some other representative of the government or some other party?

A I can't recall any details of those conversations.

Q Are you aware whether FDA requested access to the tests or the underlying technology?

A I don't know.

Q Are you aware if they were told that they were not -- that they would not make it available to the U.S.?

A I'm not aware of that.

Q I'd like to look back at the timeline that's marked as Exhibit 2.

A Thank you.

Q The timeline notes that FDA shared the EUA template with additional test developers in early February. Specifically, it says on February 7th that it had been shared with 42 different test developers, that it had been shared with 58 different test developers as of February 14th, and 66 as of February 22nd. This clearly shows that progress had been made since January 31st, when it only had been sent to 22 companies.

My question is just, why did it take so long to ramp up and provide that EUA template to all of those companies?

A I can't speak to the specifics around the interactions of the center with the companies. I do know that it's a pretty standard practice at FDA that companies would come and say, we are interested in developing a test, what can we do? And then we would engage.

Q What could have been done to speed this up?

A Well, there are a lot of technical details that I think could have been sort of aided and introduced. For example, access to virus reagents and other things that would allow for the adequate testing of a test or evaluation of a test to provide those data.

Q Why didn't that happen? Were there specific

roadblocks or challenges associated with providing that material to the companies?

A I believe part of that was knowledge of where those reagents, et cetera, were and availability.

Q Could more have been done to increase availability of those materials at that time?

A Again, [Majority Counsel], I don't know the specific details or the technical details of that. But I think that is a reasonable question to ask, of course, and a reasonable thought about how to make sure in the future these are available and what sort of system needs to be in place for it.

Q In your opinion, should that have been done?

A Again, referring to the conditional test. If it could have been done, yes, that would have been a positive thing.

Q You mentioned that it was a pretty standard practice at FDA that companies would come to FDA and say they were interested in developing a test and requesting that EUA packet. Should perhaps a different approach have been taken in this case? Given the scale of the crisis, should perhaps more emphasis been placed on proactively reaching out to those companies and bringing them on board to help develop the tests?

A So my comment that I made about "typically"

referred to normal circumstances. And I was aware of efforts to reach out to commercial entities in particular, but also to groups that represented laboratory test developers. I can't tell you when that is, but in retrospect, earlier always would have been better.

Q What were the consequences, if any, of the failure to sort of be proactive and coordinate with the companies more?

A So, [Majority Counsel], I'm going to have to tell you that I don't agree with the premise of the question. But what I can say is that the development of tests that are accurate, reliable, reproducible is key during a public health emergency. There are a lot of components that go into that, and making sure that those tests are available to as many people as possible is our responsibility.

We had concerns early on about the ability to have that take place in a fashion where they would all be reliable and to the best possible extent given the circumstances around contrived samples and all the other issues that I brought up before.

So I think it's fair to say that, in any public health emergency in general, early testing widely spread of accurate tests is important.

Q On February 15th, the timeline notes that

BARDA announced funding opportunities for developing COVID-19 diagnostic tests. Did you have any involvement in that decision?

A I don't believe so.

Q Was funding support something that the test companies had been requesting?

A Not that I remember.

Q Are you aware if lack of funding was a barrier to developing tests?

A That was never brought to my attention, [Majority Counsel].

Q Apart from engaging with the test developers, what else was FDA doing with respect to testing during this first half of February?

A I do not know in the first half of February what else was being done.

Q What were you doing specifically?

A So obviously interacting with the CDC and also internally with respect to efforts that we could make to do as much as possible to ensure the accuracy and reproducibility of these tests.

Q Were you engaging with HHS as well?

A There were engagements with HHS. I don't remember specifically, but there were specific conversations throughout the month of February.

Q What about specifically in the first half of February?

A I don't remember, [Majority Counsel].

Q Were you also engaging with the White House on testing during this period?

A I do not believe so. I mean, I might have had a conversation with Joe Grogan. I just don't remember, [Majority Counsel].

Q What about -- moving to the second half of February. What was FDA doing during that period with respect to testing?

A So during that period, engagement with test developers, there were some interactions with developers particularly around laboratory-developed tests as well as commercial entities. And we also spent a fair amount of time looking at the supply chain issues related to reagents, virus, et cetera.

Q During that period, were you engaging with CDC and HHS as well?

A Yes.

Q What were you discussing with CDC and HHS?

A So with CDC and HHS, the discussions were about the intended use of the test, any problems that were present in the development of the test, and then the deployment of the test. Which is not a core responsibility

of the FDA, but clearly we wanted to enable that.

Q Whose responsibility was that?

A CDC.

Q You mentioned earlier that, during this period, FDA was criticized including from maintaining the EUA requirement; is that correct?

A Yes.

Q Was there any discussion about waiving the EUA restriction?

A As I mentioned previously, we had discussions in February about what flexibilities we could provide that again balances the issue of making sure the tests are accurate and reliable with speed.

Q The timeline mentions, on February 24th, 2020, that the Association of Public Health Laboratories, APHL, sent a letter to you requesting FDA to consider enforcement discretion for interested public health labs to create and implement a laboratory-developed test using a standard protocol and validation without having to come to FDA for an EUA.

Do you remember that?

A Yes.

Q Was this the first time that FDA was asked to provide that enforcement discretion to allow tests to be released without an EUA?

A I can't speak to conversations that had occurred outside of this one, and specifically without me. I am generally aware of laboratory test developers communicating with the agency about the need for such flexibility.

Q Just to be clear, for the record, you said you cannot speak to that. Is that because you don't recall it?

A I did not have the conversations that I remember. So, yes, I can't recall.

Q What was discussed internally at FDA with respect to whether to grant that enforcement discretion?

A We had discussions about what the implications would be for test accuracy and for the ability to -- the ability to have the balance between speed and obviously that accuracy and what the implications would be, and what kind of oversight, if we provided flexibility, would be needed in a new regime, if you will.

Q And who participated in those conversations?

A Jeff Shuren, for sure.

Q Was the OCC also involved?

A I can't specifically state. But again, in general, both Keagan Lenihan and a representative from OCC would be involved because this would be a significant change, and any new guidance that we provided for industry would have to go through legal review.

Q And would that have included Ms. Amin?
A I don't remember.
Q Okay. On February 26th, the timeline mentions that FDA responded in writing to APHL's letter of February 24th and held a call with the association and member labs welcoming development of their own tests, telling them that several public health laboratories can jointly develop one test -- or one lab could develop a test for use by other labs under one EUA; is that correct?
A Yes.
Q Why was that decision made at that time to allow the labs to jointly develop a test or to develop a test for use by other labs?
A My understanding was that we received feedback from developers that this would be helpful in terms of expediting test review and obviously development.
Q Was a decision made not to waive the EUA requirement altogether?
A We made the decision to continually reexamine our approach, but to allow for laboratory test developers to commercialize, if you will, but put it into practice and come back to us within a certain specified period of time with the data.
Q And as you mentioned previously, on February 29, 2020, FDA ultimately issued that new policy that would

allow certain labs to develop their own tests and begin to use them before FDA completed its review. Why was that decision made just three days later? What had changed?

A I'm sorry, which three days, [Majority Counsel]?

Q So on February 26th, FDA had responded to the letter from APHL saying you can jointly develop a test or one lab can use a test that others have created under one EUA. And then it sounds like a new policy was announced three days later, on February 29th; is that correct?

A So I just want to be clear, [Majority Counsel]. If you're asking if there's a cause and effect between that response and the guidance, the answer is no. That the feedback we got from the letter that the APHL sent us was really important feedback for the development of the guidance, but we had already had discussions about how we could be pragmatic, as I mentioned, and more flexible.

Q What changed? Did you receive new information or have additional discussions? Why was the policy now announced on the 29th?

A Well, first of all, why the 29th. I mean, the policy was put together, there was processes that we go through to make sure it's consistent with the law, there has to be review at HHS, et cetera.

So with respect to the timing, if the question is

related to when that policy was actually developed and the process took place, I can't speak to that, but it was certainly before that week. It would have been -- the genesis of it would have been put together.

But the guidance was put together to try to provide flexibility. And, yes, it did incorporate feedback that we had gotten from developers, including commercial.

Q So you just mentioned that the decision was made and it just took some time to, is it fair, put together the announcement and get it reviewed and approved?

A Yes.

Q When was the decision ultimately made?

A I don't remember, [Majority Counsel], but it was certainly earlier than the 26th or the 29th.

Q Do you recall approximately when it was?

A I don't.

Q Do you recall approximately how long it took to go through the process before it was finalized?

A I don't.

Q Would you estimate that it was longer than a week?

A It would be -- I'm sorry, [Majority Counsel]. It would be a wild guess.

Q Of course. In hindsight, do you believe that the EUA requirement should have been lifted earlier?

A I do not.

Q Why not?

A As I mentioned, the review of our first hundred EUAs. And although that was a retrospective review, it's important to remember that we had ongoing communications with laboratory test developers. And I'm excluding commercial entities because that was never on the table. And, by the way, the commercial entities did not want to have that waived for them.

But because of our review and concerns around the accuracies of the test, I believe that we ultimately came to a policy that provided that balance between speed and accuracy.

Q I am going to mark as Exhibit 6 a March 5th, 2020 email exchange from Dr. Anne Schuchat to you and other individuals, and it's Bates labeled SSCC-0038035.

(Exhibit No. 6 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I would like to direct your attention to the second page 036.

In the email, Ms. Lenihan wrote, "Hi Dr. Schuchat, Dr. Hahn said he spoke with you about some ideas that would help get more diagnostic tests to market. Below are some of those suggestions. We would greatly appreciate your

approval."

What did you discuss with Dr. Schuchat?

A I don't remember the specifics, but I did discuss with Dr. Schuchat ways that FDA, in cooperation with CDC, could enable more particularly commercial tests getting onto the market and as well as LDTs. But I don't remember the specifics.

Q Do you recall any of the proposed ways that would help get more diagnostic tests to market?

A I do not.

Q Why did you talk to Dr. Schuchat at this time, March 5th, 2020, about getting more diagnostic tests to market?

A I don't remember what the genesis of this specific conversation was. What I can tell you is, in general, we had discussions across U.S. government about this and it would have been a natural conversation to occur with someone high up in CDC.

Q Do you recall who reached out to who or --

A I don't.

Q -- or why?

A No.

Q Was there concern that there were inadequate tests available at that time?

A As I mentioned before, as many tests available

as early as possible in a public health emergency is the best public outcome.

Q I'd just like to ask that question again. Yes or no, was there a concern that there were inadequate tests available at that time?

A We felt that there should be more tests available at that time.

Q Was that discussed with Dr. Schuchat?

A I don't remember if it was specifically discussed with Dr. Schuchat.

Q Was it discussed with others in the U.S. government?

A I don't know, [Majority Counsel].

Q Do you recall whether similar concerns, about the testing availability, were discussed at the task force meetings?

A We definitely discussed test availability and the need to have more tests at the task force meetings.

Q What was specifically discussed?

A I don't remember the details of the conversation, but we had broad discussions about commercial as well as laboratory test developers and how we could potentially enable them to get the tests out there as quickly as possible.

Q Directing your attention to the next email in

the chain, which is on page 035. Ms. Lenihan responded, "Thanks Dr. Schuchat. I asked the team to focus on the maximum steps we can take with you all to make sure we got as many tests out there as we could."

I know that you said you don't recall what ideas were discussed. Do you recall what steps were taken at that time to increase the number of tests available in the market?

A I don't remember, [Majority Counsel].

Q Do you recall if any proposals were not taken?

A I don't know.

Q Following your discussion with Dr. Schuchat in Ms. Lenihan's email, do you recall what happened next?

A I don't.

Q Did the approach to testing change at this point?

A [Majority Counsel], just to clarify your question. Approached by whom or by --

Q How about, let's start with FDA.

A This did not really change our approach to testing. What began at that time, [Majority Counsel], was an acceleration of commercial entities' test development.

So we had been spending a lot of time, particularly in the month of March, some in February, of reviewing data on an ongoing basis. So that didn't really change our

approach, but it did -- it was a matter of fact that more of the commercial developers were sending data to us.

Q I would like to ask the same question with respect to CDC. Are you aware if CDC's approach to testing and getting more tests on the market changed at this point?

A I don't know.

Q Were you able to get more tests out to the market quickly and in sufficient numbers to meet demand in this early March time period?

A No.

Q Why not?

A The issues that we discussed, [Majority Counsel], availability of supplies, number of tests that could be manufactured, significant supply chain issues.

Q When would those issues ultimately be resolved?

A It's a really complicated question, [Majority Counsel], because even to this date there are people who argue that we don't have enough tests available.

And so it depends on what one would think is an adequate amount of tests. And I think you've seen lots of public health experts around the country who argue there have never been enough or adequate number of tests. So I think it's, as I said, complicated.

With respect to March, we began to see at some point

in the spring the resolution of some of the reagent issues as well as the swab issues that were significant bottlenecks at that time.

Q How were those issues resolved?

A It was a multidisciplinary effort. For example, sending planes to northern Italy would be one example of it. Discussions with China, because there were certain export restrictions that were put into places, as I remember.

Q In hindsight, do you believe adequate steps were taken to resolve those supply chain issues? And I guess, as a related question, do you believe more could have been done at that time?

A So because it's multifactorial, FDA's responsibility is really about identifying where the supplies come from that are consistent with our regulations and consistent with our quality oversight, and I feel that we were able to identify those.

If I were to look back from that and answer the question from an FDA perspective, I would tell you that we did not and do not have the systems in place to do that in realtime; that it takes calls at different hours of the day and night. Because as you know, the time differences are significant particularly in China and India.

So I do believe that, from an FDA perspective, there

are approaches that could be taken to the supply chain that could allow for more rapid identification of where those bottlenecks are.

Q What would those steps be?

A Some of them would be reporting requirements by both U.S. and foreign entities regarding what the supply chain is rather than having the agency -- which we did during the crisis -- call companies; having that part of an overall database so that we could easily interrogate and understand where those bottlenecks are. Less of a manual process, more of a defined prospective process, if you will.

Q Were there other steps that would also be helpful to address those issues?

A Not off the top of my head, [Majority Counsel], right now. But I'm sure there are plenty that could be reviewed and looked at.

Q You just answered from the FDA perspective. Taking a broader perspective across all of the federal government, do you believe that adequate steps were taken to resolve those supply chain issues and could more have been done at that time?

A [Majority Counsel], I am no expert on diplomacy, interactions with foreign governments, you know, those sort of emergency response issues and also

geopolitical issues. So it's really difficult for me to make judgments about that.

But I'll go back to what I said before. It's really important to do this review, because asking the questions about what could be done better is really important. So from a medical background, there's always something you can do to be better.

Q Were these issues, the supply chain issues and possible solutions, addressed at the task force meetings during this period?

A Yes. Yes, they were.

Q Do you recall if any proposals were made at task force meetings that were not effectuated immediately?

A I'm not aware of that.

Q Did anyone raise any concerns specifically that these actions, the actions that were being taken, were insufficient to address the supply chain and other roadblocks on testing?

A What I remember, [Majority Counsel], is a significant sense of urgency, and the conversation being that we should be doing everything we can to expedite it.

Q During a visit to CDC on March 6th, President Trump said anyone that wants a test can get a test. Was that true at the time?

A Again, I'm not sure what the President was

intending at the time, but there was not enough tests at the time to meet demand.

Q In your opinion, what were the consequences of the lab contamination and the sending of faulty CDC-developed tests to labs?

A Repeat the question. I'm sorry, [Majority Counsel].

Q In your opinion, what were the consequences of the lab contamination and the sending of faulty CDC-developed tests to labs?

A One important consequence was the identification of a problem with the test which, if it hadn't been identified, would have led to inaccurate results. That's key in a public health emergency, and really gets back to the issue that I brought up that having a faulty test really is problematic for any healthcare provider, but certainly for public health officials.

Q What were the consequences of the general shortages of tests?

A I think there was a general impression, and I think it's based in reality, of not enough tests to meet demand. And as I had mentioned I think a couple times during the interview, [Majority Counsel], that more tests as early as possible is an incredibly worthwhile goal during a public health emergency like this.

Q Do you think that the number of tests could have been scaled up more quickly?

A I think I addressed that before, [Majority Counsel], in terms of the complexity of the issue. And so for example, [Majority Counsel], if there were readily available virus, if there were readily available reagents, if supply chain issues get resolved, if the geopolitical issues get resolved, then the conditional tests could -- yes. There's a lot of ifs in there.

Q Okay. Thank you, Dr. Hahn.

A Thank you, [Majority Counsel].

Q I'd like to move on to some of the therapeutics that were considered and approved during this period.

When did you become aware that hydroxychloroquine and chloroquine were being evaluated as potential coronavirus treatments?

A In March of 2021 -- 2020. Sorry.

Q How did this come to your attention?

A So I'm not exactly remembering the sequence, but there's a couple different sources.

Internally, one thing that FDA does is it monitors supply chain and monitors usage of drugs, and we became aware of a significant amount of prescriptions for the drugs and usage taking place. And anecdotally -- a lot of

this is anecdotal -- but anecdotally what we were hearing is physicians were prescribing to other healthcare providers, themselves, et cetera, as even a prophylactic and in some cases as a treatment, because there were in vitro data and one Phase 2 trial which suggested it was a benefit. And, of course, we had no off-the-shelf therapeutic at the time and people were dying. And the drug had a very long history of safety, 30 years, in the treatment of lupus and rheumatoid arthritis.

So that was the internal. And we continued to monitor that, and we had graphs that showed a substantial spike in the usage.

Also at that time, it was reported on one of the news outlets, and the President of course mentioned it at a press conference, about hydroxychloroquine. And so that, of course -- I don't know cause-and-effect there, [Majority Counsel] -- but that of course increased the notoriety of the drug, if you will.

Q Do you recall when it first came to your attention?

A I don't.

Q Do you recall what the early data or clinical indications suggested about the possible efficacy of the drugs, I guess, first as a prophylactic and then second as a treatment?

A Well, first I'll come off by saying there's -- I'll first state, excuse me, to correct the record, that there were no definitive level 1 evidence at that point for either of the clinical settings that you described.

What there was at the time was a Phase 2 trial that's been published and in vitro or test tube data basically showing that it had some efficacy against the virus, which of course are prerequisites for performing definitive trials and anecdotal.

Q Those trials, were those performed in the United States?

A Trials were performed across the world with the use of hydroxychloroquine and chloroquine.

Q Do you recall what the first study or trial that came out was?

A So not the Phase 2 trial that I'm referring to?

Q That's my question. Was that the first one, or were there additional papers and research published?

A So the first literature that I was aware of and that the agency sort of looked at was this Phase 2 trial. I forget the journal, but it was a French study in inpatients. There were reports, and I don't know how detailed they were in the peer review right now in front of

me.

But the first randomized control trial, which we consider to be the gold standard for evaluation of a drug, was, my remembrance, the recovery trial from the United Kingdom and those results came out in June of 2020.

Q For the French study, did you review it at the time?

A The agency did, yes.

Q Were there any concerns expressed about the methodology or the sample size of that study?

A In general, with Phase 2 trials, because there's no comparator arm, that would be the major concern about the data, whether -- in the medical world we use the term "selection bias" -- whether there'd be selection bias, because there's no comparison to a placebo.

It's a limitation of the study. I think you used the term "critique." So it's a limitation of the study, and any decision you make has to be made in the context of understanding the limitations of the dataset.

Q Okay.

A But going through the peer review process, it's helpful, because experts have looked at it.

Q Just at a very general level, what's the risk of the selection bias?

A So at a general level, you could -- an

investigator who's investigating could potentially select individuals for an intervention that predisposes them to response; or you could select people who don't need it and you don't know it.

So all of those meaning, in the cancer world where I'm from, are very common things that you know are limitations of Phase 2 trials.

Q Do you recall the size of that trial?

A I don't.

Q Would it refresh your recollection if I said it was under 40 individuals?

A It would refresh my recollection. I'm assuming you know that number. I don't remember that, I'm sorry.

Q That's all I'm asking for. You mentioned that hydroxychloroquine and chloroquine were discussed on a news channel or a news program.

What was your recollection?

A My recollection is that the President mentioned that at the press conference, and that he had heard it on TV.

Q And prior to that time, had you discussed these treatments with President Trump?

A I don't remember the exact time when they were discussed, [Majority Counsel], whether it was before or

after.

Q During this period, were you briefing President Trump on possible therapeutics?

A Not on a regular basis, no.

Q How often?

A I would respond to requests from the White House on where we were. We had put in place a systematic approach to therapeutic development where we kind of surveyed the landscape and looked at the science, and we provided a number of documents to the White House regarding our approach to that and how we were working with developers of the therapeutics both off the shelf as well as de novo agents.

Q And were you also discussing possible therapeutics at the task force meetings?

A Yes, it was discussed.

Q And were you also discussing possible therapeutics at the FDA?

A Yes. Oh, yes.

Q Was someone in particular leading the effort to identify possible therapeutics that would be useful for responding to the coronavirus?

A We had a number of different teams at the FDA. So there was an effort called CTAP, Coronavirus Treatment Acceleration Program, which was cross-disciplinary, and it

involved both CBER, Center for Biological Evaluation Research, as well as CDER, Center for Drug Evaluation Research, with occasional input from Dr. Shuren, CDRH.

So there was internally a group that did this, and then we relayed that information to the White House and the task force.

Q And so you mentioned Dr. Shuren at the CDRH. Was Dr. Marks the person leading the effort at CBER?

A It would be Dr. Marks and his team. I wasn't part of the day-to-day meetings, but Dr. Marks and his team would have been involved.

[Majority Counsel]. I believe we are just about at time, so we can go off the record.

(Recess.)

BY [MAJORITY COUNSEL].

Q Before the break, Dr. Hahn, we were talking a little bit about hydroxychloroquine. I am going to show you an email that that we will mark as Exhibit 7.

(Exhibit No. 7 was identified for the record.)

BY [MAJORITY COUNSEL].

Q This is a March 18th email from Robert Kadlec to AMA2, copying you and Brian Harrison. It's Bates numbered SSCC-0037728.

I'd like to direct you to the earliest chain in the

email written by AMA2. Dr. Hahn, who is AMA2?

A So that's an email address that is Secretary Azar's.

Q Secretary Azar wrote, "I don't understand the difference, but please be sure we are looking at both this and hydroxychloroquine and manufacturing. Laura Ingraham mentioned on her show that Sanofi makes hydro."

Did you understand this reference to mean that Secretary Azar learned about chloroquine and hydroxychloroquine on the Laura Ingraham show?

A I just don't know.

Q Was this the first time you had received suggestions about possible therapeutics based on TV programs like the Laura Ingraham show?

A I'm sorry, [Majority Counsel]. Is the question the first time I've heard about therapeutics, or therapeutics specifically from a TV show?

Q The first time that you received a recommendation specifically from something that was discussed on a TV show.

A I believe it was, but I can't be 100 percent sure since there was a lot of discussion in the media about potential therapeutics.

Q Did it ever happen again?

A That -- I'm sorry, [Majority Counsel]. "It"

meaning that a therapeutic was discussed on TV and then it was brought to my attention?

Q Yes.

A [Majority Counsel], there was so much incoming about potential therapeutics that I couldn't possibly say no to that just because -- you know, the sources of people's information might have been mentioned to me. I just don't remember. But I can tell you, literally on a daily basis, particularly early in the pandemic, from a variety of different reporters we would get information about potential therapeutics.

Q Did you take any action as a result of this email?

A I don't believe I did, [Majority Counsel].

[Majority Counsel], I'll just tell you, when I read this email, what jogs my memory is that -- typically, this is an FDA core responsibility, trade name, generic name, who makes the drug, where the supply is from. So it would not have at all been unusual for Dr. Kadlec to reach out to us to ask the question, where did this drug come from, who makes it, et cetera, trade name?

So I cannot tell you if that did or did not occur, but that would be a typical situation, and that would be within the FDA's core responsibilities.

Q I will show you what I'll marked as Exhibit 8.

This is a compilation of White House Coronavirus Task Force meeting agendas.

(Exhibit No. 8 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct your attention to page 22 and 23. You'll notice that there are numbers at the top center of the page.

Mr. Armstrong. Is it the right-hand numbers on those?

[Majority Counsel]. The ones at the center, the larger numbers.

BY [MAJORITY COUNSEL].

Q So page 22 refers to a March 19th, 2020 agenda, and page 23 is a second but different March 19th, 2020 task force agenda.

Do you see those agendas?

A I do, [Majority Counsel].

Q On page 22, the agenda lists "FDA Announcement - Dr. Hahn"; and then on 23, the agenda lists "Supplies Update - Dr. Stephen Hahn", with a sub-bullet regarding "FDA - Hydroxychloroquine (HC) Status."

The first question is, these agendas appear to be dated the same day and at the same time. Do you recall why there were two agendas and, if so, which one might be

correct?

A I can't speak to March 19th, [Majority Counsel]. I don't remember, which is why I can't speak to it. It was -- it did occur where one agenda was put out and then it was revised to the second agenda. I cannot tell you which one was the one that was actually used.

Q Do you recall what was discussed at that task force meeting with respect to hydroxychloroquine?

A I do not recall the specifics of this particular meeting on that day.

Q Okay. Thank you.

You mentioned before the break that President Trump spoke about hydroxychloroquine and chloroquine at a task force press briefing. Do you recall that?

A I recall the circumstances, yes.

Q During a March 19th, 2020 task force press briefing, President Trump said, "It's shown very encouraging, very, very encouraging early results and we're going to be able to make that drug available almost immediately. And that's where the FDA has been so great, they -- they've gone through the approval process, it's been approved."

He also stated about the drugs, "I think it could be a game changer."

You participated in that press briefing. What was

your reaction to that, when you heard the former President's statements?

A So we're really careful at the FDA about the words we use. So it's true that these drugs are approved; they're approved and available for certain indications.

Doctors can write prescriptions of drugs for what we call off-label, not the intended use. So this is confusing to many people, including providers. I don't specifically know whether the President was referring to the fact that it's an already approved drug, or whether he was saying it was approved for COVID, because in fact it had not been approved for COVID. And we wouldn't use that term, anyway. We would use the word "authorized."

Q Did you agree with his statements, that hydroxychloroquine and chloroquine had shown "very, very encouraging early results" and that it could be a "game changer"?

A I was very clear with the White House and the President about the fact that they were preliminary data, but they were preliminary and that we really did need to have control data in a randomized controlled trial to be able to definitively tell the American people whether these drugs would work.

Q And did you encourage President Trump to share with the American people that they had "very, very

encouraging early results"?

A Repeat that?

Q Had you encouraged President Trump to say that there had been "very, very encouraging early results" or that it could be a "game changer"?

A [Majority Counsel], is your question referring to whether I relayed encouragement to the President regarding this, or is it around a specific conversation? I'm just wondering what.

Q Let me rephrase the question.

What had you told President Trump with respect to the potential efficacy and the early indications about the use of hydroxychloroquine and chloroquine?

A So -- and I think I prefaced the previous question with this; that I had been really clear to everyone about the fact that we had preliminary data, both laboratory data and other data, clinical data -- some being anecdotal, by the way -- that did not rise to the level typically of definitive data. So I communicated that to the White House, including to President Trump.

Q And did you review his remarks prior to that press conference?

A I don't remember.

Q Sitting here today, do you believe you would have approved the statements that they had shown "very,

very encouraging early results" and that it could be a "game changer"?

A I would not have.

Q Why not?

A So, [Majority Counsel], my background, both as FDA Commissioner, but also as a cancer doctor, is that one has to be really careful about the way one as a physician makes statements about therapeutics, but -- in general approaches to people with illnesses. And I believe it was at one of the press conferences I made the comment, we want to give hope, but not false hope.

So just being cognizant to that as a provider, that's why I would have said that's probably not the best way to say it.

Q What's the concern with sharing potentially incorrect or overly optimistic statements?

A So let me just be clear.

I think it's a good thing to share that there's a potential therapeutic. I think that provides people -- that's the hope part of it. But I think that, as I mentioned, what the concern would be is what you don't want to do is provide false hope for people to think that something definitively works.

Q What's the risk if they get that information and have false hope about the potential efficacy?

A From a potential provider, it's an emotional issue for patients. It's -- you know, it's thinking that there's something out there that would help them that might not. It might, but it might not.

From an FDA perspective, we want to give as accurate information as we can possible to providers and patients. That's part of our job. And when we make decisions, we try to be clear about the level of evidence that we use to make decisions.

Q During the press briefing, you said that, "Hydroxychloroquine is a drug that the President has directed us to take a closer look at as to whether an expanded use approach could be done to see if it actually benefits patients, and again we want to do that in the setting of a clinical trial, a large pragmatic clinical trial to actually gather that information and answer the question that needs to be answered."

Did President Trump direct FDA to take a closer look at hydroxychloroquine?

A Yes.

Q What did he say?

A I don't remember the specifics of the conversation, [Majority Counsel]. But, in general, if promising therapeutics, diagnostics, or whatever came to the fore -- and this is not just a White House issue, this

is member of Congresses, governors, you know, mayors, throughout the pandemic would reach out directly to me or to others in leadership at the agency and say, hey, this is promising. Can you all take a look at it? That, [Majority Counsel], occurred I can't even tell you how many times a day and every day, at least in the beginning.

Q Did President Trump direct FDA to make hydroxychloroquine and chloroquine immediately available to the American people?

A I don't remember his doing that. The conversations we had from a general point of view were about the fact that the drug may work, it may not work, that we needed studies to actually be able to determine that.

Q Did President Trump ever direct FDA to issue an EUA?

A No. Well, not to me.

Q Did he ever direct anyone else?

A I don't know.

Q Did anyone else in the Trump administration direct you or anyone at FDA to issue an EUA for hydroxychloroquine or chloroquine?

A No. Well, [Majority Counsel], let me answer this. I don't know about every conversation that occurs at the agency. What I can tell you is I have not heard of

anyone else being directed and I was not directed.

Q You mentioned that you wanted to look at whether hydroxychloroquine benefits patients in the setting of a clinical trial. Did that happen prior to the issuance of an EUA for hydroxychloroquine or chloroquine?

A It was being actively studied, and there was one published report at the time.

Q Was that the French?

A That was the French study, yes.

Q Did a clinical trial -- scratch that.

Would the results of a large pragmatic clinical trial, as you put it, would that be necessary normally, in your mind, to provide the basis for an EUA for a potential treatment?

A And I am going to question the term "normal." So remembering that the statute behind EUAs requires may be effective risk-benefits in favor of and no alternatives available. That really depends upon the timeframe, what was available at the time, what we knew about the drug, and what data we had available that suggested the efficacy.

So you can imagine, [Majority Counsel], that it not only matters time and data that's collected, but also who's the population who's going to get it. If -- and I'll put it in cancer perspective. People who get a vaccine are healthy, in general. So the risk-benefit is in favor of

making sure it's not toxic, right? Because a lot of people are going to get it.

If you're a cancer patient with a life-threatening disease, you're willing to accept more toxicity. Remember, of course, that in spring, the case fatality rate for this was substantial for COVID.

So that was part of our calculation. That's what FDA does.

Q Thank you. I'd like to show you what I'm going to mark as Exhibit 9. This is a March 28th, 2020 email from Ms. Lenihan to Ms. Amin, copying you and Dr. Shah, Bates numbered SSCC-0037912.

(Exhibit No. 9 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct your attention to the bottom of the first page. Donald Beers wrote to a number of individuals on March 19th. "I am reluctant to get ahead of the client on this, but a reasonable expectation of events is that we are going to be facing great pressure to make chloroquine, and perhaps other drugs, available to COVID-19 patients and to healthcare workers at risk. The alternatives for" -- and then the additional text is redacted.

You don't appear to be copied on this email, but you

were subsequently forwarded it; is that correct?

A It looks like that, yes, [Majority Counsel].

Q This email was written after President Trump's remarks at that press briefing we were discussing a moment ago; is that correct?

A Could you remind me about when the press briefing was?

Q I can show you, actually.

A Okay. Thank you.

(Exhibit No. 10 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I am handing you a copy of a document titled Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force in Press Briefing, issued on March 19, 2020.

Does this reflect what time the press briefing started, Dr. Hahn?

A [Majority Counsel], I just don't remember what this refers to, whether this was the time the document was created or when the remarks were made. I just don't know, [Majority Counsel]. But if in fact the remarks were made at that time, then, yes, this email would be after that.

Q For the record, the document says James S. Brady Press Briefing Room, 11:31 a.m. Eastern time.

Turning back to Exhibit 9. What was your understanding of what Dr. Beers was referring to when he said, "I am reluctant to get ahead of the client on this, but a reasonable expectation of events is that we are going to be facing great pressure to make chloroquine, and perhaps other drugs, available"?

A So I didn't have a conversation with Mr. Beers about this, so I'm not sure what he means with respect to client or with respect to pressure.

Q Were you part of conversations with others at FDA where there was a concern about facing pressure to make chloroquine or hydroxychloroquine available to COVID-19 patients?

A [Majority Counsel], I'm pretty confident that I was. I just don't remember the specifics.

Q Do you recall anyone expressing a concern that the former President would pressure FDA to make drugs available?

A Again, [Majority Counsel], I don't have specific recollection, but that would not surprise me at all of having been involved in these conversations.

Q Why not?

A Because it was the topic of the day. As you know, at the time, this was discussed widely and a lot of people knew about it, and we were, I'll use the -- we were

the pointed edge of the stick for authorization. So this would ultimately come to decisionmaking within FDA and everybody knew that.

Q Did you feel that the former President had been pressuring FDA to make hydroxychloroquine or chloroquine available?

A What I felt, and I said this publicly before, the -- there was great pressure in general because of the urgency of the situation and the fact that people were dying. The President repeatedly expressed his interest in making sure that we moved quickly to make medical products available.

Q And is it fair to say, generally speaking, that making medical products available in the middle of a crisis is a worthy goal?

A Yes, I would agree.

Q Was there a time that perhaps that pressure was inappropriate in any way?

A Meaning ever in my tenure?

Q Yes.

A Yes.

Q What happened?

A Well, it relates in part to the hydroxychloroquine issue.

So we issued the EUA, as you know, and then we

started to collect real-world evidence. Dr. Abernethy was helping us with that, as well as others. We had an internal system that's called Sentinel which helps us look at side effects, et cetera. And we knew that trials would be reporting out. We started to survey the landscape and talked to people. When would the definitive data come in? Because one of the really important things about EUAs is the flexibility associated with it.

So my analogy as a doctor in the emergency room, somebody is sick. You make a decision to save their life based upon the best available data. You admit them to the ICU. Lots of results are coming in, and you revise your decision. In fact, if you don't revise your decision, that's bad doctoring.

A very similar situation here. We would take and constantly review all of our decisions from the context of incoming data.

So all that occurred. And of course eventually we revoked that EUA, and then we received an application for another EUA for hydroxychloroquine in the outpatient setting.

And there were discussions that I had with Mr. Navarro in particular that I would say probably rose to the level of what you just asked me with respect to pressure.

Q What happened during those conversations with

Mr. Navarro?

A Sorry, I should have said Dr. Navarro.

Q Dr. Navarro.

A I apologize, my fault.

Dr. Navarro was in receipt of data. The data that he sent to me were not randomized clinical trials, but were in general supportive of the use of hydroxychloroquine or chloroquine for COVID.

His conclusion, after review of the data, were that this was supportive of an EUA in the use and continued supportive. We took a different stance at the FDA. So that disagreement, which of course ultimately became somewhat public, was a source of pressure, to be honest with you.

Q What did Dr. Navarro say to you?

A I don't have specific recollections of all the calls. But he was very demonstrative about his belief that hydroxychloroquine would work, and was working, and that it had met the statutory standard for an EUA.

Q And how would you respond to that?

A I would tell him that we've been very carefully reviewing the data. I would point out that -- and eventually it became five. Initially there was just one randomized clinical trial, which is the highest level of evidence that we would use for making an

adjudication came out. And it made no sense to continue the EUA in the setting of a Phase 1 trial that basically indicated that, in that setting, hydroxychloroquine didn't work. And it was directly related to how we had written the intended use.

Q You mentioned that the conversations bordered on the inappropriate. How so? Why did you feel that he was pressuring you inappropriately?

A [Majority Counsel], I could be wrong, but I don't believe I said bordering on the inappropriate.

Q I apologize.

A I just want to be clear.

Just the persistence associated with the conversations about asserting that the data were supportive, given all the publicity around it and given the publicity about the rationale for our decision in the Phase 1 trial, you know, that, I felt, was pressure.

Q How would you describe the tenor of those discussions? Would they get heated?

A You know, it's so subjective, [Majority Counsel]. I guess, in general, I would say no.

Q What do you mean subjective?

A Well, it's in the eyes of the beholder. If, by heated, did you mean screaming and yelling, the answer is no. Not that I remember. If you mean sort of

definitive, the data support this kind of the way academics would argue, the answer would be yes. So it really depends on how you define that.

Q You mentioned that Dr. Navarro, was it -- did he advocate that a new EUA should be issued authorizing hydroxychloroquine in an outpatient setting, or did he do something else? Did he provide you with the text or a memo or some other work product?

A He provided me with literature. He did advocate for an outpatient EUA for hydroxychloroquine.

Q Did Dr. Navarro advocate for any other specific policies or actions with respect to hydroxychloroquine?

A Other than what I just mentioned our discussions were about, I cannot remember a time that he did.

Q Do you recall if Dr. Navarro sought funding or assistance in setting up clinical trials for hydroxychloroquine?

A I don't know.

Q Do you recall if Dr. Navarro sought to distribute hydroxychloroquine prophylactically?

A You know, I don't know. Although a number of clinical trials were being performed. Whether Dr. Navarro was involved in those -- because one of the trials was, I

believe, at Henry Ford Hospital, and he had been in close touch with the investigators there. So whether he was actively involved, I just don't know, but I do know that connection.

Q How did you know that he was in close contact with the researchers at Henry Ford?

A He told me.

Q When did Dr. Navarro advocate for reinstating the EUA?

A It would have been in the June and July timeframe.

Q When was the EUA revoked?

A That's part of the records somewhere, I'm sure. I'm sorry, [Majority Counsel], I think it was in June.

Q We will get to that.

Back to the March time period. You mentioned that -- we were discussing that President Trump referenced hydroxychloroquine at the March 19, 2020 press briefing. What happened next? What steps was FDA taking with respect to hydroxychloroquine at that time?

A We were taking a very active stance for a couple of things. One was to collect real-world evidence. So you can gather -- Dr. Abernethy was really good at this. You could gather -- when you have a collaborative

relationship, you can gather evidence from medical records, for example, in a de-identified way that's HIPAA compliant. And you can look at prescribing patterns, you can inquire about outcomes, you can inquire about toxicities.

So we were collecting those data, as you could imagine we would, and we were also collecting data around supply chain, so the APIs, the precursors, as well as the supply broadly available in the country. So we were spending a lot of time looking at that.

Q I am going to mark as Exhibit 11 a March 22, 2020 email from you to Dr. Deborah Birx that is not Bates numbered, but the subject reads, "Urgent Oz: Clinical Trial Drug Shortage."

(Exhibit No. 11 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct you to the bottom of the second page of this document. It shows that Dr. Birx on March 22nd, 2020 at 10:17 a.m. wrote, "Dr. Oz, This was posted yesterday on the CDC website and serves to address the issues you raised. Deb."

It then copies "Information For Clinicians on Therapeutic Options for COVID-19 Patients."

In response, Dr. Mehmet Oz responded, "Thanks for sharing, but this does not address the shortage issue. We

already have an IRB for prophylaxis and applying for treatment trial today, but don't have drugs to complete, so please share expectations that can inform our work. Can we at least get batches of drugs for a hundred trial patients? If you don't wish to put in writing, please call."

Dr. Birx subsequently forwarded this to you and Dr. Redfield, and you responded, but most of the information in the email was redacted. But you did say, "Do you have any time to talk about this?"

Did you ultimately speak to Dr. Birx about this issue?

A Dr. Birx and I spoke quite a bit about this issue. Whether it was in response to this email, I can't specifically say. But, yes, we had multiple -- as did Dr. Redfield and I and occasionally Dr. Fauci.

Q You said you had multiple conversations about this issue. Was it about the drug shortage generally, or specifically to Dr. Oz's request?

A Drug shortages generally, and therapeutics in particular.

Q What was your reaction to Dr. Oz's email and request?

A So my reaction was this was a significant problem. So one of -- there were a couple of things that we were concerned at the agency: The surge in use, off-

label, if you will. Now, we don't regulate the practice of medicine, so that's not our domain to say whether doctors should prescribe medication, but we were seeing it.

We have to respond to that because -- there are two major issues here. One is the people who receive these drugs for FDA-approved indications, they were having trouble getting those. That's a core responsibility, and those are drugs that are approved for those conditions, so lupus and rheumatoid arthritis.

The second was we really felt strongly, and I personally felt strongly, that we needed randomized clinical trial data. If there were no drug available to actually do the studies, we would never get the answer.

So, to me, it was really important that we had drug supply, one, for those who had approved indications; but, two, to perform the clinical trials.

Q Was any action taken to respond to Dr. Oz's request?

A Not that I am aware of.

Q Are you aware whether any drug supplies were provided to Dr. Oz for the trial?

A I'm not aware.

Q Dr. Oz is a well-known TV host in addition to being a doctor. Are you aware of how Dr. Birx came to communicate with him about those?

A I am not.
Q Did you ever communicate with Dr. Oz related to this?
A I don't believe so.
Q Are you aware whether others in the Trump administration communicated with Dr. Oz?
A I don't know.
Q Did you ever communicate with other TV hosts related to the pandemic?
A Yes.
Q Who?
A Laura Ingraham.
Q What did you discuss with Laura Ingraham?
A So I was introduced to Laura Ingraham by folks at the White House. And we would communicate about what she was hearing with respect to the pandemic and at least initially regarding hydroxychloroquine.
Q Who at the White House introduced you to Ms. Ingraham?
A I don't remember who introduced me, but I do remember being at a White House meeting in the Oval Office with her.
Q When did that meeting occur?
A [Majority Counsel], I don't know. I'm sure you can refresh my memory.

Q Approximately, do you recall when it was?
A March, April. It's in that timeframe. Certainly, I don't remember it being June, July.
Q Do you recall who was at that meeting?
A There were two doctors, who I believe that Laura Ingraham had on her show, or had previously on her show, who had data regarding hydroxychloroquine.
Q Who were those doctors?
A I don't remember their names. I'm sure it's in the press somewhere.
Q Apart from Ms. Ingraham and these two physicians, who else attended the meeting?
A The President was there. And I don't know -- I don't remember who else was there.
Q Were there other White House staff in attendance?
A It would be a guess. My guess would be yes, but I don't know for sure.
Q You mentioned that hydroxychloroquine was discussed. What specifically?
A What was discussed was these doctors' data that they had available to them regarding the drug, in support of using the drug as a treatment for COVID-19.
Q You mentioned that you talked to Ms. Ingraham about other topics. What specifically?

A Typically, she --

Mr. Armstrong. Excuse me, pause to go off the record.

(Discussion off the record.)

BY [MAJORITY COUNSEL].

Q Before we went off the record, I had asked, did you discuss other topics, topics other than hydroxychloroquine, with Ms. Ingraham?

A Yes, I did.

Q What other topics?

A Ms. Ingraham would, if she heard about other therapies -- and I don't remember specifics around that -- or interesting scientific information, she would refer that to me. It happened more in the beginning, but it was not at all out of line compared to what others around the country did as well. I mean, it was a daily occurrence.

Q Going back to the Oval Office meeting that you were just referencing that you attended with Ms. Ingraham, the two physicians, and President Trump. Did the President provide any directive to you or others at that meeting with respect to hydroxychloroquine?

Mr. Armstrong. May I object here. The White House counsel's office in recent weeks has asked that we respect any communication between Dr. Hahn and the President, Vice

President, or the chief of staff. Not that we can't discuss those conversations, but that, if we do, we keep them at a high level where it's talking about concerns and impressions or topics, and it's not kind of a transcribed account of the actual conversation itself.

[Majority Counsel]. Are you instructing your client not to answer the question?

Mr. Armstrong. I am not. I am relaying the White House's ask, and just I want that to be on the record. And, if you would, it would be appreciated if we could keep those at that level.

I've got two branches here, and Dr. Hahn is not going to be in the midst of that battle. But I just want to raise that.

[Majority Counsel]. Thank you. I am going to ask the question, and if you need to object if you think that it's getting into any potentially privileged territory, I would just ask that you put it on the record so that we can build the record and move forward in that way instead of perhaps avoiding the topics entirely.

BY [MAJORITY COUNSEL].

Q Dr. Hahn, let me just re-ask the question.

Did President Trump provide any directive to you at that meeting, or shortly after that meeting, with respect to -- that was a terrible question. Let me strike that.

Did President Trump provide any directive to you at that meeting with Ms. Ingraham?

The Witness. Can I speak to counsel?

[Majority Counsel]. Yes.

(Discussion off the record.)

The Witness. Not that I am aware of.

BY [MAJORITY COUNSEL].

Q Did the President provide any directive to you with respect to hydroxychloroquine after that meeting?

A No, he did not.

Q Did anyone else --

A Let me clarify what I meant by that.

Other than the urgency of the situation and the speed with which we were doing it. But a directive about a specific outcome, no.

Q You were discussing earlier the shortages of hydroxychloroquine and chloroquine in the country at that time. What actions was FDA taking to address those shortages?

A It's part of our statutory authority to be able to interact with suppliers of both API, so precursors of drugs. And these are both generic drugs and so they're -- often generic drugs, both manufactured, but also the precursors, are made in foreign countries and about 70 percent of them in India and China.

So we spend a lot of time working with manufacturers to see how we could have domestic production, that's really hard to ramp up quickly, but also how we could make sure we got API and actual drugs from these countries. So we spent a lot of time looking at the supply chain issues.

(Exhibit No. 12 was identified for the record.

BY [MAJORITY COUNSEL].

Q I am going to hand you what has been marked as Exhibit 12. This is a March 25th, 2020 email from Janet Woodcock to Robert Charrow and you, Bates numbered SSCC-0037716.

I'd like to direct you to the top of the second page -- or maybe the bottom of the second page. At the bottom of the page, Mr. Charrow wrote to Ms. Amin, "EUA for Donated Drug. When do you expect it to issue?"

Ms. Amin forwarded the email to Dr. Woodcock, to you, and others, and Dr. Woodcock responded, "What EUA are you referring to? We are working on the chloroquine right now, should have it done by the time the testing is done (3-4 days). The hydroxychloroquine one we have not gotten a lot of information on. It is a US-approved drug and we'd like to reserve 600,000 doses of 200 milligrams each for the clinical trial."

This email was in turn forwarded to you and

Mr. Charrow. Do you see that?

A Yes, I sure do.

Q Do you recall what the proposed clinical trial was that Dr. Woodcock was referring to here?

A I don't remember this specific one, but there were multiple. And we had been keeping track of that, so double digit numbers of trials that had been proposed or were ongoing.

Q Was it a reference to the clinical trial that Dr. Oz proposed in his email?

A I don't know.

Q Do you recall if FDA assisted Dr. Oz in any way with his clinical trial?

A I don't recall that at all.

Q Moving up on the page, Mr. Charrow responded at 3:33 p.m. He wrote, "As per my discussion with Stephen, the EUA I am interested in would be for donated hydroxychloroquine that would not necessarily be in clinical trials. Some of the donated drug would be used for clinical trials, but most would likely not be."

Do you recall the discussion that was referenced by Mr. Charrow?

A I don't remember the specifics of the conversation. What I do remember, [Majority Counsel], is that we knew that the problem, as I described previously,

was great surge in demand, limited supply, people with FDA-approved indications, people who were writing off-labeled prescriptions, which was leading to the surge in demand, and then the clinical trials.

From an FDA perspective, I would have normally communicated that these are the major concerns we have in getting as much of the drug into the system as possible to address those, because they're all really important.

Q Do you recall how the drug was going to be used in this circumstance?

A So our intention at FDA was the drug to be used for all of the three situations that I just described; for FDA approved indications, for clinical trials for sure, and also to meet the demand for off-label. We, again, don't regulate the practice of medicine so we don't control that, and that really has to be an individual patient-doctor discussion. But if we see it and we see pressure on the system, we try to respond to make supply available.

Q Did anyone raise concerns about the surge in demand specifically, that that could be problematic beyond from just the supply standpoint?

A I think we all -- I mean, because those of us who are clinicians and practicing clinicians understand that the tension between off-label use of drugs is

incredibly common, but also the fact that this puts pressure on the system as a whole for the issues that I just described.

And so there was definitely discussion about the fact that this had implications for the U.S. healthcare system.

Q Moving up on the document, Dr. Woodcock responded, "The clinical trial I am referring to would only need 600,000 doses. It would go to treat healthcare workers exposed to COVID-19 agent."

It continues, "We can do an EUA for CHQ along with the chloroquine one."

Do you recall whether FDA was discussing a clinical trial to treat healthcare workers exposed to the COVID-19 at that time?

A Yes. I don't know if it's this specific trial, but as I mentioned, we were keeping track of all the trials. As you know, investigators have to apply for an IND to perform a clinical trial with an investigational agent or an off-label in this case, but investigational in that case.

So we would be aware if someone had applied for that. And there were multiple trials that were looking at treatment, both inpatient and outpatient, preexposure prophylaxis. So I work in an ICU, I know I'm going to be exposed, so I'll pretreat myself, and then postexposure

prophylaxis. So yes.

Q I'd like to direct your attention back to Exhibit 8, which is the compilation of the White House task force agendas. I would like to direct your attention specifically to page 29, which is on March 27th, 2020 agenda.

At Roman VII, it reads, "FDA Update on Plasma & Treatment Action Plan - Dr. Stephen Hahn." The sub-bullet says "Chloroquine Efficacy."

Did you provide an update on chloroquine at this task force meeting?

A [Majority Counsel], I can't recall a specific meeting. What I can tell you is that we provided regular updates on the COVID treatment acceleration program, CTAP. And within that context, we would have provided information about these drugs, their availability, clinical trials that were scheduled, and what the current status of the data would be.

Q At this time, so March 27th, 2020, what was the current status of the data or understanding of possible efficacy?

A So we had some published data. But really what we were looking at was collected data in the real-world setting. So from medical records.

Q And what does that indicate?

A So early at that point, in terms of efficacy, the data were very preliminary. And, [Majority Counsel], just -- I'll say this in a kind of unscientific way. But you couldn't necessarily -- you could not draw definitive conclusions from what we were seeing either way at that time.

[Majority Counsel]. I'd like to mark as Exhibit 13 a March 28th, 2020 letter from Dr. Rick Bright regarding Request for Emergency Use Authorization for Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease.

(Exhibit No. 13 was identified for the record.)

BY [MAJORITY COUNSEL].

Q What is this document, Dr. Hahn?

A This is a letter of request for the issuance of an EUA for the drugs that are listed there, chloroquine phosphate or hydroxychloroquine sulphate, for the use and treatment of coronavirus disease.

Q Just to clarify, is this the letter requesting the EUA or the --

A Oh, I'm sorry.

Q -- or the actual issuance of the EUA?

A This is -- I'm sorry, let me read it. I

apologize.

This is the issuance of the EUA.

Q Who was involved in making the decision to grant this EUA?

A This decision was made and is the responsibility for the Center for Drug Evaluation Research.

Q And who was the ultimate decisionmaker within that?

A Dr. Woodcock.

Q Did you participate in discussions regarding whether this EUA should be issued?

A Yes.

Q And with whom?

A With Dr. Woodcock.

Q And what was discussed?

A The data behind it, where the reviewers were.

The way this happens, [Majority Counsel], is that a request comes in, in this case from BARDA. They provide a data packet to support it. Our reviewers review it. They come to a conclusion. It goes up the chain of command at CDER, and then ultimately the center director signs off on it.

Depending on the importance/urgency of the situation, that may or may not get discussed with the Commissioner.

Q In this situation, did it get discussed with

the Commissioner?

A Yes.

[Majority Counsel]. Can we go off the record just a minute?

(Recess.)

[Majority Counsel]. We can go back on the record.

BY [MAJORITY COUNSEL].

Q At the time that this EUA was issued for hydroxychloroquine, did you agree with the decision?

A Yes.

Q On page 2 of the EUA, it reads at the middle of the page, "Based upon limited in-vitro and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19."

Are you aware which particular studies or national guidelines were relied upon in granting this EUA?

A The main study was the French study that we discussed. I'm not sure about the national guidelines.

Q Did anyone discuss concerns about the basis for issuing this EUA at the time?

A I think, in general, we discussed the pros and cons of this. So, yes, there were extensive discussions about it, particularly at the center level, but Dr. Woodcock and I did as well.

Q What cons were discussed at that time?

A So the cons that were discussed is -- and it's not really a con. But the discussion around, did this meet the level -- the statutory-required level of data to support may be affected.

Because as you can imagine, [Majority Counsel], "may" is a really -- there's a lot of gray in "may." And we came to the conclusion that it did and that the risk-benefit was in favor of it.

And also, which is very typical, [Majority Counsel], of the FDA, there have to be pragmatic components of this. For example, if we were ever to get an answer that would really definitively tell us, we need a drug to perform the clinical trials and we needed to make sure that people who needed it for approved indications had it. So there was a significant pragmatic component to this.

Q At some point, did you come to believe that hydroxychloroquine was not effective in treating the coronavirus?

A Certainly when the recovery trial results were reported, that was a significant result. And at that

point, my opinion was we had level 1 data that shows that it's not working.

Internally, we had a discussion, [Majority Counsel], that it's very possible that -- and, [Majority Counsel], I'm going to use the term -- "clinical trial" term, so I apologize ahead of time. But if the effect size is small, so if it's a couple of percent benefit, you need a trial of like hundreds of thousands of people to detect that.

So a trial doesn't definitively say no, but it says, in this setting, under these circumstances, the answer is no with high probability.

So we continued to understand that it might have some effect and that the laboratory data might be correct, but we had to go with the data that were available, vis-à-vis my analogy to the doctor in the emergency room and the ICU, updated data.

Q By what time, what date did you start to form the opinion that hydroxychloroquine was not effective?

A June, when the recovery trial results came out.

Q Did you start to have concerns before then?

A We were monitoring in real-time, so it depends on what you mean -- and I don't want to parse words, I'm sorry, [Majority Counsel], but what you mean by concern. It's our job to be concerned and monitor. It's our job to

look at the data. And when there is a threshold or a trigger that's pulled that makes us, say, come to the conclusion that it's not effective, that's when it's our duty to make revisions or revoke EUAs. And it happened throughout the pandemic. It's happening now.

So it isn't like June 3rd we saw some real-world evidence data and I said, oh, it's not -- or Janet did or whoever. It's -- except for when the recovery trial came in, because that was pretty definitive and it was the first randomized trial.

Q Did you start to see preliminary indications that suggested it might not be effective?

A And this is where real-world evidence hurts and helps. We were seeing preliminary evidence on both sides of the equation.

[Majority Counsel]. I'm going to mark as Exhibit 14 an April 6, 2020 email from you to Mr. Grogan. It does not have a Bates number on it, but the subject line is "Journal publisher raises red flags about French malaria drug study."

(Exhibit No. 14 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct you to the second email in the chain. She wrote, "I think that the issue of patient

selection is one that is going to come up over and over again, as per our conversation this morning."

What was the issue of patient selection that Dr. Abernethy was referring to?

A [Majority Counsel], the patient selection issue is what we discussed about the limitations of Phase 2 trials; that one of the biases that gets introduced in a noncomparative trial is patient selection bias. So who gets selected for it and whether that sort of changes the conclusions you can draw from it.

Q What did you specifically discuss with Dr. Abernethy?

A I don't remember the conversations specifically. But in reference to this email, we would have discussed, having both been clinical trialists, the issue that we're all aware of, which is that Phase 2 trials have this limitation.

And Dr. Abernethy -- I'm going to connect it to the last answer. Dr. Abernethy would provide the real-world evidence to me, and one of the biases of real-world evidence, despite measures to try to control for it, is patient selection bias.

Q Why did you forward this email to Mr. Grogan?

A Because there was a lot of interest at the White House on collection of data. I wanted them to be

aware that these criticisms existed. You know, [Majority Counsel], a lot of this is about education, right? You asked me the question about what are the limitations. You probably already knew the answer when you asked the question of me, but there are a lot of people who don't know that, and I think it's really important for there to be awareness of what are the levels of evidence that are used by the agency. Why would we not -- why would we prioritize level 1 evidence, a randomized trial, over something like this? Here's a core reason.

Q I am going to hand you a document that I will mark as Exhibit 15. This is a compilation of some text messages between you and Dr. Abernethy. The first page is Bates numbered SSCC-0036417.

(Exhibit No. 15 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to direct your attention to the second page that's marked 429.

A Yep.

Q On April 8th, 2020, you asked Dr. Abernethy, at the very bottom of the page, "My meeting on HQ data got pushed to this morning. Any new data or development since 5 pm yesterday?"

Were you and your team closely monitoring the data on

hydroxychloroquine during this time period?

A Yes. And Dr. Abernethy was terrific about sort of monitoring the, if you will, the healthcare records around the country in a de-identified way. And she would put together PowerPoint presentations, or her team would, so that I could update people about the status. So I was asking for that.

Q Were you having daily updates on hydroxychloroquine?

A I don't believe we had daily updates.

Q About how frequent do you think the updates were?

A At least initially a couple times a week, but it tapered after that.

Q Dr. Abernethy responded at 8:22 a.m., "Looking to see if I see anything new now."

She continued, "I am reading through the emails you are sending - this is a real problem (the example from Laura I)."

And the rest of the text is redacted.

And then you responded, "I hear you."

I'd like to unpack these messages. What was the "real problem (the example from Laura I)", that Dr. Abernethy was referring to?

A [Majority Counsel], I'm going to -- this is

going to be speculation because I don't remember the specific circumstances. But the data that we received from a variety of sources, including the doctors that Laura Ingraham related that she had on her show, they were observational. They weren't even Phase 2 trials. So that was where you would go into your practice, look at who got the drug, and look at outcome and draw conclusions from it.

The next email refers to Dr. Zelenko, the same set of data. The problem there is that that's even lower than a Phase 2 trial. Because at that point it's not just patient selection, it's an issue of not -- because in a Phase 2 study, you would have defined criteria about who would be entered.

This is an observational, some people call it case cohort trials, and the conclusions you can draw from that are very limited. So therein lies the problem.

Q What is the concern with that type of study that Dr. Zelenko was performing? You said it was even lower than a Phase 2 trial.

A Right. So if you do a Phase 2 trial, typically you have an IRB that's been reviewed by an ethics committee, you have a consent form. There are exclusion and inclusion criteria. You're trying to define the study population to reduce this selection bias. It's still there, it's just lower in that setting, and ethics

committees review that.

When you do an observational study, what you're doing is, I treated a whole bunch of patients or this collection of doctors did with X. I'm going to go back and look at the medical records, I'm going to look at what happened to them and I am going to draw conclusions.

That is -- without a specific inclusion and exclusion criteria, so that level of evidence is a lot lower. And it's problematic. It's very difficult to draw doctor-type conclusions about how to treat someone based upon a collection of anecdotes, basically.

Q Dr. Abernethy had also said, with respect to the Zelenko data, "Just want you to know what I am worried about."

Do you know what she was specifically worried about?

A I can't speak specifically to that issue. But what I can tell you is that it was likely related to this issue of the level of conclusions that could be drawn, or not drawn, frankly, more importantly.

Q Did you have additional discussions about these issues?

A Dr. Abernethy and I discussed this throughout the pandemic. And it wasn't just related to this issue; it was related to collection of other types of data and evidence.

Q By the date of this text message, April 8th, 2020, did you have concerns -- were there more indications that perhaps hydroxychloroquine or chloroquine were not effective for treating the coronavirus?

A As I said, we were monitoring in realtime and we had data on both sides suggesting both. And, again, it's why you need level 1 evidence to ultimately come to some conclusion.

Q Okay.

[Majority Counsel]. We can go off the record.

(Recess.)

BY [MINORITY COUNSEL].

Q So we talked about treatments. Treatments are obviously still an issue today. Is it important from an FDA perspective to review and evaluate any possible treatment to a disease that's killed almost a million people?

A Absolutely.

Q And those possible treatments would come from multiple sources, not just your review of literature, but it could come from other doctors that you know out in the field, non-doctors out in the field. I mean, really, if it's brought to you, you should evaluate it?

A [Minority Counsel], yes. I'll again comment on the word "should."

We, during the pandemic, used a science-based approach to that. So were there data that supported it and did it make sense to us, knowing that we had seen this broad spectrum of different types of treatments. So we were very open to receiving information from any source to look at this without bias to begin with, but we did assess on the basis of science. And we rejected some because we didn't think the science supported it.

Q So obviously, there would be treatments that worked for other things that you would know, on its face, would probably not work for COVID that you shouldn't waste staff time in evaluating?

A Yes, that might be the case. Also, if someone presented information that looked intriguing and we hadn't thought about it before, we would consider it and take a look and suggest a pathway moving forward.

Q So the early evaluation of hydroxychloroquine and chloroquine, like you said, was a science-based approach and was not a drug that would have been, on its face, thrown out immediately?

A No, it would not have been thrown out immediately.

Q You were asked about, during your tenure, if there was pressure to keep the EUA or instated in the EUA on HCQ, and mentioned Dr. Navarro; is that correct?

A Correct.

Q Was there anyone else that pressured you or made you feel uncomfortable about HCQ?

A [Minority Counsel], I wouldn't say that Dr. Navarro made me feel uncomfortable. Was he persistent? Yes, as I mentioned all the conversations.

So in answering [Majority Counsel]'s question, yeah, I mean, it was pressure because he was very persistent about it. But no one else exerted other pressure, other than the urgency of the moment. And I've been on the record multiple times saying that.

Q Is there -- and I understand I'm going to play semantics a little bit -- is there a difference between persistence and pressure? We all work on the Hill, we get a lot of questions from a lot of different people 10, 15 times a week. I consider that persistence, but not pressure.

A So I would say you are right. We receive calls from members of Congress, and I did, literally every day. Now -- and from governors and mayors, et cetera. And by the way, it was a bipartisan sport. And I appreciated it because I didn't know everything that was going on at the agency 100 percent at the lower level, so it helped me to have that perspective.

Some of it was information that could help expedite,

some of it wasn't, and we had to make that decision internally. But I never rejected that from the sources we got it from because, as you point out, it's an emergency and we had to make the best decisions possible.

I also did not judge that as being pressure. I can tell you that people disagreed with my assessment of it. They have told me that, people in the press, people on the Hill, et cetera.

It's why I appreciated [Majority Counsel] clarifying for me what she meant about this, because that, to me, is an important component of this. But when [Majority Counsel] asked me the question about Dr. Navarro, I did see that as pressure because, not of the persistence per se of the message, just sort of how many times and almost how relentless it was.

Q Okay.

BY [MINORITY COUNSEL].

Q Is it fair to say that you were having a robust academic debate with Dr. Navarro? He would listen to you, you would listen to him? It sounds like it was a back-and-forth.

A Yeah, there was some back and forth, but it was -- yeah. You know, without getting into gross details, it was often one-sided. And you'd have to ask Dr. Navarro if he actually listened to what I said. But it was a

back-and-forth about the data, and we had a fundamental disagreement about the data and then what supported it.

BY [MINORITY COUNSEL].

Q Was Dr. Navarro your direct report in the federal government?

A No.

Q Did you make any decision based on Dr. Navarro's statements?

A No.

[Minority Counsel]. All right.

The Witness. Let me just be clear. Dr. Navarro brought to my attention that an EUA came in. We didn't make a decision to review the EUA because he told us, but we did review the EUA. So I want to be clear that that might be on the record that that was brought to my attention by Dr. Navarro, but by no means did we say we were going to review the EUA because he told me about it.

BY [MINORITY COUNSEL].

Q The review of the EUA was based on science and FDA --

A Procedures and policy.

Q -- procedure, not Dr. Navarro's statements?

A Correct.

[Minority Counsel]. I have a few more questions on therapeutics.

BY [MINORITY COUNSEL].

Q At the time, there were a lot of different commentators, medical and nonmedical commentators. I heard a podcast about budesonide being a great treatment, and that caught my attention because I use budesonide in a sinus rinse. So that's an off-label use right, I think, there, but it of course is supposed to go in a nebulizer. So is that one? Did you look at budesonide?

A I don't recall looking at budesonide.

Q But doctors prescribed it, right? Is that your --

A I'm not aware of that.

Q -- understanding?

A Again, it wouldn't surprise me. There were a lot of off-label uses of drugs for COVID-19.

One could argue that corticosteroids were an off-label use for COVID-19. It's not really because it's a generic widely-used drug.

But my point is doctors were trying a lot of things. I was a provider. I do not blame them for trying things. If I had heard about a study and I had a sick patient and the risk-benefit ratio seemed right, who knows, I might have made the same decision. And really, again, it's the privacy of a doctor-patient relationship.

Q Hydroxychloroquine in the early days, before

the studies and the data came out, I walked into my local CVS and I said to the pharmacist, who I have a great relationship with, what do you think about hydroxychloroquine? And she said, I don't know. It's not -- this is not -- it's not indicated for COVID. She said, but a lot of people are prescribing it. Doctors are prescribing it for their family members. She's, like, I'm having a run on my pharmacy, and she said, I shut it down. She said, I quit distributing it.

So is that something that is your understanding, pharmacists have that authority to sort of stop filling prescriptions if they have any knowledge of?

A So at the local level, pharmacies can decide not to stock a drug and not have it available. It's a private business. Where medicine gets regulated, as in you may not prescribe it, Dr. Hahn, is at the state level, not at the federal level.

So that would not be anything that FDA would be involved in. Our job at FDA would be to say to the doctor, doctors, here's the evidence in support and against it. Read this literature, make an informed decision in the privacy of a room with your patient assessing the risks and benefits. Doctors do that every day.

Q So a lot of doctors, you would agree, early on, in like March, April, May, were prescribing

hydroxychloroquine?

A Some of my colleagues.

Q Is that your understanding?

A Yes, some of my colleagues -- I heard from friends and colleagues in academia who you would think would have access to most of the data. There was real fear out there and, yes, that was happening.

Q And you're not aware of any of these doctors being all Republicans or all Democrats? I live in Arlington, and this was happening in Arlington, so I think it's safe to assume most of them were Democrats. But you're not aware of any --

A No.

Q -- like political bias for or against hydroxychloroquine, are you?

A No, I am not. And I will just tell you, there were governors and mayors who contacted me about the availability of the drug, and that was also bipartisan. That at the time was not, seemed to be, a partisan issue at the time.

Q And if you're out there in America in, say, Seattle or where COVID happened earlier, would it almost be malpractice not to look at all these options if your patients are dying or being hospitalized?

A I'm really careful about the use of the term

"malpractice." It depends on the local standard of care.

Q Not malpractice in the legal sense.

A I would say, in the conditional tense, a doctor should try to make him or herself aware of the literature regarding treatment of a disease that's for treating something as serious as this and examine all the possibilities of treatment. That's what a doctor would do, typically.

Q Do you feel like -- or is it your -- or would you agree with the statement that -- so you said President Trump conveyed a sense that we needed to move quickly to make all medical products available to the American people and those that treat.

There's been some reporting recently, and The Wall Street Journal I think did an op-ed, President Trump -- and you were probably engaged to a certain extent -- in Operation Warp Speed. So there was definitely an urgency in those early days. And we've seen Delta and Omicron, and really the sense of urgency probably should not have -- and I'm not saying it did. But do you think that there was sort of a downtick in the sense of urgency to develop, to make available more therapeutics?

The Wall Street Journal published an editorial that said that, in recent years, we've engaged in Operation Snail Speed vis-à-vis therapeutics. Do you have any

knowledge of that?

A So I have no knowledge of what's happening in the current administration. I can tell you that we, from the earliest days, March, developed our program at FDA to accelerate treatments for coronavirus. We thought it to be really important and we started with off-the-shelf drugs and assessment of those followed by the development of new drugs. So remdesivir was an example of an off-the-shelf drug, for example.

So our foot was on the pedal the entire time about that because we realized that would be an issue. I can't really speak to the issue of what the priorities are now because I'm not involved in it.

Q Okay. Going back to the last exhibit. Dr. Abernethy said, "I will send you thee slides on the Brazil study. Bottom line is that the dose of CQ rec" -- which I think CQ is chloroquine; is that right?

A Yes.

Q And rec I think probably means recommended -- "by Chinese led to increased deaths and cardiovascular events."

A Yes.

Q So it looks to me like the Chinese were doing testing around chloroquine. Is that your understanding of what she was saying?

A That was my understanding. And I believe there was even published literature.

Q And it looks like it didn't work; is that right?

A What Dr. Abernethy is referring to is a Brazilian study which compared two doses of a drug; one is a high dose and one is a low dose. And what I believe she is saying here is that the high dose was a dose recommended by the Chinese from their studies.

Q Do you have any information related to -- have you ever dealt with the Chinese government on therapeutics?

A No.

Q So the Chinese recommended the high dose, and that didn't work?

A And the Brazilians compared it, and what they saw associated with the high dose -- or, you know, I should say what the dose that was recommended by the Chinese in that study for the Brazil led to increased risk of cardiovascular deaths. So they stopped the trial.

Q Thanks for clarifying that.

BY [MINORITY COUNSEL].

Q To clarify the answer to one of your answers from the Majority counsel. It was Dr. Janet Woodcock that issued the first EUA for hydroxychloroquine; is that correct?

A Yeah. That's a really good question. The center, and therefore representing the FDA, issues the EUA. But Janet Woodcock was the center director, so she would have final signoff, and only under extraordinary circumstance would a commissioner reverse that.

Q So Dr. Woodcock was final signature out the door?

A The responsible party.

Q Did you evaluate her decision on that EUA?

A I did. I spoke to her and I looked at the document, yes.

Q Do you know if Dr. Woodcock is someone that can easily cave to political pressure?

A Dr. Woodcock is not someone who can easily cave to political pressure.

Q And is she currently the acting commissioner for the FDA for the Biden administration?

A I believe so, still. Yes.

[Minority Counsel]. Thank you.

(Lunch recess.)

BY [MAJORITY COUNSEL].

Q Dr. Hahn, before the break we were talking about hydroxychloroquine. I'd like to mark a new exhibit, mark as Exhibit 16 an April 11th, 2020 email from Patrizia Cavazzoni to you, Ms. Lenihan, and Dr. Woodcock, Bates

numbered SSCC-0037720.

In the email, Dr. Cavazzoni writes, "We discussed within the Center the question of whether the EUA could be expanded to include outpatients with COVID-19. This is something we don't support at this stage, due to the heightened risk of serious or fatal arrhythmias in the outpatient setting."

(Exhibit No. 16 was identified for the record.)

BY [MAJORITY COUNSEL].

Q Dr. Hahn, do you recall discussing the concern of heightened risk of fatal arrhythmias in the outpatient setting from the use of hydroxychloroquine?

A I recall the conversations around cardiac toxicity.

Q What was discussed?

A It's a well-known effect of these drugs of something called QT prolongation, which is a precursor to abnormal heart rhythms, which can be serious. So it's something that was top of mind -- it should be for physicians, but certainly on the regulatory side -- that this is something that physicians should be aware of.

Q Did you agree with Dr. Cavazzoni's assessment?

A Yes, I did.

Q And you shared her concerns about the

potential risks to using hydroxychloroquine in an outpatient setting?

A I'm sorry, what was the question, [Majority Counsel]?

Q Did you share her concerns about the potential risks to using hydroxychloroquine in an outpatient setting?

A With whom, [Majority Counsel]? I'm sorry.

Q With Dr. Cavazzoni.

A It was from Dr. Cavazzoni.

Q Did you agree with her? Did you also share her concerns about that risk?

A Oh, I'm sorry. Did I personally share those same concerns?

Q Correct.

A Yes.

Q Were any steps taken with respect to expanding the EUA to cover outpatients at that time?

A We did not take steps to expand the EUA.

[Majority Counsel]. I'd like to mark as Exhibit 17, it's a May 8th, 2020 email from you to Dr. Deborah Birx, Tyler Ann McGuffee, and Ms. Lenihan as recipients. For the record, it does not have a Bates number but the subject line is "Follow up discussion (5/8) 3:00 p.m. Ward Room."

(Exhibit No. 17 was identified for the record.)

BY [MAJORITY COUNSEL].

Q On the second page of this email, Ms. McGuffee wrote, "Dr. Birx is requesting to convene a follow-up discussion with principals and asked whether you and other doctors on the task force would be able to attend."

The two responses are largely redacted, but you'll see on the first page that Dr. Birx writes, "This was just to give us cover for the" -- redacted -- "discussion."

Do you recall what this meeting was related to?

A I do not. One clue is it sounds like Dr. Woodcock was given a dial-in number. Typically, Dr. Woodcock would be involved in discussions around monoclonals and antivirals.

Q Okay.

A But I can't tell you for sure. I just don't know.

Q Do you recall what Dr. Birx may have been referring to when she said "this was just to give us cover"?

A I don't. We had meetings a lot among the doctors and, you know, we discussed a wide range of topics. So it wasn't always labeled in the meeting subject what we were doing. So maybe she was referring to that. Again, it's speculation.

Q Thank you. On April 24th, 2020, FDA issued a

drug safety communication cautioning against the use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or in a clinical trial due to risk of heart rhythm problems.

Why was that issued?

A [Majority Counsel], as I had mentioned, we were collecting real-world evidence. And this is very typical for the agency, but particularly COVID. Are we seeing safety signals? Are we seeing efficacy signals, as we discussed, regarding any drug either approved or authorized? So this was in line with that.

And when we see something -- the agency has a lot of experience, because you have to ask the question, when does it raise the level of giving a warning to physicians? And the Center for Drug Evaluation and Research decided that it had reached that level and that we needed to tell physicians.

Because the other part of this, the flip side is, [Majority Counsel], if you see one or two reports of something, it doesn't necessarily mean that it's a serious concern because it could be just related to something else. But when you start to see a pattern, that's when you need to tell folks. So we monitor on an ongoing basis to be able to do that.

Q Were there discussions at that time about

whether FDA should rescind the EUA for hydroxychloroquine?

A We continuously discuss the issue of what to do about the EUA. As you saw, the discussion about whether it should be expanded, the discussion about the safety alert. And then, of course, we were waiting for the results of randomized trials to maybe give us a sense of whether it should be modified.

And, [Majority Counsel], I know I said this before, but for almost every EUA we were looking at new incoming data that would help modify potentially.

Q Thank you. I'd like to direct your attention back to Exhibit 13, which was the March 28, 2020 authorization for hydroxychloroquine and chloroquine.

A Yes.

Q First, just to clarify, you mentioned previously that this was decided by Dr. Woodcock.

Do you remember that testimony?

A Yes.

Q I'd like to direct your attention to the last -- second-to-last page of the document, which shows that it was signed by Denise Hinton. Does that refresh your recollection about who was ultimately the decisionmaker on this?

A You mean does it change?

Q Or does it change your recollection?

A No, it doesn't. So this is an internal process and Admiral Hinton is our chief scientist, and all EUAs go through Admiral Hinton. Now, Admiral Hinton has the opportunity, I suppose, to either reject or accept it, but the decisionmaking -- and I don't believe that ever happened during the pandemic. But this is a process of how it goes through the Commissioner's office.

So I totally stand by what I said about the fact that the decision was made by Dr. Woodcock in CDER.

Q Thank you. As I think we mentioned previously, on June 15th, 2020, FDA revoked the emergency use authorization for hydroxychloroquine and chloroquine. How was that decision reached?

A This is a deliberative process by the center, and it's -- I'm going to say it again, so I'm sorry to be redundant. But the incoming, all the data -- we look at the totality of evidence, including the randomized -- the recovery trial. And if it justifies and rises to the level of changing -- either changing the intended use or contraindications added or revocation, that's done.

This -- and this is an example of a decision that is, again, made at the center level, but would be something that would be informed to the commission.

Q What considerations were considered, for lack of a better word, in making that decision?

A So pretty straightforward. May be effective, risk-benefit ratio is in favor of it, no alternatives available.

And so in all three sort of situations here, a randomized trial that showed it wasn't efficacious, now some safety concerns that can be or may be not associated but probably are. And then the third one was we had other drugs for inpatients, which is remdesivir.

Q Who was involved in that decision?

A The revocation?

Q Yes.

A The center. I can't give you specific names, but that's a center-level decision.

Q And so which center in particular?

A Center for Drug Evaluation and Research. It might have been that Dr. Cavazzoni was now the interim head, but it would have been Dr. Cavazzoni or Dr. Woodcock if she was still the head of center. I don't remember the date of that transition.

Q Did you agree with the assessment or the decision to --

A Yes, I did agree.

Q I'm going to mark as Exhibit 18 a compilation of text messages between you and Colin Rom, which is Bates SSCC-0036729.

(Exhibit No. 18 was identified for the record.)

The Witness. This is 18, correct?

[Majority Counsel]. Eighteen, yes.

BY [MAJORITY COUNSEL].

Q I'd like to direct your attention to the second-to-last page of the document, which is Bates numbered ending in 825.

On June 25, 2020, you wrote a text message to Mr. Rom. And I apologize, the text is not entirely clear, but it appears to read, "I need you to work with Anand's team to create hydroxychloroquine TPs for the VP. Olivia requested it. I would like to review first."

Who does Anand reference?

A Anand Shah was a deputy commissioner.

Q Do you understand, was Olivia a reference to Olivia Troye?

A Yes.

Q What did you discuss with Ms. Troye? How were these talking points to be used?

A So I don't remember the specific conversation. But from a higher level, Olivia would contact me and say the Vice President intends to either receive questions or talk about X. Could you, from the agency, provide talking points?

Which, I have to tell you, I really appreciated because Olivia and the Vice President really wanted to have accurate information to be able to communicate. So we always readily availed ourselves of that request or provided information in response. And typically, I wanted to review it to make sure that it was accurate from my perspective.

Q Do you recall what the scope or subject matter of the talking points were supposed to be?

A I don't.

Q Why would talking points be needed for the Vice President on hydroxychloroquine at this point in time, ten days after the EUA would be revoked?

A I really don't know. I don't remember. But, [Majority Counsel], as you know, it was a media press conversation that continued. I mean, it continued really until fall, maybe beyond.

Q After the EUA was revoked, were there continued discussions within the Trump administration about hydroxychloroquine?

A Yes.

Q You mentioned the conversations with Dr. Navarro previously. Is that just one example? Were there additional?

A I would have queries and discussions with

hydroxychloroquine in a variety of venues; for example, my regular meetings with the Secretary, other members of the task force. So, yeah, there were ongoing discussions about all sorts of therapeutics, hydroxychloroquine being one of them.

Q Who do you specifically recall discussing hydroxychloroquine with?

A I discussed it with the doctors. So Dr. Fauci, Redfield, and Birx. I kept them informed a lot because they're physicians and clearly interested in the therapeutic side.

Q What did you specifically discuss with them?

A I would give updates about what our decisionmaking was. So before we issued the revocation, and I knew it was coming, I let the docs know.

Q Did the doctors on the task force agree with the decision to revoke the EUA?

A I'm trying to recall the specific discussions. [Majority Counsel], I'll say it this way. Nobody disagreed. And sort of at a high level, yeah, I think there was consensus that it was the right thing to do.

Q Is it fair to say that the doctors agreed with the assessment that hydroxychloroquine was not effective and had a risk to certain patients, a severe risk of heart arrhythmias and other issues?

A I don't remember the specific details of the conversations. But in the context of the revocation, there was general agreement that it was the right thing to do.

Q Apart from the doctors on the task force, who else did you discuss hydroxychloroquine with?

A As I said, Dr. Navarro would be one. It would be brought up at the task force. There's a lot of people present, the Vice President, you know. I'm sure I discussed it with Olivia as well just the circumstances around it, because it was often clearly topical. It was big news.

Q What do you recall discussing specifically with the Vice President?

A I don't remember specific conversations other than in the context of the task force. And what would happen is that I would be asked to speak about why we took a certain action.

Q Did you discuss hydroxychloroquine with President Trump after the revocation?

A After the revocation, I did have discussions with President Trump about therapeutics, including hydroxychloroquine, after the revocation.

Q What did you discuss?

A Just in general, the data that we used to support our decision, my support of that decision, and that

we would continue to look at data.

Q Did President Trump express any disagreements with the actions taken by the FDA?

Mr. Barstow. I think that's where we're probably close to the line.

Mr. Armstrong. That's really towards the line of asking about the specifics of the conversation. Could he respond generally in terms of the topic itself, if not the response from the President of the United States?

[Majority Counsel]. To be clear, are you asserting a privilege?

Mr. Armstrong. It's not my privilege to assert.

Mr. Barstow. Yes, I'm instructing Dr. Hahn not to answer the question.

[Majority Counsel]. Okay.

BY [MAJORITY COUNSEL].

Q In that case, Dr. Hahn, if there is a response that you can provide that will navigate the privilege lines that your counsel or Kevin have discussed with you, then, please, I'm happy to take anything that you can share with us.

A [Majority Counsel], all of the discussions that we're referencing at the White House were along the lines of providing information about the basis for our decisions. Some people disagreed, some people didn't; some

people agreed as I mentioned. Our decision was our decision, and it was left at that.

Q Did President Trump direct you to take any action with respect to hydroxychloroquine?

(Discussion off the record.)

The Witness. [Majority Counsel], no.

BY [MAJORITY COUNSEL].

Q No, he did not?

A He did not.

Q Are you withholding any information from your answer on the basis of privilege?

A No. And can you restate your question so I can be completely sure here?

Q My question was, did President Trump ask you to take any action with respect to hydroxychloroquine?

A Okay. So the answer is no.

Q After the EUA was revoked, are you aware whether any other administration officials continued to take action to promote hydroxychloroquine for use as a coronavirus treatment?

A Well, I mentioned Dr. Navarro. I think that's a matter of the record that he did. And I mentioned also that he and I had repeated conversations.

Q President Trump continued to promote hydroxychloroquine publicly, including re-tweeting messages

on July 28th, 2020 that touted the drug as a cure to the coronavirus crisis.

Do you recall that?

A I don't recall that specific tweet, but I do know that there were multiple references over time.

Q Did you have any reaction to the references that President Trump made about hydroxychloroquine during this period?

A Other than what I have told you, which is that I stood by our decision, no.

Q President Trump also reportedly brought up hydroxychloroquine in an August 2020 phone call to NIH Director Francis Collins expressing his displeasure about the revocation of the EUA.

Were you aware of that?

A I don't remember that at all.

Q Did you ever learn of that from discussions from Director Collins or anyone else?

A [Majority Counsel], this is the first time that I can remember hearing about it. Perhaps it occurred, but I can tell you this is kind of news to me right now.

Q Are you aware whether President Trump took any other actions to push for hydroxychloroquine in the summer or fall of 2020?

A I'm not aware of any specific actions.

Q Earlier, you were discussing some of your interactions with Dr. Navarro with respect to hydroxychloroquine, which I believe you characterized as relentless and one-sided.

You asked if -- and I'm characterizing this because I don't have the language in front of me. But I believe it might have been characterized as a sort of academic debate. Did you agree with that characterization?

A So, in part, in that it was an exchange over interpretation of data. So that is a sort of classic academic discussion. We came to different conclusions of the data in front of us.

Q Does Dr. Navarro have a scientific background?

A I believe Dr. Navarro's Ph.D. is in economics. I believe, I don't know. Other than that, I don't know.

Q Was he a physician?

A I do not believe Dr. Navarro is a physician.

Q Are you familiar with Steven Hatfill, who was a medical adviser on Dr. Navarro's team?

A No. I mean, I might have heard the name. I don't recall anything now.

[Majority Counsel]. I am going to mark as Exhibit 19, a September 22nd, 2020 letter from Dr. Hatfill to Mark Meadows.

(Exhibit No. 19 was identified for

the record.)

BY [MAJORITY COUNSEL].

Q Have you ever seen a copy of this letter Dr. Hahn?

A I have not.

[Majority Counsel]. For the record, this is Bates numbered GWU-0001135.

BY [MAJORITY COUNSEL].

Q In this letter, Dr. Hatfill criticized FDA and the COVID-19 treatment panel for keeping early infected patients quarantined at home without treatment until they became so ill that they had to be admitted to a hospital. Once in hospital, they would be given HCQ, which would not work well because the patients were now too ill.

Is this a critique that you had heard previously from Dr. Navarro or others?

A No.

Okay, [Majority Counsel], let me be clear. So I had heard critiques about how our failure to keep the authorization and expand it to outpatient setting had led to people's deaths. That I had heard, that criticism. What I had not heard is the statement about keeping people at home.

Q Thank you. Do you recall if there was discussion about providing hydroxychloroquine to people in

a widespread manner for prophylactic use?

A I understood that there were a number of clinical trials that were being looked at in the postexposure and preexposure setting, and off-label.

Q Are you aware if there was data at this time with respect to the efficacy of early use of hydroxychloroquine?

A There were uncontrolled data that suggested that it might be a benefit. And, theoretically, it's not a far leap to say that a drug that has a small effect size could actually be better when the burden of disease or the burden of virus is lower. It's a very reasonable hypothesis to test.

And one other part of this that I was consistently having, FDA doesn't regulate the practice of medicine. If a physician decided to give this in that setting, in the preexposure or postexposure or early disease setting, that's a decision that a physician needs to make. Now, I want them to understand all the risks and benefits so they can advise their patient.

Q The letter continues, "The President has been grossly misadvised by the COVID Task Force on the proper pandemic response to COVID-19."

It then continues, number 1: "Two members of the COVID-19 Task Force (Drs. Fauci and Hahn) need to be

urgently replaced."

Were you aware that Dr. Hatfill had advocated for you and Dr. Fauci to be replaced?

A I had not.

Q Did you ever hear whether Dr. Navarro shared those views?

A I had not heard.

Q Did you ever hear of anyone else at the White House advocating for you to be removed from the White House Coronavirus Task Force?

A Not that I remember.

Q What about outside of the task force?

A I don't remember any circumstance where that was the case. It could have been.

Q Finally, on page 2, the letter states, "The US COVID-19 strategy must be changed to a focused, community-outreach approach involving the outpatient and prophylactic use of hydroxychloroquine with Zinc supplementation. The focus is on the early treatment of COVID outpatients with their close contacts."

In the subsequent paragraphs, he advocates for setting up community health centers, help lines, and other resources to help educate, promote, and distribute hydroxychloroquine in communities.

Mr. Armstrong. Where does it say this in the letter?

I apologize.

[Majority Counsel]. Bullets 2 through probably 5.

Mr. Armstrong. Thank you.

BY [MAJORITY COUNSEL].

Q Are you aware whether there was ever consideration at the White House for advocating for widespread prophylactic use of hydroxychloroquine?

A I'm not aware.

Q Are you aware if any actions were taken based on Dr. Hatfill's recommendations in this letter?

A I'm not aware.

Q When did you become aware that convalescent plasma was being evaluated as a potential coronavirus treatment?

A Early on in the pandemic. I became aware in March when Peter Marks and I discussed this. But, really, in the earliest parts of the pandemic the Chinese, for example, had been studying plasma as early as February, I believe.

Q How did it come to your attention?

A So plasma has been used to treat infectious disease, I believe, for close to 100 years. And it makes sense, because convalescent plasma contains antibodies from natural infection and it is in general very safe. So it's a natural therapeutic to look at. And we were very

interested in pursuing this as a relatively -- or I should say, a potentially effective therapeutic for COVID-19.

And in fact, we really tried to encourage the academic community to perform randomized clinical trials. That effort failed at least initially, and so we initiated with the Mayo Clinic what's called an expanded access program where we made it available to physicians around the country under this expanded access program as an investigational, and then data were collected to look at outcomes. It was our way of trying to get real-world evidence around the use of plasma.

Q Were you involved in the decisionmaking process for granting an EUA for convalescent plasma?

A The would have continued at CBER, Center for Biological Evaluation Research, as CDER was for hydroxychloroquine. That decision was made at the center level, but I was very closely involved in the discussions with Dr. Marks.

Q What did you discuss with Dr. Marks?

A From the beginning, we discussed what kind of evidence would be needed. Dr. Marks also discussed this with Dr. Woodcock. And so we had multiple discussions about what evidence would fulfill the statutory requirements for an EUA.

And because we weren't likely to get a result from a

randomized clinical trial soon, the center focused on making sure that, as early as possible, we could get a read on this from the expanded access program.

Q You mentioned Dr. Marks and Dr. Woodcock. Were others involved in the discussions around a decision to grant an EUA for convalescent plasma?

A Within the agency?

Q Starting within the agency.

A So there would have been a whole team, just like with hydroxychloroquine, probably Keagan Lenihan was involved. I'm sure someone from the Office of the Chief Counsel was involved, and certainly the center.

Now, the Commissioner and the Commissioner's office would not typically -- and we weren't from that I remember -- involved in the center level review of data and discussion. That's sort of kept there. That's communicated up the chain of command. So that is typically -- that is what occurred, excuse me, for plasma.

Q What about outside of FDA?

A Plasma generated a great interest on the task force and specifically among the doctors. So Drs. Fauci, Redfield, and Birx, Dr. Giroir, Dr. Kadlec.

Q Were there others in the White House that were focused on convalescent plasma?

A There were a number of people -- I'm blanking

on names -- but there were a number of people in Mr. Kushner's office who were very interested in this. And we had -- Dr. Marks and I had multiple discussions about it.

Q I guess, first, did you discuss this with Mr. Kushner specifically or just --

A I don't think so. The folks who worked around him, yes, for sure. I could be not remembering a conversation, but I do not think we did.

Q You said that there were a number of people in Mr. Kushner's office who were interested in this. What did you discuss with them?

A Whether the data -- the questions were usually straightforward. Do the data support that it may be effective? Do we think it's safe? What's the availability?

So, you can give plasma by intravenous injection kind of like a blood packet, but you can also concentrate it and give it as a shot, which would be used potentially as a prophylactic or a treatment, much easier to distribute than this. The question of whether it should be given in the inpatient or outpatient setting, because it's more difficult to give in the outpatient setting, those were the sort of medical discussions that we had.

Q Was there any discussion about the timeline

for possible approval of an EUA?

A Yes.

Q With Mr. Kushner's staff, specifically?

A Ultimately with Mr. Kushner's staff. But early on it was mostly focused, as I remember, at the task force.

Q Did you discuss the decision on convalescent plasma -- strike that.

Did you have discussions about convalescent plasma and the possible decision of granting an EUA with individuals at HHS?

A [Majority Counsel], just to be clear, are you asking about within the Secretary's office or --

Q I was thinking agency-wide, not just the Secretary's office.

A Okay. So, yes, discussions with Dr. Kadlec because ultimately it was BARDA that requested the EUA, so that would be a natural discussion. I had discussions with Dr. Fauci from NIAID, and Dr. Collins from NIH, Dr. Redfield and Dr. Giroir. That's what I remember at this point.

(Exhibit No. 20 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'd like to show you what's been marked as

Exhibit 20. For the record, this is an August 19, 2020 email from Paul Alexander to you as well as a number of other individuals, and it is Bates numbered SSCC-0015402.

On August 19, 2020, Dr. Alexander wrote, "Hi Dr. Hahn and Anand, see this table as per discussion today."

Do you recall having a discussion with Dr. Alexander about convalescent plasma?

A I don't remember a specific discussion. It could have occurred, [Majority Counsel].

Q Do you recall meeting Dr. Alexander?

A Oh, yes.

Q How did you get introduced to Dr. Alexander?

A At HHS, through Mr. Caputo's office.

Q Did you have discussions with Dr. Alexander?

A Yes, we certainly had discussions about COVID in general, evidence generation. He had a real interest, as mentioned here, in what levels of evidence would be necessary to support decisions by doctors and the academic community, for example.

Q You said you discussed COVID generally. What did you discuss with Dr. Alexander?

A In general, therapeutics, diagnostics. Just a general discussion around COVID-19.

Q In the email, Dr. Alexander continues on, "Michael and Wolf, this was the evidence I was referring

to, it's the current 18 studies on convalescent."

He also says, "I share this to help give us cover in our decisions. It is to me" -- "It to me is well-positioned. My view is that CP should be used and is showing to be safe."

Did you ask him to perform this analysis?

A No.

Q Did you discuss this analysis with him?

A I don't remember. I don't believe so, but I really don't remember, [Majority Counsel].

Q What was your understanding of what he meant by that the analysis was "to help give us cover in our decisions"?

A I'm not sure of what Dr. Alexander meant from cover from decisions. In general, what Dr. Alexander wanted to do was to review the data and, as we talked about before, level of evidence. He refers to bias in here in studies, and sort of come to some conclusions about whether studies would have bias or not that might affect how we make decisions.

Q Do you recall reviewing this?

A Do I remember looking at it?

Q Yes.

A No, I don't specifically remember looking at it. It jogs my memory a bit that I did receive this, but I

don't remember the details of reviewing it, [Majority Counsel].

Q Did you use this analysis in any way?

A For agency decisions?

Q In general, in any way.

A No. I mean, I suppose other than looking at it. But in terms of how we made decisions, no.

Q Do you recall providing his analysis to anyone?

A I don't remember that, [Majority Counsel], at all.

Q Did Dr. Alexander play any other role with respect to evaluating or authorizing convalescent plasma?

A So I want to be really clear about this. These decisions, again, are made at the center level. And although we always would listen to outside input, the decisions are clearly made based upon our review of the data by the reviewers and the center director. And that is true here.

Q Did you have any other conversations or did you receive communications from Dr. Alexander with respect to convalescent plasma?

A I don't remember. But I did receive multiple communications about a variety of subjects, COVID related, of course.

Q Approximately how many times do you believe that you met with Dr. Alexander during your time at FDA?

A Face to face?

Q Yes.

A A handful I'm guessing. But my guess is it's less than five.

Q What about phone calls?

A Not often. And I just don't remember exactly the number of calls, but it wasn't very often.

Q Less than five or more than five?

Mr. Armstrong. Don't guess.

The Witness. I don't remember, sorry.

BY [MAJORITY COUNSEL].

Q Can you tell us more about the specific topics? You mentioned COVID generally, you mentioned his research interest around how studies are conducted. What other topics did you discuss with Dr. Alexander?

A I don't remember specifics, but I think, broadly stated, most of it focused on therapeutics.

Q Which therapeutics?

A As I said, I can't recall the specifics.

Q Do you recall whether Dr. Alexander advocated for any particular actions with respect to therapeutics?

A Dr. Alexander clearly had his opinion about actions that we should take, just like half of the members

of Congress and the White House. It was nothing other than the usual from what we were hearing, [Majority Counsel], I mean, literally every day.

Q What were the opinions that Dr. Alexander shared with you?

A So, again, I can't talk about specifics. But this would be sort of the -- this wasn't necessarily opinion, but what I'm intimating or guessing from this is that he's suggesting that these would be data that support a positive decision for issuance of an EUA for plasma.

Q What actions did Alexander suggest -- Dr. Alexander suggest that should be taken with respect to the pandemic more broadly?

A I don't remember any specific actions that he recommended we take, other than these are the data, they might support the use of X or Y. But in terms of saying -- if that's what you're asking, did he say the FDA should authorize blank or you should take this specific action, I don't remember any circumstances where he did that.

Q Understanding that it's been a while, but how did these meetings with Dr. Alexander come to take place? Would they have been scheduled in advance?

A I don't believe so. Typically, I believe it's if I was at HHS for the day and I was meeting with other

people, particularly if I went down to Mr. Caputo's office, he would be there or he would be brought into a meeting from somewhere else.

Q Did you regularly meet with Mr. Caputo?

A Not -- I mean, it depends on what you mean by regularly. All of our comms went through HHS. So I had discussions because comms were really important. And that was the gatekeeping for -- or that office was the gatekeeper for our communications.

Q What do you mean that that office was the gatekeeper for communications?

A So I think as occurs in every administration, although by no means am I an expert, formal communications from the agency go through a chain of command that certainly would involve HHS in that office and sometimes the White House.

Q Was FDA required to provide public messaging or other communications to Mr. Caputo for approval before release?

A We were required to go through the chain of command, which was through that office. I don't know if it went specifically to Mr. Caputo, but they were required to go through that office. That was standard procedure from the beginning.

Q And was that with respect to particular types

of public communications or was it with respect to everything?

A [Majority Counsel], even when Mr. Caputo wasn't there, I believe it was for all of them.

Q Press releases?

A Press releases, you got it.

Q Interview requests?

A Interview requests.

Q Public briefings or other public events?

A You know, I don't know the details there, but my guess is yes. If I was asked to speak at an event, my guess is that there was HHS signoff on that. I don't specifically know that.

Q Did Mr. Caputo's office ever make substantive changes to public messaging or other communications that FDA sought to release?

A Not that I remember, but there's some circumstances that I wouldn't be involved in the details of that.

What I can tell you is I reviewed everything before I said something. And also, sort of every night I would get, this is our press release on X. So I would be aware of that.

Q Who at FDA would have knowledge of whether Mr. Caputo's office ever tried to make substantive changes to

public messaging or other communications?

A We had an Office of Media Affairs, OMA, and they would be the folks who would. And then there was another group in charge of OMA that would be responsible for a broader set of communications. When I left, it was Michael Felberbaum.

Q Was someone else in charge at other points during the year?

A Yes.

Q Who?

A Oh, gosh. I'd have to have something jog my memory, I'm sorry.

Q Of course. Did Mr. Caputo's office ever block or refuse to permit FDA to release some sort of public messaging or other communication that FDA was seeking to release?

A Just, in general, HHS had veto power over things like interview requests, public releases, et cetera. That wasn't just on the comms side, that was also on the legislative side. That was the way the system worked.

Q And did HHS utilize that veto power?

A Yes.

Q When?

A I mean, there were a variety of circumstances where that occurred. Also, one that I can think of right

now is you showed me this timeline that Senator Alexander asked for, and we were told we couldn't provide that to the committee.

Q Who told you that?

A Directly from HHS. I don't know who specifically.

Q What -- do you recall what was discussed?

A No, I don't.

Q Did you receive any reason why that information could not be provided?

A No, I did not.

Q Did anyone express any concerns about withholding that information from Congress?

A I did.

Q What did you say?

A I mean, you know, Senator Alexander, who is chair of our authorizing committee and oversight committee, asked for a document that I thought was relevant to COVID-19. We were happy to provide it. So I thought it was important knowledge for people to have.

Q Were you ever permitted to share that information with Senator Alexander?

A Not to my knowledge.

Q You mentioned that that was one example. Do other examples come to mind?

A If I put more time into thinking, perhaps something would come up. But often -- for example, I would get an interview request, and there was pretty tight control of cycles that folks were or were not allowed to talk to certain press. So there were those circumstances. I can't give you specifics, but that's another thing that comes to mind.

Q When you say certain press, were there certain outlets?

A National media versus local versus talk radio, those sorts of things.

Q Okay. Were there certain topic areas that were --

A There didn't seem to be a pattern.

Q It has been widely reported that HHS blocked CDC from issuing some public communications during the pandemic, including public briefings. Did you experience the same thing at FDA?

A I can't recall if that occurred in terms of public briefings.

Q We were talking specifically about HHS. Did the White House ever similarly veto or block public messaging or public communications that FDA sought to have?

A Not that I'm aware of specifically around public messaging or communication.

Q Thinking back as to your communications with Dr. Alexander -- and I apologize, I don't have the exact words that you said, but I believe you expressed something that Dr. Alexander had views.

What did you mean by that?

A Well, the way I interpreted it, [Majority Counsel], is points of views that another physician would have about a set of data and circumstances. And as you probably saw me not in the Twitter sphere as well as in published data, physicians around the country had a lot of opinions about COVID response, therapeutics, diagnostics, et cetera. So I really saw it in that context.

Q Did you agree with Dr. Alexander's opinions?

A Not always, no.

Q What did you disagree with him about?

A I mean, I don't have specifics here, [Majority Counsel], for you, but conclusions drawn from the data. There were probably -- and I'm saying probably, because I don't have the specific circumstances where I did not agree with the conclusions drawn.

Q Okay. Thank you. It has been widely reported that in August 2020, President Trump called Director Collins and accused NIH of moving too slowly to approve the vaccine or therapeutics, including convalescent plasma.

Have you ever heard this?

A I've heard reports of a meeting, not necessarily the subject that you're describing.

Q Just to be clear, did you hear this just from what was in the press, or did you learn it from someplace else?

A I learned it from people in the administration.

Q What did you hear?

A That there was a meeting with Dr. Collins around NIH's objection to FDA's process and decisionmaking around convalescent plasma.

Q Who did you learn this from?

A Members of the White House. I'm trying to think who I heard it from. It might have even been from Dr. Collins. We had a meeting at the White House about plasma, the data that we needed, this time schedule, et cetera. It was a multidisciplinary meeting. I believe it was at that meeting that I heard from Dr. Collins that a meeting took place.

Again, [Majority Counsel], I'm recalling from a year-and-a-half ago and I'm doing my absolute best.

Q I appreciate that. Thank you. Did you ever learn what President Trump said to Dr. Collins during that meeting?

A Not the specifics, no. Other than expressing

dismay over NIH potentially putting up roadblocks, if you will, to decisionmaking on the regulatory side. That's what I had heard. Whether that happened, that is totally second- and thirdhand.

Q According to the book Nightmare Scenario, President Trump stated to Dr. Collins, "My polling numbers are looking really good, but you doctors are killing me. We've got to have the data on Friday or it doesn't matter."

Had you ever heard this?

A No.

Q Were you aware of any discussions with President Trump or members of the administration regarding the need to authorize convalescent plasma or another treatment or vaccine prior to the Republican National Convention?

A This is the first that I've heard that, [Majority Counsel].

[Majority Counsel]. I'm going to mark as Exhibit 21, an August 22nd, 2020 tweet from President Trump.

(Exhibit No. 21 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I apologize, it was harder to find a complete image graph for some of these than others.

Dr. Hahn, do you recall this tweet?

A I do.

Q In the tweet, President Trump wrote, "The deep state, or whoever, over at the FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives!"

What was your reaction to this tweet, Dr. Hahn?

A I was disappointed in it. I thought that perhaps some clarification needed to be put in front of the President, because we -- FDA doesn't control who gets put in clinical trials to test vaccines and therapeutics. That's not our role. And I really wanted to understand what the President's concerns were regarding this. But that was sort of my response to this.

Q Did you have any discussions about it with President Trump?

(Discussion off the record.)

The Witness. Okay. Repeat, I'm sorry, moving from thing to thing here.

BY [MAJORITY COUNSEL].

Q Did you have any discussions about this tweet with President Trump?

A Yes.

Q What did you discuss?

A So at a general level, we discussed -- I inquired about what was meant by it. I discussed what FDA's role is. And we had a general discussion about our approach to -- you know, to medical product approval.

Q How would you characterize the tenor of that conversation?

A Very cordial.

Q Did you provide your explanation about what FDA's role was with respect to clinical trials to the President?

A I did. I explained in general how FDA approaches it.

Q What else did you discuss with the President?

(Discussion off the record.)

The Witness. I gave the President an update on convalescent plasma.

BY [MAJORITY COUNSEL].

Q What did you tell him?

A I talked about our process regarding this and -- I don't remember the specifics, but we either were nearing a decision or had made a decision.

Q Did President Trump give you any order or directive at that meeting?

A No.

Q When did this meeting happen?

A It was not a meeting, [Majority Counsel]. Sorry, just to be clear, it was a phone call. And it was the day -- I think this was August 22nd, and 23rd was the press conference with the plasma, I believe. So this happened on Saturday the 22nd.

Q Do you recall approximately what time of the day the telephone call happened?

A I believe it was afternoon.

Q Did you seek to talk to the President?

A Yes, I did.

Q Who did you communicate with to set that up?

A I believe I -- and, again, I'm guessing here. I believe I called the White House operator.

Q Did you discuss -- did you discuss this tweet with anyone else in the White House?

A I did.

Q Who?

A Mr. Short.

Q What did you discuss?

A I asked for his advice on how to handle this.

Q What did Mr. Short say?

A He said I should talk to the President directly.

Q Did you express any concerns to Mr. Short?

A [Majority Counsel], what do you mean by

concerns?

Q You can interpret concerns however you see fit.

A Okay.

Q What does that word mean to you?

A Okay. You'd make a great doctor, flip it back to the patient.

(Discussion off the record.)

The Witness. [Majority Counsel] -- and I was going to say this before this sidebar. But they were basically the same concerns I had. So I expressed -- you asked what was my reaction. I discussed that with Mark and said what's your advice? Because I feel like I need to clarify.

BY [MAJORITY COUNSEL].

Q What was Mr. Short's reaction?

A He said I think you should talk to the President directly.

Q Did Mr. Short give you any directive --

A No.

Q -- apart from that?

A No.

Q Did you talk to anyone else at the White House?

A I don't believe so, [Majority Counsel].

Q What about at HHS?

A No, I don't believe so, there either.
Q Did you take any action as a result of this tweet?
A [Majority Counsel], if you're asking the question was there regulatory action that we took as a result of the President's tweet, the answer is no.
Q What about anything other than regulatory action?
A There was -- I mean, I have no knowledge of anything that I or others at the FDA did that was a cause and effect from this, other than the call, sorry.
Q Just for the record, is there any information that you're holding back on the basis of privilege for any of these answers?
A Other than specifics of the conversation, which I don't have a complete recollection of anyway, but no, I'm not holding back on the broad issues related to it.
Q Approximately how long was your phone call with President Trump?
A I don't remember the exact time, but minutes.
Q In your opinion, was there any validity to the statement that the President made in his tweet or statements?
A Well, the President was expressing an opinion, it seems to me, and perhaps there was information he had

received which wasn't accurate. So I wouldn't characterize it as incorrect. I would characterize it as that my impression was that maybe he didn't have the full facts associated with our processes, and it was important for me to give him that information.

Q Did you believe that there was a deep state at FDA that was making it difficult for drug companies?

You already answered whether they had any role in testing vaccines or getting people to test vaccines and therapeutics. But more broadly, did you believe that there was a deep state at FDA that was making it difficult for drug companies to do anything?

A No.

Q Was anyone at FDA taking steps to delay an answer on vaccines and therapeutics until after November 3rd?

A I don't know the answer to that question.

Q Were you hoping to delay the answer on the therapeutics and vaccines until after November 3rd?

A Absolutely not.

Q Are you aware whether anyone else received calls about the need to authorize -- strike that.

On August 23rd, 2020, FDA granted the emergency use authorization for convalescent plasma. Who made the ultimate decision to authorize the EUA?

A Dr. Marks and the review team at the Center for Biological Evaluation Research, CBER.

Q When was that decision made?

A That weekend.

Q Do you recall what day?

A Dr. Marks had communicated to me maybe even the week before that they had come to this conclusion. They were reanalyzing data as it came in just to have as complete of an accurate picture as possible. But the decision to proceed had mostly been made pending this additional review, and it was coming in on a regular basis.

So I remember talking to Dr. Marks on Friday and Saturday, and it had been pretty much decided at that point that the EUA be issued.

Q You said it was pretty much decided. Was there any aspect that was still contingent or wasn't finalized at that time?

A Just final review of the data. The data -- [Majority Counsel], the term is "cleaned up." We needed to make sure that there was QA, quality assurance and quality control over the data, and that we were understanding that. And that just takes some time.

And what FDA does is sift through all of the lines of data. So really it was just to be sure that we made the absolutely best decision.

Q Do you recall when the final decision was made to issue the EUA?

A I believe it was Saturday evening or Sunday morning.

Q So is this after the tweet from President Trump and after your phone call?

A I believe so.

[Majority Counsel]. We are at time, so we can go off the record.

(Recess.)

BY [MINORITY COUNSEL].

Q Majority counsel left off with the decision to give an EUA for convalescent plasma took place after the tweet. But to be clear, it was not because of the tweet?

A Yeah. Let me be really clear about this, [Minority Counsel], it was not because of the tweet. As I mentioned, the week before -- I mean, I had multiple discussions with Peter Marks about this. And, you know, it's not signed until it's signed. But we had decided, as I said, that we were going to issue the EUA; that we had met the statutory requirements. So we were crossing some Ts and dotting some I's, yes.

But we -- and, as I told you, I was speaking to Dr. Marks on a regular basis and we made that decision -- or he had made that decision, he and his team.

Q So the timing of the tweet, Exhibit 21, and the timing of the EUA for convalescent plasma are not related whatsoever?

A They were not related whatsoever.

[Minority Counsel]. Thank you. That's all we have.

[Majority Counsel]. I'm going to mark as Exhibit 22 an August 23rd, 2020 email that you wrote to Dr. Marks copying a number of other individuals. It does not have a Bates number, but the subject line is EUA Update - Confidential and Predecisional.

(Exhibit No. 22 was identified for the record.)

BY [MAJORITY COUNSEL].

Q On August 22nd, 2020, at 8:16 p.m., Dr. Marks wrote, "Dear Commissioner, The EUA should be signed off by Denise by about 10 AM tomorrow. The ASPR is doing a final review of their revised submission based on OCC review, and then Denise can sign."

Is this consistent with your recollection that the decision was being made on Saturday night of the 22nd?

A Yes. The final decision, yes, [Majority Counsel].

Q What role did ASPR provide in doing that final review?

A ASPR would have reviewed the comms approach,

not the scientific review, just to be clear.

Q Thank you. The email continues. "Though there may be benefit for all non-intubated patients, as previously, the strongest data are in the non-intubated patients less than 80 years of age treated within 3 days of diagnosis with high titer convalescent plasma - at 7 days there is a 35% improvement in survival."

"From my perspective it is a definite go."

Was it your understanding that Dr. Marks was recommending that FDA approve -- or authorize convalescent plasma for EUA?

A Yes, [Majority Counsel]. And as I mentioned, this was an ongoing conversation. The weekend before, the week before, the same conversation occurred. And as I just mentioned to Minority counsel, this was a matter of crossing the Ts and dotting the I's.

Q At the time of the EUA announcement, were you familiar with the efficacy data for convalescent plasma?

A Yes.

Q I understand that you mentioned that everyone was dotting the I's and crossing the Ts with respect to issuing the EUA. Had FDA issued similar decisions like this on Sundays before?

A We were issuing EUAs and signing off 24/7 during the pandemic.

Q To your knowledge, did President Trump or any members of his administration communicate that he thought FDA should approve convalescent plasma?

A Do you mean authorized? Sorry.

Q Authorized, yes. I apologize.

A No, it's okay. I just want to make sure we get it right for the record.

So there was no -- so I can tell you, it depends on what you mean by administration. But I would have conversations with folks at the White House where they would ask the following questions. Do you think it's safe? Do you think that it's probably effective or that it may be effective? And of course the answer to that is, yes, all of our data suggests that where, as I say, crossing the Ts and dotting the I's.

It was the doctors -- and I received multiple calls from the doctors -- Dr. Giroir, Dr. Redfield, Dr. Birx -- who were expressing strong support for moving forward with the EUA.

Q On August 23rd, 2020, you participated in a press conference with Secretary Azar and President Trump at the White House to announce the EUA. How did that press conference come about?

A We had issued the EUA in the morning. It was decided by the White House typically -- which, as you

remember with remdesivir, we did the same thing on the day of the issuance, there was a press conference to let the American people know about it.

Q Were you involved in planning the press conference?

A Not at the White House level. But at the FDA level, we reviewed the comms statements.

Q Who was involved in preparing the comms statements?

A Our comms team. Keagan was involved, Keagan Lenihan, was involved. I believe Dr. Marks was there as well.

Do you mean preparing or in the conversations? I'm sorry, [Majority Counsel], just to be clear.

Q Let's do both. So who prepared them?

A Preparing would come directly from the Center, the data that would go into it to make sure it was accurate. OCC, the Office of Chief Counsel, would review it from the legal perspective, and then the comms team would shape, make sure everyone had seen it and reviewed it, and then it would typically go up to ASPR for review at HHS.

Q Was anyone specifically in charge of validating data or statistics for the convalescent plasma messaging?

A Yes. That would be CBER.

Q So Dr. Marks?

A And his team, yes.

Q And his team. During the press conference you stated, "I just want to emphasize this point because I don't want you to gloss over this number. We dream in drug development of something like a 35% mortality rate reduction. This is a major advance in the treatment of patients, this is a major advance" -- you continued -- "a 35% improvement and survival is a pretty substantial clinical benefit. What that means is, and if the data continue to pan out, 100 people who are sick with COVID-19, 35 would have been saved because of the admission of plasma."

Do you remember that?

A Oh, I remember that.

Q President Trump and Secretary Azar also made similar claims about the benefits of convalescent plasma at the press conference, correct?

A Correct.

Q After the press conference, you and Secretary Azar and President Trump were widely criticized for citing inaccurate statistics about the benefits of convalescent plasma during the conference.

Do you recall that?

A I do.
Q Did you agree with the criticism?
A I did.
Q Why?
A I should have been -- I mean, this is really important for a physician and for public health officials.
For context, remdesivir had a similar 30 percent reduction in mortality, but these are relative risks and I should have been very clear that it is a relative risk in reduction. So it was inaccurate the way I presented it. And I apologized for it because, at the end of the day, those representations need to be accurate. And I have repeatedly and will continue to repeat that statement.
Q In what way was that statement inaccurate?
A It's relative, not absolute. So it isn't 35 out of a hundred. It is if 10 people were going to die, the reduction would be 35 percent from the 10 people. So it's, of course, relative.
Q How did you come to cite that inaccurate statistic at the press conference?
A So the number in terms of relative risk reduction is not inaccurate. That came from -- and I'm holding up the email that you gave to me -- as you can see, directly from the center in their analysis when Dr. Marks says there's a 35 percent improvement in survival at seven

days.

So that number came directly from the scientists who reviewed the data. My error was not clarifying that it was a relative risk reduction.

Q Were you provided a script or talking points for your remarks at the press conference?

A Yes, mm-hmm.

Q Who prepared that?

A The agency did.

Q Comms staff or scientists?

A Everything was reviewed by the scientists, but comms staff would prepare it.

Q I'm going to hand you what's been marked as Exhibit 23. This is an August 23rd, 2020 email from Emily Miller to you and two other individuals. It is not Bates stamped, but the subject line reads: Update TPs.

(Exhibit No. 23 was identified for the record.)

BY [MAJORITY COUNSEL].

Q This email is heavily redacted, but it appears that you were emailing with others about talking points related to convalescent plasma EUAs.

Does that appear to be correct?

A Yes, that does appear to be correct.

Q At 3:04 p.m., Kevin Bugin emailed you saying,

"Hi Steve, In this bullet," but the remaining text is redacted.

You replied, "Yes, you are absolutely right. I like 35% increase in survival."

Do you recall what Dr. Bugin suggested?

A No, I don't recall what he suggested.

Q What did you mean by your response?

A That a 35 percent relative increase -- relative increase in survival is a substantial treatment effect. And if that pans out with the data as it goes on, that's a good thing for patients. I like that.

Q What did you mean by you "like that"?

A Like I just said, it's a substantial benefit for patients. And also, because in the context of this, it's very safe. So if you look at the therapeutic window, the risk-benefit ratio with this sort of magnitude benefit is substantial.

Q Emily Miller responded, "Message positive always. And can phrase it in real language as" -- and the rest of the text is redacted.

Do you recall what Ms. Miller suggested?

A I don't.

Q What was your understanding of what Ms. Miller was recommending by saying, "Message positive always"?

A You know, we were at a time in the pandemic

where there was a lot of discouragement about what was happening, the resurgence in COVID. And, you know, with these data, it was appropriate to provide hope to people, message positive about it.

Q Did you have other conversations with Ms. Miller about seeking positive messages to release to the American people?

A I don't remember. I don't think so, but I don't remember that.

Q Was FDA looking for opportunities to release positive messaging?

A Not opportunities to release positive messages. Opportunities to release messages that were consistent with the data and the science. If they were positive, then we wanted to emphasize the positivity of it.

Q Did you receive -- did you have similar conversations with others outside of FDA about wanting to message positively?

A Possibly, [Majority Counsel]. I just don't remember specifics around that.

Q Do you recall if you ever received this instruction from HHS?

A Instruction to?

Q To message positively.

A No, I do not recall having received that

instruction from HHS.

Q You mentioned that there were talking points. Who specifically prepared your talking points?

A I don't know who, but it would be the comms team at FDA.

Q Are you aware of how President Trump and Secretary Azar came to make misleading statements at the press conference?

A I don't know what their thought processes were. But we provided information to the White House and HHS.

Q Did they follow whatever information that FDA provided?

A You'd have to ask them specifically about that. But what I can say is we provided the information that I had. And you've heard the output. So I think -- I can't draw the conclusion of what went through the thinking for that.

Q Do you recall if they departed from a particular script or information?

A I don't recall.

Q What happened after the press conference? Did you have discussions about whether any follow-up action needed to be taken?

A There really wasn't any follow-up action at

the agency other than to apologize and to continue to message about the correct sort of interpretation of the data -- the accurate interpretation, relative risk reduction.

Q How did you come to the decision that you needed to apologize?

A Well, I saw the response, and it was the right thing to do. I had gotten advice about it as well and I believed it was right to do. Ultimately, it's my responsibility. I said it. I needed to make the decision about what to do in response.

Q Who did you have discussions with?

A Multiple people. Certainly inside the agency and some folks outside the agency as well.

Q Who within the agency?

A I don't remember everybody, [Majority Counsel]. Probably Keagan Lenihan would be one of them.

Q Did you discuss whether you should apologize with Emily Miller?

A You know, I don't remember that. Probably not, [Majority Counsel], but I don't remember specifically.

Q Why do you say that?

A Because I took the action on my own. I didn't ask for permission to do that from the normal channels.

Q Why not?

A Because I wanted to move quickly, and I wanted to correct the record on behalf of the agency.

Q Did anyone specifically advise you to apologize?

A Yes.

Q Who?

A A colleague, Wayne Pines, who I had known.

Q What was Mr. Pines' position?

A Mr. Pines was hired as, I believe -- and I could have the classification wrong, [Majority Counsel], so -- as a contractor or consultant. I forget. There's an actual specific term for that. So he had a contract, and really to help with communications.

Q Did you know Mr. Pines before coming to FDA?

A I did.

Q How long had you known him?

A Six months or so, something like that.

Q Okay. Did anyone else advise you to apologize and correct the record?

A Not that I remember.

Q Did anyone suggest that you should not apologize?

A No. I mean, after the fact. But, you know, I think there was a lot -- and I'm only saying this because it was in the press commented that there were people in the

administration who thought that I shouldn't have.

Q Did you ever learn that people in the administration thought you shouldn't have apologized from any other source apart from the news media?

A So your question is had I heard this other than -- no. No one specifically spoke to me about that.

Q And you didn't hear it secondhand?

A I don't think I did hear it secondhand. I might have, [Majority Counsel], but I just don't remember.

Q Did you have any discussions with Secretary Azar about this?

A Not that I remember.

Q Did you have any discussions with President Trump?

A Not that I remember.

Q Did you have any discussions with anyone at the White House?

A I don't believe so.

Q Did you have discussions about whether Secretary Azar or President Trump should similarly issue apologies or correct their previous statements?

A Are you asking did I have those discussions?

Q Yes.

A No.

Q Are you aware of whether others did?

A I don't know.

Q Apart from the decision to apologize, did you have discussions about whether to take any other actions as a follow-up or as a consequence of the press conference?

A Yes. We had internal discussions about how to provide ongoing data and accurate information about the data that supported this. So we put together a lay summary, which was a sort of distillation of the clinical data that would be relevant for the public to read about why the decision was made. And we did an ongoing assessment of the data to make sure that the data held up.

Q Was that document or information released publicly?

A Yeah. The lay summary was, I believe, yes. I think I referred to it in my late September testimony before the HELP Committee.

Q Did you make any other decisions -- strike that.

Did you have discussions about whether to take any other actions as a consequence of the misstatements that were made during that press conference?

A I'm not sure I exactly understand what you mean, [Majority Counsel].

Q Did, for instance, you discuss whether FDA should make changes to the review and approval policy of

public statements to ensure that the information was accurate?

A I made a personal decision, [Majority Counsel], at the time that, as Commissioner, if I thought it was important to communicate directly to the American people, that I would do so.

Q Did you have discussions about whether to terminate or reassign any employees who were involved in the press conference?

A Yes.

Q Who?

A Emily.

Q Why?

A Emily became a story. And rather than this being about convalescent plasma and its benefit, the correction that I made in the apology, it became about an individual. And it was my judgment, and my call alone, that that was not good, that that hurt our ongoing efforts, and I asked Emily to be reassigned.

Q And was she in fact reassigned?

A Yes.

Q Where?

A Within the Commissioner's office. I don't remember exactly where.

Q But she stayed at FDA?

A Correct.
Q Was the reassignment a demotion?
A No. Let me put it this way. I don't know about the GS characteristics of this, but I can tell you that, from my perspective, it was not in my view a demotion, just to move to a different setting where she could contribute.
Q Had you lost confidence in Ms. Miller's abilities to perform her job?
A I wouldn't necessarily say lost confidence as much as, when I looked back on the comms team, what I saw as a substantial amount of turmoil in the team, the outcome from this, the fact that it became a story. I put that together as something that we really needed to change, because confidence in the agency, particularly with upcoming vaccine decisions, was going to be critical and I made the decision.
Q It has been reported that Mr. Pines had his contract cancelled by HHS; is that correct?
A Well, I believe the official is that FDA cancelled the contract, but it was on advisement from HHS.
Q Why was that decision made?
A We were told that the contract was potentially inconsistent with longstanding policy.
Q Who told you that?

A I don't remember exactly. I remember having a conversation with Keagan Lenihan about it. But it was communicated from HHS. I'm not exactly sure where.

Q Are you aware of what that policy specifically was?

A I remember at the time having a discussion. I just don't remember now what that policy was.

Q Was the decision made -- strike that.

Was there any discussion that Mr. Pines' advice that you should apologize had any connection to that later decision that his contract needed to be cancelled?

A I'm sure there was discussion. I don't remember it specifically.

Q Why do you say you're sure there was?

A It would be a natural conclusion for someone to draw. Whether it was accurate or not, you know, that would be conjecture.

Q But, to be clear, you're not aware one way or another that HHS officials were making a pretextual decision to cancel his contract because they were unhappy with the advice he gave you?

A I am not aware of that, correct.

Q Did you ever hear that HHS officials were angered by your apology?

A I did not hear that HHS was angered, at least

in realtime.

Q What about later?

A The press reports we spoke about.

Q How did you issue your apology following the press conference?

A On Twitter, and then with interviews in the media.

Q Did you write the tweets that you released yourself?

A It was written for me, and then I edited it. I always looked at them when there were circumstances like this.

Q You mentioned earlier that you were concerned about the potential impact the erroneous statements could have on FDA's credibility; is that correct?

A That's correct.

Q Why was that a concern at this time?

A You know, we're in the middle of -- we have a divided country, a divided Congress, we have a presidential election, a once in a hundred-year pandemic, confluence of a lot of issues, we had upcoming vaccine decisions. And it was our opinion at the agency that, in order to save as many lives as possible, we had to not only look at the data and potentially authorize the vaccine, but make sure that people would be willing to take it.

Q And were you concerned that this press conference could make people concerned about FDA's ability to safely or accurately authorize a vaccine?

A I was worried that it might have impact, yes.

Q Did you discuss that with anyone?

A I'm sure I did, [Majority Counsel]. I just don't remember the specific discussions.

Q Did you ever hear any reaction to your apology from officials from the Trump White House apart from what was in the press?

A No.

Q Did you ever discuss it with anyone at the White House?

A Specifically the apology?

Q Yes.

A Not that I remember.

Q Okay. Thank you.

It has been reported that a number of Trump administration political appointees were hired to fill key positions at FDA that were previously filled by nonpolitical civil servants. Is that true?

A I don't know about the historical record of whether career folks were in those positions; but there were a number of political appointees that the Trump White House asked us to take.

Q Who at the Trump White House asked you to take those?

A Well, it wasn't through me directly. It was through Keagan Lenihan. It was the Presidential Personnel Office, PPO.

Q Were you provided a reason why the White House wanted to fill those positions?

A I did have discussions with PPO about what sort of functions the people might apply.

Q What did you discuss?

A Just what the role was, what the purpose was, what advice they would be providing. Those sort of general discussions.

Q What roles did they seek to appoint people to?

A One was on the comms side, Emily Miller as an example. Another was on the policy side, particularly around inspections, increasing domestic manufacturing as opposed to relying on foreign countries. Those are the two big ones. Drug quality was another one.

Q Did you agree to the recommendation to fill these positions with political appointees?

A So just to be clear about this. Whether you could characterize it as a recommendation I think is up to debate. I did interview the people, I did talk to them. I did outline what I thought the parameters of the job would

be just so that everyone is on the same page. And so then, yes, I did agree.

Q What do you mean by whether you could characterize it as a recommendation is up to debate?

A It wasn't clear at the time whether the agency and I could say no.

Q Okay.

BY [MAJORITY COUNSEL].

Q Why is that?

A Just there was not clarity around that.

Q Who communicated that to you?

A Keagan Lenihan.

BY [MAJORITY COUNSEL].

Q Did you specifically ask a question of whether it was a order?

A I'm not sure, but I think it came up in sort of the context of discussing folks.

Q Did you ultimately -- you said you interviewed all of the individuals who the White House passed their names along?

A Yes, I did.

Q You mentioned Ms. Miller. Who were the others?

A David Gertler was the other one, and that's the extent of what I can remember.

Q Was John Wolf Wagner another individual who fell into this category?

A Yeah. He was -- I'm not sure it was from PPO as much as it was from Mr. Caputo and ASPR.

Q And did Mr. Caputo recommend him or was it similarly potentially --

A That was more of a recommendation. And we had a discussion about it and I interviewed John.

Q Starting with Ms. Miller, what were your views of her from your interview?

A She gave a very, I think, clear and I thought good assessment of the communication problems at HHS and at the FDA. And I liked her recommendation to develop a sort of strategic communications plan that could bleed into the time period of vaccines, make sure it was all coordinated in together.

Q Did she have the type of background that you would normally consider for the position?

A Well, she certainly was somebody who had been involved in comms. We had other depths of experience in the comms shop, so it seemed to be complementary to that.

Q Did she have a scientific background?

A Not that I remember, no.

Q Or work at other public health or scientific agencies?

A She might have. You're jogging my memory about something in her background that might have been related to public health, but I'm speculating.

Q What about Mr. Gertler. What were your impressions about him from the interview?

A David had been involved in the private retail pharmacy side, so had the perspective of sort of being on the ground for that. He also had a perspective on sort of the quality assurance of drugs, was particularly interested in the quality of drugs that came from China.

Q Did he have the background that you would have normally considered for this position?

A Yeah, he did have both a scientific and a pharmaceutical background, particularly real-world experience and pragmatic experience. I'm sure there are others who might have had more experience in that, but that was present in his skill set.

Q What about Mr. Wagner. What were your impressions of him when you first met him?

A He had been at the VA in a similar role, which I believe was a larger role, so I was kind of surprised that he was recommended to be at FDA. But given the situation and the magnitude of the pandemic, you know, I had a really good conversation with him. I think he -- certainly based upon his VA experience and his

experience in government and with the media.

Q Would you have hired each of these individuals but for the recommendation or order that you received from the White House personnel office or Mr. Caputo?

A I mean, that's speculation, [Majority Counsel]. And not being in the situation of seeing a whole bunch of alternatives, it's hard for me to say.

Q So to be clear, did you have any communications where you sought to reject any of the recommended candidates?

A I did not have communications around rejection. I had communications around trying to clarify what the expectations were.

Q You mentioned that Ms. Miller was reassigned. Did you ultimately fill her vacant position with a career official --

A I did.

Q -- or political?

A Career.

Q Did Mr. Wagner stay on at FDA through the end of your position?

A No, he didn't.

Q What happened with him?

(Discussion off the record.)

The Witness. He had a medical event.

BY [MAJORITY COUNSEL].

Q And so he was not removed or reassigned due to any performance or other issues?

A So the answer to your question, which I think was couched in the negative, is he was reassigned by Michael Caputo to a position at HHS.

Q Okay.

A But his tenure with us was interrupted by the medical event. Sorry, I know that's kind of confusing, but I want to be accurate.

Q I appreciate that. What about Mr. Gertler; did he continue on at FDA?

A He did.

Q What was your relationship with Mr. Caputo? How would you characterize that?

A It was cordial. We sometimes had discussions about what were the best strategic approaches for the agency from a comms point of view.

Q How often did you work together?

A It depended. Early on when we first started, all the principals at HHS met with him on a regular basis, probably every week or every other week. It dropped off for a time.

Q Did he share proposals with respect to particular comms strategies for FDA?

A I remember him sharing proposals about comms strategies for HHS, but not -- I don't remember anything specifically for HHS, but how FDA fit into the HHS comms strategy.

Q Moving on, are you aware whether President Trump or any member of the administration sought to speed up the review or approval of any coronavirus treatment?

A You're asking did President Trump or anyone in the administration attempt to speed up. So the answer is, in general, the Trump administration, the President on down the administration was all about trying to get speedy approval of medical products for COVID.

So in a broad sense, the answer is yes, because in that -- the President was all about that, the speed part of it.

Q Did this -- were you ever concerned by the desire to speed up the review and approval of therapeutics?

A That part of it, no, because -- I mean, we were in a public health emergency and it was totally appropriate to ask the question, what can you do to speed this up to get lifesaving treatments, vaccines, et cetera, into the hands of people?

So I actually think, for all of public health in the United States, asking the question what can we do to speed things up is good. My job is to make sure that we follow

the processes that assess the science in the best possible light and make sure that the career scientists ultimately review those data and made the decisions.

Q So you said that they were asking questions. And then is it fair to say that you would respond to those questions and sometimes --

A Yes.

Q -- say, this is possible, this is not?

A Yes.

Q What type of reaction would you receive if you said we can't do that?

A It depends on the circumstance, but there was always an attempt to try to understand and to push back. There was a general sense that, you know, in some circumstances -- again, it depended on just the topic, but that there was bureaucratic slowness associated with this as opposed to a rational reason for the time that it took.

Q Did you agree that there was a bureaucratic slowness?

A Well, I do agree that the agency, HHS, et cetera, that we all could have done better from a process point of view. I mean, it has to undergo legal, ethics, et cetera, review.

I do not agree on the scientific side, because I -- if you look at vaccines, it took us three weeks to

review a completed application that was tens of thousands of pages long, and that would normally take months.

So I was pretty confident on the scientific side we were pushing hard to do those reviews. But I think you could reasonably argue that the processes otherwise took longer than might have been necessary. And I totally understand why. Making sure that you're doing things that are consistent with the law, I don't have to tell you, is really important.

Q What specifically could have been done better from a process point of view?

A I think we were able to do that with vaccines. We had a multidisciplinary team that we put together that looked at -- we put together a Gantt chart. What were the beginning and end steps with time for the vaccine authorization, and who had what?

And so pulling all those pieces together and saying this needs to get done in the fastest possible time. What do you think you can do? I found that very helpful in terms of trying to shorten that timeframe.

Q It has been reported that President Trump met with HUD Secretary Ben Carson, Phoenix Biotechnology Vice-Chairman Andrew Whitney, My Pillow founder and CEO Mike Lindell, Mark Meadows, and others in the Oval Office in July 2020 regarding oleandrin.

Had you ever heard that?

A That there was a meeting? Yes, I had heard that.

Q Did you participate in it?

A I did not.

Q Why not?

A I don't know why not.

Q Were you invited?

A Not to my knowledge.

Q How did you later learn about this meeting?

A I received an email message from -- you mentioned his name.

Q Andrew Whitney?

A Yeah, that such a meeting had taken place.

Q Did you know Mr. Whitney prior to this time?

A I don't believe so.

Q What did Mr. Whitney say in the email?

(Discussion off the record.)

[Majority Counsel]. We can go off the record.

(Recess.)

BY [MAJORITY COUNSEL].

Q Before we took the break, Dr. Hahn, I asked what did Mr. Whitney say in his email to you?

Mr. Armstrong. I am going to direct my client to not answer that and actually ask HHS.

Mr. Barstow. And his answer to that would reveal commercial confidential information, and so he can't reveal it today.

[Majority Counsel]. Okay.

BY [MAJORITY COUNSEL].

Q Did you have any additional discussions with Mr. Whitney or anyone else about the meeting in the Oval Office with President Trump?

A I had discussions with Secretary Carson, with Mr. Meadows, and again with Mr. Whitney.

Q What did you discuss with Secretary Carson?

A Just, in general, his belief that the data that supported oleandrin as a therapeutic was strong, and he encouraged us to take a look at it.

Q And did you take a look at oleandrin following Secretary Carson's recommendation?

A Yes. This wasn't the first time that Secretary Carson had mentioned this to me, so this was an ongoing issue. But yes is the answer to your question.

Q And what result? Did you come to an assessment about the potential efficacy about oleandrin?

(Discussion off the record.)

The Witness. Trying to give you an answer. So yes, I did. But really this wasn't a Commissioner-level decision, this was a center-level decision.

So I did discuss it with the center leadership, Dr. Cavazzoni. And they looked at the application, they got back to the company with what their recommendations were. And what is public knowledge is there is a 483 from the FDA about problems associated with it.

BY [MAJORITY COUNSEL].

Q Did FDA issue an EUA for oleandrin?

A Not to my knowledge.

Q To be clear, could an EUA have been issued during your tenure as an FDA Commissioner that you would not have knowledge of?

A Yes, it could have happened, yes. Of any medical process; is that what you mean?

Q Yes.

A Yes.

Q Under what circumstances?

A So just a hypothetical here, [Majority Counsel], not anything that I know specifically. There could have been a diagnostic test early on that is one of a hundred of the same.

You know, unless it was something new substantially added to the supply, new mechanism of action from a therapeutic point of view, new type of drug, et cetera, it typically wouldn't have come to my attention. And we had issued ten times more EUAs, during COVID, not during my

tenure, than all other public health emergencies combined. So, I mean, the numbers were staggering, double the workload, et cetera.

Q How many EUAs were issued?

A I knew you were going to ask me that. You know, I can't give you an exact number, but it was quite a few.

Q You mentioned you had discussions with Mr. Meadows about the Oval Office meeting. What did you discuss with him?

(Discussion off the record.)

The Witness. So, [Majority Counsel], I'll answer generally. We had a discussion about the application and the status of the application.

BY [MAJORITY COUNSEL].

Q Did Mr. Meadows ask you to take any action specifically?

(Discussion off the record.)

The Witness. Yes, there was direction, but no action was taken.

BY [MAJORITY COUNSEL].

Q What direction did he give you?

Mr. Armstrong. I think that's over the line that we've been asked to abide by the White House counsel's office.

BY [MAJORITY COUNSEL].

Q You said that no action was taken. Did you have concerns with the directive that he gave you?

A Again, it depends what you mean by concerns. But these decisions are made at the center level. The center level makes the decision based upon the science and the data. If the science and data don't support a decision, we won't make the decision is the bottom line. And we did not make the decision.

Q It has been reported that President Trump sought to have FDA review oleandrin as a potential coronavirus treatment. Are you aware of whether that's true?

A I don't know what you mean by sought. It was made aware to me that the President was interested in this. And as throughout the pandemic, whether it was President Trump, senators from states around the country, governors, they asked me to take a look. I did. Sometimes I pushed forward with it, and not necessarily decisionmaking, but the review, sometimes I didn't. So it was completely in line with what happened throughout the pandemic.

To me, in this situation, nothing unusual other than you need to take a look at this.

Q Did you have any discussions about Mr. Trump's interest in oleandrin?

A Discussions with whom, [Majority Counsel]?

Q With President Trump.

A No.

Q Did you have discussions about Mr. Trump's desire to have FDA review it with others?

A Secretary Carson and Mr. Meadows.

Q What was your reaction to your conversations with Mr. Meadows and Secretary Carson?

A [Majority Counsel], would you mind clarifying what you mean by my reaction?

Q Did you have any reaction? Did you consider the request to be inappropriate?

A As I said, throughout the pandemic we would have lots of requests. You know, we would like you to look at X. I took those all into consideration, and at the end of the day I made it clear to everyone who made those requests to me that we would be making decisions at the center level based upon the science and the data.

Q Were you contacted multiple times about oleandrin by Secretary Carson?

A Yes.

Q How many times?

A I don't remember.

Q More than five?

Mr. Armstrong. What do you not remember?

The Witness. I don't remember the number. Possibly yes, [Majority Counsel], but I don't.

BY [MAJORITY COUNSEL].

Q What about Mr. Meadows?

A Yes. Are you asking --

Q Did you have multiple conversations with him?

A Yes.

Q Do you recall how many?

A Under five.

Q Did you have conversations with others in the White House or in the Trump administration, more broadly, about oleandrin?

A Not that I remember.

Q Did President Trump express interest in FDA authorizing monoclonal antibody treatments such as those made by Regeneron and Eli Lilly?

A Yes.

Q What do you remember?

A Well, as you remember, the President got ill and it's public record that he received the Regeneron product under an EIND. And he believed that that product helped him recover from COVID, and he shared his personal medical history with me and his course and asked me to speak to his doctors. So he had an interest in it, yes.

Q Did Mr. Trump ask you to speed up FDA's review

and approval of Regeneron or any other monoclonal antibody treatment?

A The President, President Trump, always asked about -- or not always -- but when we spoke, asked about the status of what we were doing on the therapeutic side and then vaccines. And his message was consistent. I need you to do it as quickly as you can.

And I, just at a high level, would provide information about our processes, because at the end of the day, our processes are in place to save lives and to prevent harm.

Q It has been reported that President Trump and Mr. Meadows pushed you to accelerate the agency's review and grant EUAs for the monoclonal antibody treatments made by Regeneron and Eli Lilly. A senior official reportedly told The Washington Post that you received multiple calls from the White House in early October saying "the message is clear, let's get it done." Is that true?

A I don't believe that's true, [Majority Counsel].

Q Did you have discussions with Mr. Meadows about the monoclonal antibody treatments?

A This I'm fairly clear about -- and during that frame that you're describing, no.

Q Approximately how many calls did you receive

from President Trump about the monoclonal antibody treatments?

A [Majority Counsel], a couple, a handful. Often, though, I would provide him with updates. I was often proactive about giving him -- because of his personal interest in this -- about updates on these issues.

Q Did you take any action as a result of your phone calls with Mr. Trump?

A No.

Q What was your view of the possible efficacy of the monoclonal antibody treatments at that time in early October 2020?

A There were limited datasets. Phase 2, randomized trials. So there was a comparator arm, but they weren't definitive Phase 3 randomized trial. So a similar story to what we have heard before, but the data was encouraging on the efficacy side.

Q Did you have any concern at that time about potentially authorizing the treatments?

A Yes. On the toxicity -- there's two issues. One is on the toxicity side.

So patient selection -- we'll go back to that issue -- is really important in patient versus outpatient, how sick the person is. And then the other issue is something called escape variance, which is, would the

administration of monoclonal antibody lead to variance of concerns.

Q On October 8th, President Trump claimed that the Regeneron drug was a cure and a gift from heaven, and stated, "We're going to make them available immediately. We have an emergency use authorization that I want to get signed immediately."

What was your reaction to that statement?

A I don't actually remember that statement, [Majority Counsel].

Q Were EUAs ultimately issued for the Regeneron and Eli Lilly monoclonal antibodies?

A Yes.

Q When?

A I'm sorry?

Q Do you recall when?

A I don't recall when. I mean, it was in that timeframe, late October, early November. I believe -- well, we could check. Just, it would be a guess on my part. But, yes, they were ultimately authorized.

Q Was the timing influenced in any way by President Trump's interest in the treatments?

A No.

Q It has been reported that top health officials and national security officials in the Trump administration

created a plan in the summer and fall of 2020 for global vaccine donations. The officials reportedly planned to initially prioritize vaccine doses for strategic allies like Israel, Canada, Taiwan, South Korea, and some European nations, prioritizing those donations over donations for low and moderate income countries.

Were you aware of that?

A No, I was not.

Q Are you aware of who was leading discussions about global vaccine donations during the pandemic?

A No.

Q You mentioned previously that you spoke to President Trump and provided briefings to him about the timeline for review and approval of the vaccines; is that correct?

A Correct.

Q What did you discuss with President Trump?

Mr. Armstrong. One more time?

BY [MAJORITY COUNSEL].

Q What did you discuss with President Trump with respect to the vaccine timeline?

A They were general discussions about -- more so than timeline was a -- in fact, I tended not to discuss timeline just because it was dependent upon the receipt of data. But an explanation, for example, of what it meant

for a data safety monitoring board to look at the data and check off if -- I mean, it's just a complicated process, to try to provide perspective on all of that process.

Q How would you characterize the conversations?

A Cordial.

Q Are you aware whether President Trump or any member of the administration sought to speed up the review or approval of any coronavirus vaccines?

A There was a great deal of interest. And I think across the board there was an interest in having the review sped up as much as possible.

Q Are you referring to Operation Warp Speed, or other aspects that would attempt to speed up the review and approval?

A So Operation Warp Speed would have been one. That would have been on the development side. But once the data were handed off to us, that was our responsibility.

So we had oversight over the clinical trial, obviously, and we wanted to do everything we could to expedite that. And we also did a rolling review, meaning that a significant amount of the data were reviewed before the final dataset came.

But the final dataset, for example, in the Pfizer -- well, in the applications were substantial. And this is all public data, so I'm being really careful here,

but were reviewed at the VRBAC meeting.

But the bottom line is there's a lot of data to review, so we go line by line. So when those data are submitted to us as an application, then the clock starts and we really push hard to get that done.

That's what I was referring to before. Typically for a vaccine it takes four months, six months. We compressed that to three weeks.

Q Did you have any concern that compressing that period would impact FDA's ability to evaluate the safety and efficacy of the vaccine?

A No, for two reasons. One is we had spent a lot of time -- as I said, we put together a Gantt chart as to what the steps would be. We tried to remove any of the roadblocks to that. That's one.

And, secondly, we were going to be flexible. If we found a problem with the data, we would take longer. I mean, we were not going to cut corners in our assessment, and we were going to follow the letter of our vaccine guidance.

Q Was that important?

A Very important.

Q Why?

A Because it was about -- I mean, it's a vaccine. It's about doing the right thing for the American

people.

Q Were you concerned that the American people might doubt the strenuousness of FDA's review process or recommendations made with respect to the vaccines?

A Yes. There's a lot of public statements about the fact that, you know, I was concerned that people think we might be cutting corners.

So the irony of the situation is that there were folks who thought we were taking too much time and folks who thought that we might be cutting corners and that it might not be safe or effective. So I think -- not perfect -- but I think the agency did a good job of trying to weigh the risk/benefit of that.

Q I'd like you to take out the August 22nd, 2020 tweet from President Trump, Exhibit 21.

This is the tweet where President Trump stated, "The deep state, or whoever, over at FDA is making it very difficult for drug companies to get people in order to test the vaccines and therapeutics. Obviously, they are hoping to delay the answer until after November 3rd. Must focus on speed, and saving lives! @SteveFDA."

Did you have any discussions with President Trump specifically about your concern that -- your concern that the American people needed to understand the strenuousness of FDA's review process and that no corners would be cut

with reviewing and approving the vaccines?

A Just at a general level.

Q Were you concerned that President Trump's statements like the August 22nd tweet might cause the public to lose confidence in FDA's work?

A [Majority Counsel], I was concerned about the entire environment: A presidential election, bitter divisions in the country and in Congress. And, to me, it was a pretty significant combination of factors that led to a decrease in science and confidence in science and medicine, et cetera.

So there were multiple factors. It wasn't only this tweet. It was, I have to tell you, the entire set of circumstances.

Q Did you discuss those circumstances with President Trump directly?

A I did not.

Q Did you discuss those concerns with people at the White House?

A I discussed in general terms at the White House how the political atmosphere in general, as I just described, I was concerned was affecting confidence.

Q Did you make suggestions about what action should or should not be taken?

A I made suggestions with respect to what our

communications strategies should be around letting people know that we weren't cutting corners; that we were doing everything we could to ensure that these were as safe and effective as possible.

Q Did statements like that made by the President in his tweet, did that impact the morale of your staff?

A Yes, it did.

Q How so?

A I think the staff felt -- not "I think" -- but the staff felt that this was -- and they had been working really hard, our workload had doubled, and they also were worried about the potential impact that it would have on the public perception of the agency. There's a lot of pride at the agency and what they do.

Q Who expressed those concerns to you?

A From multiple sources, center directors, our chief of operations, within the Commissioner's office as well.

Q Who can you recall specifically discussing those concerns?

A I mean, I don't recollect specific conversations, but I do know that it was brought up.

Q Were you concerned specifically that President Trump's statements could impact public confidence in FDA's work and the safety and efficacy of the vaccine?

A Taken in isolation, to me it was the broad context of what was going on and the multiple conversations. The people who said they wouldn't take the vaccine if it was authorized under President Trump's watch. The vitriol and the divisions that we had in the midst of a presidential election.

So I wouldn't say there's one specific thing that did that, but I can tell you that our feedback from our stakeholders who we met with repeatedly was that this environment was problematic from that perspective.

Q But to be clear, that included the President's statements?

A That included.

Q President Trump referenced November 3rd Election Day in the August 22nd tweet. He also made numerous comments publicly suggesting that vaccines could be available before Election Day.

For instance, on September 4th, 2020, he said, "We remain on track to deliver a vaccine before the end of the year and maybe before November 1st."

At any point did President Trump express a goal to you of having coronavirus vaccines available before the election?

A I'm sorry, [Majority Counsel], repeat the question.

Q At any point did President Trump express a desire to have the vaccines available before Election Day?

A No.

Q Did others?

A No.

Q Did President Trump express a goal of having vaccines by November?

A President Trump expressed his desire for these to be approved as quickly as possible to save lives.

Q Did others in the White House express a desire to have the vaccines approved in October specifically?

A There was no one at the White House who contacted me and expressed a desire for a specific timeframe for emergency use authorization.

Q Did you hear it from others?

A You know, it was reported in the press, but I'm not -- not directly from others, at least that I can remember at that time.

Q Okay.

[Majority Counsel]. We are at time. We can go off the record.

(Recess.)

BY [MINORITY COUNSEL].

Q So, Dr. Hahn, you were talking about during -- about the vaccine, that you were concerned about

the entire environment around it, the President's tweets, other things going on.

Does that include the, at the time, Democratic candidates for president and vice president statements?

A Yes, it does.

Q So at the time vice presidential candidate Harris said if Donald Trump tells us to take -- tells us that we should take it, meaning the vaccine, I'm not taking it. Was that concerning?

A Yes.

Q Candidate for President Biden at the time said, "If and when the vaccine comes, it's not likely to go through all the tests that need to be done and the trials that are needed to be done."

Was that concerning?

A Yes.

Q And did the vaccine go through all the tests and trials that needed to be done?

A It did go through all the tests and trials that needed to be done to evaluate it.

BY [MINORITY COUNSEL].

Q I have a few sort of broad questions.

Were you ever involved in any discussions related to school closures?

A Just broadly at the task force. But that

wasn't really the FDA's jurisdiction, so --

Q Okay. Do you have an opinion on whether the virus came out of a lab and that could be an accident or purposeful -- hopefully not -- but came out of a lab or evolved naturally?

A I am not an expert at this at all, so I really can't speak to it.

Q Would you think that Dr. Redfield would be an expert on that?

A Dr. Redfield would indeed be an expert on that.

Q Two days ago, Dr. Redfield told Bret Baier on Fox News that he believed that the virus very likely could have come out of a lab based on -- and he didn't really get into the science -- but he said based on the fact that it was so infectious to humans. And Dr. Fauci recently said that, quote, "Card-carrying virologists believe that it evolved naturally."

Do you think that Dr. Redfield would be, quote, a "card-carrying virologist"?

A I think Dr. Redfield is a noted infectious disease doctor and public health expert. So I don't know about card-carrying, I don't know what that means, but certainly is an expert in the field.

Q Thank you. Would you certainly give -- would

you lend any credibility to what Dr. Redfield would say on this topic?

A Absolutely.

Q It sounds like yes.

A Yes.

[Minority Counsel]. Thank you.

BY [MINORITY COUNSEL].

Q Dr. Hahn, I have a couple questions. You've spent a lot of time take talking about emergency use authorization. Are you familiar with compassionate use authorization?

A I am.

Q Can you please describe generally what that is?

A We refer to it at the agency as EIND, Emergency IND, investigational drug application.

What it is, if a company agrees, a physician can ask for the emergency use of an investigational agent to treat someone who is in an emergency situation. If that's permitted, if the company allows it, we have a very simple application. We usually review it and allow it after 24 hours, or not, depending on the circumstances.

Q Did you have any conversations with Dr. Birx about a possible compassionate use authorization for COVID-19 vaccine?

A Not EIND compassionate use. We did have a discussion regarding expanded access programs started throughout the terms. It would be another way of getting vaccines. It was the mechanism we used to evaluate plasma, gathering real-world evidence. So we did have a discussion about that for vaccines.

Q Did you have any discussions about this with either of the two major vaccine providers?

A Those conversations did take place at the center level. I believe also Dr. Birx had conversations. But those discussions would have to have agreement by the companies.

Q But you did not personally have them?

A I did not personally have them, no.

Q Thank you.

BY [MINORITY COUNSEL].

Q I have one more. Do you think it's important to understand the origins of SARS-CoV-2?

A Yes, I do.

Q Do you think that one day we will know the origins?

A I hope that we do.

Q Do you think that China has been forthcoming and has assisted the world in understanding the origins?

A I don't know the details about that. What I

can tell you is that we felt that, from a public health perspective on the task force, that the details of the disease, for example, were not relayed and communicated in a way that would have fostered the appropriate public health response across the world.

Q In the task force in those early days, was the lab leak theory ever discussed?

A Not that I remember at the task force.

Q Did you ever have any conversations with Dr. Fauci about the lab leak theory?

A I don't believe so.

Q Did you ever have any conversations with Dr. Fauci about EcoHealth?

A I don't know what EcoHealth is.

Q Okay.

[Minority Counsel]. Then, again, thank you.

[Majority Counsel]. Dr. Hahn, would you like to keep going?

The Witness. Please.

BY [MAJORITY COUNSEL].

Q In September 2020, it was widely reported that FDA was working on new guidance that would be followed before authorizing a vaccine-related EUA.

How did that come about?

A [Majority Counsel], if it's the guidance that

I think you're referring to, that was August, September, October.

Q Okay. Then when did that process start?

A In the summer.

Q In the summer? And why?

A So we felt strongly that we needed to provide guidance to industry about what actually would be required, provide as much transparency about that to industry, so we started off with a vaccine guidance that was issued, I believe, the end of June, early July. Then we provided additional guidance about what criteria we would be looking at for an actual EUA.

So the first guidance was about, here's how to develop the vaccine. The second guidance was about these are the data we need to see to feel comfortable, again, potentially providing an authorization. No promise, but this is what we needed to see.

Q Who led this effort to develop this new guideline?

A We did, at the FDA.

Q Was there one person specifically that was leading the effort?

A Well, the vaccine division under Dr. Marks and CBER, Center for Biological Evaluation Research.

Q You said that the purpose of the guidance was

to provide clarity or transparency to manufacturers. What specific criteria was discussed that would be put into the second piece of the guidance about what --

A We would need to see --

Q -- you would need to see? Exactly.

A So we would need to see data from at least one adequately powered randomized trial on the efficacy side. And then with respect to toxicity, we wanted to see the median follow-up of participants in the trial had completed at least 60 days of follow-up.

Q Were those the provisions that were ultimately incorporated into the guidance that was issued?

A Yes.

Q Were additional requirements discussed, but ultimately not put forward in the final guidance?

A Discussed by whom?

Q By anyone at FDA.

A I don't know, actually. I mean, so the process at FDA, we would discuss the whole range of things. I mean, as you can imagine, it's a very complicated process, and we would look in the literature, we would look at our own experience.

So I guess my answer to that is, yes, we probably discussed a lot of things, but it came down to this as the most appropriate and pragmatic way to assess the vaccines.

Balancing, again, with speed, with making sure we got the decision right.

Q How did the decision come to be made to require 60 days of evaluation after the second dose?

A Well, we had looked at the literature and our own experience with when toxicities would manifest themselves.

Just to put it in perspective, with the normal time of the vaccine, you're going to have potential toxicities develop well after the data's submitted. So even under normal circumstances, there's practically no medical product that you can 100 percent guarantee in the real-world setting won't have some unexpected toxicity.

So the question is, how do you stratify the risk versus the benefit? In this case, we looked at the literature, saw where the overwhelming majority of toxicities were seen except for the very rare toxicities, and came to the conclusion that 60 days was an appropriate measure for that.

Now, a part of that calculation was if you could predict an efficacy floor, which we did, of 50 percent, how many lives would be saved if it was in fact efficacious and deemed safe at 60 versus 90 versus 120? And it was very clear from our analysis in that risk-based approach that 60 was a reasonable place to sit.

Q Were you aware of whether higher standards or lower standards were -- fewer days, more days -- were proposed in the medical literature or by anyone at FDA?

A I don't know about at FDA, but I am aware that the WHO stated publicly and published that they would look at 90 days.

Q Why did the determination come to be made that 60 was better than 90?

A Again, we looked at our own experience internally as well as the literature as to when toxicities were seen. We felt -- so, [Majority Counsel], it's an issue of how many more lives could be saved if we did it 30 days earlier versus what are the risks associated with this? And this is a core FDA responsibility is to assess the risk-benefit ratio.

Q You said this process started in August. When was the guidance ultimately released?

A October, early October. You're talking about the guidance on the data we'd need to see for EUA?

Q Correct.

A Yeah.

Q Can you take me through the process of how this started in August and why it took ultimately until October for it to be released?

A So the whole initial guidance started in

April, May, issued in late June, July as we went through the process.

Now, I think it's important to remember that although it certainly seems like it took a long time, we were communicating on a regular basis with industry about what our expectations were. So -- and the trials could always be modified based upon what we ultimately came up with.

But we came to this conclusion in August, September, and then we went through the process of having it reviewed and approved through the normal mechanism of HHS and then to the White House.

Q When did you ultimately send it up for approval to HHS and the White House?

A I don't remember exactly. My guess, it would be September.

Q What was the reaction?

A Initially, there were questions about it, we provided clarification, and it looked like it was going to be allowed to move forward.

Q What were the questions?

A Very similar to your questions: Why do we pick the 60 days? Why the median follow-up? What is that based upon? Scrutiny over the scientific and clinical rationale for what we were seeing.

Q Did FDA receive any pushback?

A Yes.

Q Of what? What happened?

A There were questions about whether the 60-day meeting follow-up in particular was appropriate given the urgency of the situation.

Q Who raised that concern?

A Questions were raised at HHS as well as at the White House.

Q Who at HHS?

A Some of it emanated from the Secretary's office.

Q From Secretary Azar specifically or others in the office?

(Discussion off the record.)

The Witness. All right.

I had a conversation with Secretary Azar, the team did, Paul Mango in the Secretary's office, I believe Brian Harrison was involved as well, the Secretary's chief of staff. And it was around the timeline, scientific rationale, all the issues that we had just discussed.

BY [MAJORITY COUNSEL].

Q And approximately when was this discussion?

A Mid to late September.

Q And what was specifically discussed in that meeting or call?

A I think it was multiple meetings and calls. But just the issues that I've discussed, around the scientific and clinical rationale for the guidance.

Q How would you characterize those calls and meetings?

A Again, cordial.

Q Did they ask FDA to make changes to the time period?

A Not initially.

Q What happened?

A It went to the White House. There were objections about it and there were suggestions made about adding additional language. Some of it was around availability of the vaccines and distribution, which isn't in our bailiwick, and others were really pushback about the issue of the 60 days.

Q So I want to go through that in a little more detail. You said that there were objections at the White House about it. Who objected to that?

A I had discussions with multiple people at the White House, including Mr. Meadows, but also others. And I'm forgetting their names, I'm sorry. But there were quite a few people involved in it. Mr. Mango was also involved in it from HHS.

Q What do you recall discussing specifically

with Mr. Meadows?

A Just the rationale behind this, just as I did with Secretary Azar and the reason for it. And I provided the scientific and clinical justification both verbally and in writing.

Q And did he specifically question the need for a 60-day post-review period?

A He asked in general about this, including all of the above.

Q Did he ask for changes to be made?

(Discussion off the record.)

The Witness. He did not ask for changes, but he did ask for me to discuss it with the team at the White House and HHS, which included some of the people I can't remember, I'm sorry, and also Paul Mango.

BY [MAJORITY COUNSEL].

Q And what happened during that discussion?

A I, again, provided the scientific rationale.

Q And after this meeting, did you have approval to move the guidance forward? Or what happened next?

A Well, multiple meetings, [Majority Counsel]. I wish it had been just one meeting, but it wasn't. And no, we did not.

Q Why not?

A I think that folks wanted us to consider

making changes to it.

Q What changes?

A I mentioned one was a distribution change. There might have been others as well.

But just to be really clear about this, I felt very strongly about the fact that our scientists had created this guidance, I totally supported the science and the clinical data behind it, and I objected to any suggestion that it be changed because I really felt that the state needed to stay in the scientific and clinical domain, and I also felt any changes would be obviously reported and would further reduce vaccine confidence.

Q So what happened next?

A In early October, Mr. Meadows called me and told me that it had been approved by the White House and we could go forward. And we subsequently published the guidance.

Q Had a copy of the guidance previously been provided to anyone outside of the Trump administration?

A Yes.

Q Who?

A To industry.

Q Had the White House approved providing the guidance to industry before?

A So we didn't call it guidance at the time. We

had communication with them as they were constructing their Phase 3 trials. So we communicated that outside of formal guidance. Which happens a lot informally. It wouldn't typically be something that we would communicate or need approval for.

Q So when were those -- when was that happening? When were those discussions or when was it provided to industry?

A My understanding from Dr. Marks is that happened in the summer.

Q And so are you saying it was not uncommon to have discussions with industry about standards that might not ultimately come to pass?

A No. Standards that wouldn't necessarily be put into a formulated formal guidance.

You know, these informal conversations occur with developers all the time. This is the current clinical situation, this is what we're looking at, this is our experience with your drug, vaccine, you name it. This is what we're recommending to you that you have as part of your package. Those discussions occur at levels of the agency every day.

Q And so how does the interplay work if it's not -- if it's discussed with industry but not formally --

A A guidance?

Q -- formally a guidance?

A That's what we call TA or technical assistance. Industry in general tends to follow it because you're talking to the reviewers who are going to look at your application.

Q How long did it take between the guidance being raised to HHS and the White House and it ultimately being approved?

A [Majority Counsel], it would have to be a guess, but several weeks.

Q Several weeks? What were the consequences, if any, of that delay?

A I don't think that there were -- I mean, let's just put it this way. There weren't any consequences from the clinical development point of view in the way the studies were conducted, because we had already communicated that was something that we were interested in seeing. I think it was unfortunate that there was a lot of press around this. And, again, the whole environment context contributed to a lack of vaccine confidence.

Q If the guidance had already been communicated to industry, what was the reticence from HHS and the White House to formalize it?

A I don't know.

Q It has been reported that the guidance

document was provided to members of industry, possibly slipped into a binder due to concerns that the White House would not approve it.

Do you recall if that is correct?

A So I don't recall slipped into binder. Perhaps what you're referring to is that by policy, and I believe law, we are required to publicly release documents before a VRBAC committee. So in anticipation of reviewing the criteria with EUA with the Vaccine Related Biologics Committee, VRBAC, included in that was what we had communicated to the industry. So not formal guidance, because it hadn't been approved, but what we had previously communicated with industry.

Q And did FDA seek approval from HHS or the White House to provide that document?

A We would not do that, because it's required as part of our processes in the interest of transparency before a public meeting to provide what has been communicated to -- it may even be in statute. I don't know. I don't know the answer to that question.

But it would be highly unusual, maybe even not consistent with statute for us not to have public release of documents that had been given to industry about what we were expecting to see.

Q Was there any reaction from White House

officials or HHS officials when that document or when that information was provided to them?

A Well, I proactively reached out to the White House to let them know that this was going.

Q And was there a reaction?

A Not that I remember.

Q Did anyone express concern or displeasure over it?

A Not to me.

Q Did you hear about it being discussed with others?

A I did not.

Q What interests were driving the changes or what concerns were driving the changes that were being sought in the guidance?

A You know, it was couched in general terms, in terms of speed, how can we quickly get this done to save lives. And then the other one was, how do we ensure -- there was a lot of concern around payment, who was going to pay for it, and whether we could put something into the guidance document that sort of expedited decisions around payment.

So I had discussions with Administrator Verma to determine if anything we put in our EUA would influence that, and the answer was no.

So, to me, again, introducing changes to a document that our scientists had put together, unless there was a really good reason, was kind of, you know, something we -- I was not in favor of.

Q So you said you weren't in favor of it, and I think you at least intimated that you felt strongly --

A I did.

Q -- that you didn't want to make changes. Did any of the meetings or calls get contentious on these issues?

A Not that I remember.

Q Were any of the suggested changes proposed by the White House or HHS ultimately made to the final document?

A No changes were made to the document, in the original document we submitted for review.

Q On September 23rd, in response to a reporter's question regarding the EUA guidance, President Trump said, "We may or may not approve it. That sounds like a political move because when you have Pfizer, Johnson & Johnson, Moderna, these great companies, coming up with the vaccines and they've done testing and everything else, I'm saying why would they have to be, you know, adding great length to the process?"

Do you remember that?

A I don't.

Q To be clear, was FDA's decision to issue this guidance a political move?

A It was not.

(Exhibit No. 24 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I am going to show you an Exhibit marked as Exhibit 24. It's a September 26, 2020 email from Peter Marks to you and Ms. Lenihan, Bates stamped SSCC-003773.

If you would look at the top of page 1, Dr. Marks wrote, "The WHO's proposed safety follow-up for vaccines trials is 3 months starting two weeks after the final vaccination for the entire population (not just the median). Therefore, one could actually say that we are not as stringent.

"If you don't mind, please let me know if anything develops over the weekend with the guidance."

Do you know why Dr. Marks sent this email on September 26th?

A Dr. Marks and I were communicating every day about this, and he was instrumental in providing information around the scientific and clinical rationale for this.

His point that he was trying to make here, or is

making here, is that our guidance represented a very pragmatic assessment of it, and one could argue that it needs to be more stringent such as the WHO had. We did not agree with that and chose the 60 days.

Q Was this perhaps used as a response or rebuttal to criticisms or concerns expressed by officials at the White House or HHS that 60 days was inappropriate or too long?

A I believe that this was shared.

[Majority Counsel]. I'd like to mark as Exhibit 25 a September 29th, 2020 email from Peter Marks to Ms. Lenihan and you, Bates stamped SSCC-0038009.

(Exhibit No. 25 was identified for the record.)

BY [MAJORITY COUNSEL].

Q If you look at the bottom of the email exchange, Dr. Marks wrote, "Dear Commissioner and Keagan, Assuming no word on the guidance? It would really be helpful to know whether this is going to go or not. The ambiguity here is actually creating more problems than a decision one way or the other. Thanks."

Ms. Lenihan responded, "I have not heard anything. The Commissioner is continuing to push and call colleagues at WH and HHS."

Then, finally, Dr. Marks responded, "Thanks. I would

propose by COB we make a decision to call this DOA or not."

Are you aware why Dr. Marks was expressing a proposal that the vaccine guidelines might be DOA?

A He -- are you asking me was he declaring them DOA? I'm sorry, I'm not exactly sure.

Q I apologize, it's probably a bad question.

What was your understanding of what he was proposing? Was he suggesting that if a decision was not made, that by the end of the day, that the guidelines should be dropped?

A Yes.

Q And did you further discuss that with Dr. Marks?

A I did.

Q What did you discuss?

A I indicated to Dr. Marks that I thought this was really important for vaccine confidence that we were continuing discussions, and that we should continue to have patience and push it forward.

Q In Dr. Marks' original email, he said, "The ambiguity here is actually creating more problems than a decision."

Are you aware of what problems he was mentioning?

A I'm not.

Q Or referring to? Okay, thank you.

In October, it was reported in Politico that

officials at HHS and the White House had pressured FDA to change its terminology for vaccine approval to start referring to emergency use authorization as pre-licensure. Is that accurate?

A Not that I am aware of.

Q Did you ever hear someone advocate for the EUA be called a pre-licensure?

A I'm thinking, [Majority Counsel] -- and, again, this is speculation, so I'm not completely sure that this may be related to this issue regarding reimbursement by CMS.

Q It was reported in the press that you were hell-bent against any modification of definitions because it would be viewed as a politicization of science. Is that something that you recall?

A Recall that report in the press?

Q No, just generally, that you were concerned about any modification of a definition.

A As I said before, I felt strongly about this because I felt that this was important from a clinical and scientific point of view where scientists had done their due diligence, and I thought it was important and connected to vaccine confidence.

Q It has been reported that Secretary Azar discussed whether to remove you from your position in

October 2020. Did you ever become aware of that fact?

A Through the press.

Q Apart from the press, did you have any discussions about it?

A No.

Q Are you aware --

A With Secretary Azar? Is that what you're asking?

Q With anyone in the federal government.

A Possibly. I don't specifically remember. More from the press.

Q Are you aware of why Secretary Azar may have considered removing you?

A You'll have to ask Secretary Azar that question.

Q Many of the documents that you turned over in response to the Select Subcommittee's request appear to indicate that they were printed in October 2020; is that correct?

A You know, I don't know.

Q If you look at Exhibit 25, for instance, you'll see that it says, at the very top, Monday October 26, 2020 at 11:31:07 a.m.

A Ah, okay.

Q Is it your understanding that that reflects

the print date?

A It seems a little early to me, but -- you know.

Mr. Armstrong. If you know. Do you know what that reflects?

The Witness. I don't.

BY [MAJORITY COUNSEL].

Q Do you have any understanding of any alternative reason why that date would be on the document?

A I don't have any explanation for that, [Majority Counsel].

Mr. Armstrong. I just want to interject, you phrased the question as the records that Dr. Hahn had turned over. He did not turn over any documents, it was HHS. I just want that to be -- right?

[Majority Counsel]. Noted.

[Majority Counsel]. In response to the Committee's request.

[Majority Counsel]. And these were documents that were in Dr. Hahn's possession originally, correct?

Mr. Barstow. Yes.

BY [MAJORITY COUNSEL].

Q So my question is this. Do you recall printing documents -- printing these documents in the October 2020 timeframe?

A I remember printing documents. I don't specifically remember late October.

Q When do you recall doing it?

A More like the November timeframe. But, again, it's all a blur.

Q What motivated you to print out these documents?

A I had been told by the agency on multiple occasions that the federal records rule allowed me to have copies of documents for personal recollection, and that's why I printed this.

Q Were you concerned that you would need access to these documents?

A As you can see, I was concerned that I might not remember all the circumstances around this. And so if I needed to refresh my memory, and since it was allowed under law, I decided to do it.

Q Why did you think you might need to refresh your recollection or have access to the documents?

A It was a busy, complicated time. I can't tell you that I expected to be right here right now, so that would be inaccurate to say that I anticipated this, but --

Q Were you concerned that you might be forced out of your position?

A That did not motivate me to print these

documents.

Q But were you concerned at any time that you might be terminated?

A You know, I would not use the word "concerned."

Q What word would you use?

A I would use I was aware. But I also was aware that I had a job to do.

Q You said you were aware. What were you aware of?

A Through the press that, you know, someone might not want me to be in that job.

Q Did you ever have conversations with Secretary Azar about this issue specifically?

A No.

Q Anyone else at HHS?

A Let me rephrase that. I remember having one conversation with Secretary Azar, and I'm not sure if it was about the firing part of this, but about press reports in general and how they were mischaracterizing his position. And I want to be accurate with you, I just don't remember if it was around this specific issue.

Q What do you mean that -- press reports that were inaccurate or --

A Statements about me in the press that were

ascribed to him.

Q What specifically?

A I don't remember. I just remember, now that you brought it up, that conversation occurring.

Q Were these statements in the press of him criticizing you or the other way around or something else entirely?

A In general, criticisms of the actions of the agency.

Q Which agency?

A FDA.

Q FDA?

A Yeah.

Q What do you recall of those conversations with Secretary Azar? What did he discuss?

A Just in general, the fact that this was reported in the press and, you know, that it wasn't an accurate characterization of how he felt.

Q And what was Secretary Azar's reaction to the conversation?

A Well, he didn't react. He was the one who told me that.

Q Got it. What was the tenor of the conversation?

A It was very nice, very cordial.

Q Did you ever discuss with anyone else whether there was an intent to possibly terminate you from your position as FDA commissioner?

A This was a topic of conversation at the FDA. And if I told you otherwise, I'm sure you would not believe that, but you could imagine that Commissioner -- reports of his being fired or her being fired, that's news. So, you know, I had to address it internally because it -- what I told folks is don't concentrate on the externalities. Do your job, get it done for the American people, and do it the best you can.

Q Was any action taken against you during this period to limit your role, responsibilities, or authority?

A No.

Q As FDA was completing its review of the EUA applications for the Pfizer and Moderna vaccines, did anyone in the Trump administration attempt to move up the timeline?

A For review, [Majority Counsel], that timeline?

Q Yes.

A Not that I am aware of.

Q What about for approval -- or authorization, excuse me?

A So there were multiple discussions with Mr. Meadows about the timeline. I shared the Gantt chart

and what we had proposed as well as the proposed timeline.

Q What did you discuss -- what did Mr. Meadows ask you or discuss with you?

A The discussion was -- the discussion was try to shrink this as much as possible.

Q Did you receive any directives or orders from Mr. Meadows during those conversations?

A I don't believe so.

Q Did you take any action based on those conversations with Mr. Meadows?

A We, [Majority Counsel], continued to take action to try to reduce the timeline as much as possible, understanding that the sooner we could get the vaccines out the better. But, again, Peter and I were in very close contact. We met every day. We stayed on top of what the review process was. And if Peter said he needed more time to get something done, then he needed more time to get something done.

[Majority Counsel]. I'm going to mark as Exhibit 26 a December 5th, 2020 email from you to Ms. Lenihan, Bates stamped SSCC-0038089.

(Exhibit No. 26 was identified for the record.)

BY [MAJORITY COUNSEL].

Q I'll direct you to the bottom of the first

page. At 4:32 p.m., you wrote to Dr. Marks, "I also very much appreciate the conversation around firmness of our December 10 and December 17 VRBAC dates. I am in complete agreement that we absolutely need the time to complete the rigorous scientific reviews that your teams are going."

Why did you write this email?

A To document a conversation about my confidence in his team and their ability to get the job done.

Q Was there a suggestion that the VRBAC date should be moved?

A You know, I don't -- so I don't remember there being a suggestion specifically about December 10th and 17th, but I think there was a general desire to see everything be expedited as much as possible.

Q If you look to the first email in that chain, you wrote to Ms. Lenihan, "The issue surrounding the firmness of the October 10th and October 17th relates to a call that Bob Kadlec made yesterday to Peter. Bob asked that Peter move the VRBAC date up to October 9th in order to accommodate contract issues that ASPR/OWS has made with sponsors."

What was your response to this request?

A So, [Majority Counsel], I believe this relates to the October VRBAC meeting, the first one that we had where we were reviewing the guidances and what the process

and procedure would be in the review process, which is separate and distinct from the dates in December for actual review of applications. That's my recollection of this.

Q Why did you mention the October dates?

A Again, for documentation around the fact that ASPR had asked for a change in that date. And we were not inclined to provide that change given the fact that it's a publicly established date, we have to provide notice, potential opportunity for comment, and documents related to it.

Q Did anyone in the Trump administration push specifically to move up the December 10th and December 17th VRBAC dates?

A Not that I remember. But, again --

Mr. Armstrong. Could we pause for a second?

(Discussion off the record.)

The Witness. There's a possibility that I made an error in my typing this email. I apologize, I'm not completely sure about that. But I do have a remembrance of another ask by Dr. Kadlec, and so I can't completely tell you that I know the answer to your question other than I don't remember there being specific requests other than to speed the timeline.

BY [MAJORITY COUNSEL].

Q Thank you.

A But I can tell you that we were pretty firm in whatever VRBAC dates we set. Again, one, we have a process that requires public notification and documents to be released; and, two, you know, there's a confidence issue here as well.

[Majority Counsel]. I'm going to hand you what I will mark as Exhibit 27. This is a December 11th, 2020 Tweet.

(Exhibit No. 27 was identified for the record.)

BY [MAJORITY COUNSEL].

Q President Trump wrote, "While my pushing the money drenched but heavily bureaucratic @US_FDA saved five years in the approval of NUMEROUS great new vaccines, it is still a big, old, slow turtle. Get the damn vaccines out NOW, Dr. Hahn @SteveFDA. Stop playing games and start saving lives!!!"

Do you recall seeing this tweet?

A I believe so.

Q What was your reaction?

A By that time, I believe we were really close to issuing the authorization. So as I remember -- was this in the morning?

Q It appears to say 7:11 a.m.

A And I'm again trying to remember, but I

believe that the morning of the 11th we had already made the decision to issue the EUA.

Q When do you believe that decision was made?

A I believe it was before the tweet. We would have to check the records, but that's the remembrance of this, is that decision had already been made.

Q Do you remember that decision was made that morning or --

A Or maybe even Thursday evening.

Q Okay.

A The exact time -- but it was pretty darn close.

Q Did you discuss the President's tweet with anyone?

A I don't remember. You know, in general, the President's tweets were discussed both in the media, but also in the agency. We have a morning meeting every day at 9:00, a big organizational meeting, and it would often get brought up.

Q Did anyone express concerns about the President's tweet or similar sentiments that were being expressed?

A Not that I remember. But, again, what I told you before, it was forget the externalities and focus on getting the job done.

Q Were similar sentiments expressed by anyone else in the administration to "get the damn vaccines out now"?

A Mr. Meadows was similarly interested in making sure it happened as quickly as possible.

Q What did Mr. Meadows tell you?

A Again, from a high level point of view, get them out.

Q It was reported that on the same day as the President's tweet you received a call from Mr. Meadows. Is that what you're referring to?

A I don't remember.

(Brief pause.)

BY [MAJORITY COUNSEL].

Q Do you recall when you had the call with Mr. Meadows?

A It was around that timeframe. I just don't remember the specifics of time and date.

Q Did Mr. Meadows order you to get the vaccine out?

A Not that I remember, no.

Q Did he give you a directive?

A Mr. Meadows was, you know, again, as I said before, just generally clear about that he wanted it done as quickly as possible.

Q What was Mr. Meadows' demeanor?
A Demonstrative. I guess that's the best word I could come up with.
Q What was his tone of voice?
A That's really hard for me to -- I mean, he was very demonstrative about getting this out as quickly as we possibly could.
Q Did he yell?
A I just want to be as accurate as possible. I think some could interpret what he said as yelling. I, at the time, thought he was just sort of being, as I said, very demonstrative about what he thought.
Q Was your future service as Commissioner discussed during that call?
A If it's the call I think you're referring to, there were press reports about that. And the answer to that is, no, from my perspective. That there was a truncated statement made, I didn't completely hear it, I asked for clarification, and the call ended.
Q What do you mean there was a truncated statement?
A It seemed like a partial statement, not a full one. And I didn't hear it and I asked for clarification.
Q What was that statement?
A I don't remember the specific details; but I

thought at the time that, you know, it could be perhaps related to my position. But, again, I want to be fair, because I did not hear the actual statement, and that's why I asked for clarification.

Q Did it sound like he was suggesting he would have you fired if you did not approve the vaccine?

A Asking that question, the answer is no. He did not say to me that you will be fired if you don't approve. He did not say that.

Q But he said something that made you think he might be referring to your position?

A He said something that I thought needed clarification about my position. I just can't -- I didn't hear the content of it, and that's why I asked for clarification.

Q But he hung up before giving it to you?

A Correct.

Q Are you aware of why he hung up?

A Not really. We had a discussion about 30 minutes to an hour later, it was very cordial, and we referred to it and, you know, sort of like in the heat of the moment sort of thing.

Q How long was the first call?

A My recollection is 15, 20 minutes, something like that.

Q What about the second call?
A Five minutes.
Q What was discussed during the second call?
A Press reports around this, because it had already been leaked to the press. And it might not have been 30 minutes, it might have been longer than that, but it was later that same day as I remember.
Q Was anyone else on the call with you?
A Dr. Marks was.
Q Did you discuss it with Dr. Marks afterwards?
A I don't think so. Well, you know what, I think we probably just discussed it in general. I do not think we discussed the specific remark, that I can remember, [Majority Counsel].
Q Did you discuss the call with anyone else?
A Keagan Lenihan.
Q What did you discuss with Ms. Lenihan?
A Exactly what I just described to you.
Q Did you take any action following the call?
A No.
Q When was the first vaccine ultimately authorized under EUA?
A I believe on the 11th. We had a -- the 10th was the VRBAC meeting. We had a meeting with the team to discuss the results of the VRBAC meeting. We made a

decision at that time to go ahead with the authorization and then had to complete the paperwork. And I believe -- and we'll have to check the public record, but I believe we issued a statement at 7:00 a.m. about that.

Q So just walk me through the timeline for the day. So a statement was issued at 7:00 a.m., approximately?

A Yeah, I'm thinking, [Majority Counsel].

Q And so that was before President Trump issued the tweet?

A That's what I'm remembering here, yes.

Q When did you speak with Mark Meadows the first time?

A Earlier in that week, I believe it was. I may be getting my dates wrong, but it was before that time.

Q Okay. So do you recall if it was shortly before the 11th, or could it have been a few days?

A I just don't remember, [Majority Counsel], I'm sorry.

Q When was the second call with Mark Meadows? Was it the same day?

A Yeah, it was the same day. And, again, I'm probably getting the dates confused, to be honest with you, but it's just -- that's the sequence. How it relates to the particular decisionmaking, I'm not completely

remembering.

Q And so Mark Meadows may have made a comment putting into question your future service as Commissioner of FDA?

A I am not saying that. What I am saying is that I did not hear the comment and I asked for clarification.

Q Okay. Did you ever ask Dr. Marks whether he heard the statement?

A I don't believe so.

Q And when the EUA was authorized, who made the ultimate decision to do that?

A Dr. Marks, and the Center for Biological Evaluation Research.

Q And did you agree with the decision to issue that?

A Absolutely.

Q During a rally on June 20th, 2020, President Trump stated, "Testing is a double-edged sword. When you do testing to that extent, you are going to find more people, you are going to find more cases. So I said to my people, 'Slow the testing down please.'"

Are you aware if anyone was ever instructed to slow the testing down?

A I don't have firsthand knowledge of that.

Q Did you ever hear it from someone else?
A We discussed it at the doctors' meetings.
Q What was discussed?
A Just that that was something that the President had said.
Q Did anyone suggest that they had heard similar sentiments from President Trump?
A I don't remember if there was a specific discussion with President Trump.
Q Or about whether President Trump had given -- expressed that sentiment?
A Yeah, I believe there were multiple discussions that took place. I just don't remember with whom and where. But a topic did come up at the doctors' meeting.
Q Did anyone suggest that they had been told to take any action to slow testing down?
A No one suggested that to me.
Q Did you ever see evidence that testing was slowed down or limited in any way?
A No direct evidence of that, [Majority Counsel].
Q You said no direct evidence. Did you see any indirect evidence?
A Just that the fact that it was discussed,

that -- you know, it was an issue that was brought up; it was discussed from a scientific and medical point of view, but I didn't -- and I guess what I mean by direct is I didn't see or hear about anything that told, for example -- they certainly did tell us stop authorizing tests. And I never heard anything of saying to CDC or anyone else stop doing tests, stop supporting manufacturing, et cetera.

Q It was widely reported that some areas of the country were facing testing shortages as well as lengthy delays in processing test results during the summer of 2020. Did you discuss those test shortages and delays with President Trump?

A I did not have a conversation with President Trump about that.

Q Did you have any conversations with members of the coronavirus task force?

A We discussed those issues regularly.

Q What was discussed specifically?

A Just about, at almost every meeting Admiral Giroir would provide an update regarding testing, availability, number of tests performed, et cetera, and also measures that were being taken to try to increase the use and availability of tests.

Q Is it fair to say that recommendations were

made to address these issues?

A I can't remember specific recommendations, but it's fair to say that there most likely were.

Q Do you recall whether any recommendations were rejected with respect to expanding testing or resolving delays in test processing?

A I don't remember any rejection of that.

[Majority Counsel]. I'd like to mark as Exhibit 28 an August 6, 2020 email from Ms. Lenihan to you, Bates numbered SSCC-0037982.

(Exhibit No. 28 was identified for the record.)

BY [MAJORITY COUNSEL].

Q The subject line reads, "LDT Discussion with AMA." What does LDT refer to?

A Laboratory developed tests.

Q And does AMA refer to Secretary Azar?

A It does.

Q In the email, Ms. Lenihan says, "Sir, putting everything together in one email so you have it for the 5 pm with the Secretary. Attached are the talking points around the concerns with the statement."

Did you meet with Secretary Azar that day to discuss LDTs?

A We had a phone call.

Q What did you discuss during the phone call?
A A proposal by HHS to publicly state that we, as FDA, no longer had jurisdiction over the review -- mandated jurisdiction over the review of EUAs.
Q Was this the first time that you were hearing about this proposal?
A No.
Q When did you first learn about the proposal?
A We started discussing something along these lines in the summer, I believe July, early July of 2020.
Q How was this brought to your attention?
A It was brought up from HHS to the FDA team, and then ultimately in a conversation that I had with Secretary Azar and his team.
Q What was discussed?
A Around the issues of, you know, there was concerns that --
(Discussion off the record.)
The Witness. So we had been told that there was a determination that perhaps FDA's oversight during public health emergencies at laboratory-developed tests was illegal. And there was a specific -- I think an Administrative Review Act that it potentially was violating. And they asked us to take a look at this and come up with some formulation about how we could address

it.

Q And what were the tenor of those initial meetings?

A Again, cordial.

Q What happened? Was FDA able to come up with a workaround or a --

A Yes, we had come up with a compromise. I don't remember, counsel had sent me an email to that effect and we thought that we had an agreement around it.

Q And what was that agreement?

A I don't have the specifics in front of me. In general, which has been publicly reported, our stance was that while the law was -- there was a lot of gray in this law, particularly during a public health emergency, that given the importance of reviewing the LDTs we would want to continue to do that because it is a public health emergency. But that, with respect to the LDTs as a whole, that this should be visited at a legislative level and at a policy level in the future.

Q Why did you think that it was important for FDA to regulate LDTs?

A Well, during a public health emergency, we talked early on about the inaccuracies associated with those tests and how that could significantly influence decisions that were made for the care of patients.

Q I believe you said you thought that you had an agreement on a path forward. What happened next?

A I'm not exactly sure what happened, other than the document you're referring to was a proposed web statement that we would put out, which went back to the original proposal stating that we would no longer require mandatory reviews of LDTs and that we were determined -- we had determined that they were illegal.

Q How did this -- are you aware of how this issue first came up? If there was, for instance, a lawsuit challenging FDA's interpretation of the rule or some other reason that this legal review was performed?

A I'm not aware.

Q Had you had prior discussions with Secretary Azar or anyone where the concern was expressed about how FDA was interpreting the rule or the oversight that they were performing with respect to LDTs?

A I don't remember a conversation about how we were interpreting the law. I do remember conversations about whether FDA's oversight over LDTs in general was stifling innovation and making it more difficult for LDTs to be commercially available.

Q Who raised those concerns to you?

A I believe Brian Harrison did.

Q Did you agree with him?

A No, I did not.
Q What did you tell him, if anything?
A Well, in general, I and our team expressed what I said to you; which is that we had data to show that the oversight was important, that our February 29th revision of our guidance to provide regulatory flexibility was kind of where we ended up, but we felt it should continue, and that we were very happy to revisit this in the legislative and policymaking process.
Q Turning back to Exhibit 28. Ms. Lenihan said that she was attaching or providing talking points around the concerns with the statement. What concerns did she specifically raise with respect to the statement?
A These were concerns that were vetted at the center level by the scientists, by Jeff Shuren and by the Commissioner's office and by the Office of Chief Counsel. And the concerns are, as I stated before, which is that we -- it was a longstanding position held by the agency understanding that it was a gray area in the law, and we did not agree with the conclusion that it was illegal for us to have oversight of LDTs.
Q The email lists an attachment, FDA LDT Web Announcement - July 28 DRAFT. Was it suggested that FDA should announce changes to the LDT regulation on FDA's website?

A Yes.
Q Who proposed this?
A HHS.
Q Did you agree with that proposal?
A No.
Q Why not?
A As I stated, we had a different interpretation, and it was a longstanding interpretation at the agency that preceded me by many years and had been over -- and had been -- I don't want use the word "propagated," but had been a longstanding legal stance by the agency.
Q Was that announcement on FDA's website ever made?
A No.
Q Did you meet with Secretary Azar on August 6th, as Ms. Lenihan's email suggested?
A We had a call.
Q A call. How would you characterize the tenor of that call?
A It was tense.
Q Did he raise his voice?
A Secretary Azar was again very vocal and demonstrative about what he thought was the right answer here. I think you would have to ask him about what his

state was at the time.

Q Did it upset you?

A I would say mildly it upset me, but I didn't feel, like, personal about it.

Q It was reported that you and Secretary Azar had screaming matches about this issue. Is that accurate?

A It's inaccurate. I did not scream at all during the conversation -- well, frankly, ever, with the Secretary.

Q Was it accurate to say that Secretary Azar screamed at you?

A I think you'll have to ask the Secretary whether he considered that to be screaming. As I said, it was demonstrative and vocal.

Q I'm putting the question to you since you're in front of me. Would you consider it accurate to say that Secretary Azar screamed at you?

A He raised his voice. I wouldn't say screamed.

Q Would you say yelled?

A He raised his voice, [Majority Counsel]. That's how I can characterize it.

[Majority Counsel]. We are just at the hour, so we can go off the record.

(Recess.)

BY [MAJORITY COUNSEL].

Q Dr. Hahn, on August 19, 2020, HHS announced that FDA would no longer require premarket reviews of LDTs, including coronavirus LDTs, absent notice and comment rulemaking; is that correct?

A That's correct.

Q Is this what you had been discussing previously, the legal determination that you disagreed with?

A Yes.

Q Did you consent to this announcement made by HHS?

A No.

[Majority Counsel]. I'm marking as Exhibit 29 an August 20th, 2020 email from Robert Charrow to you, Bates numbered SSCC-0037960.

(Exhibit No. 29 was identified for the record.)

BY [MAJORITY COUNSEL].

Q Mr. Charrow wrote, "In light of yesterday's posting on LDTs, thought it would be helpful if you were able to read over our legal rationale for the posting. Accordingly, I've attached the OGC memorandum."

What purpose did the OGC memorandum provide, to your understanding?

A It was their legal rationale. And I suspect

that this email was a means of documenting that it had been passed along to me.

Q You mentioned that you had the discussions with Secretary Azar over this. Who else was involved in the discussions over the decision to no longer require the premarket review, and to ultimately announce it on August 19th?

A [Majority Counsel], just to be clear do you mean overall that specific call? What do you --

Q Overall.

A Yeah.

Q Who generally was working on this?

A There were a number of people at HHS who were involved, Brian Harrison; on our end, Keagan Lenihan, Anna Abram, Stacy Amin, center directors, and specific on this particular situation was Jeff Shuren and his team.

Q Are you aware of why HHS decided to make this change at this particular time?

A No.

Q Apart from you, did anyone else express concerns about the change?

A To me? Other than internal discussions, I do not believe so.

Q Did you discuss the changes with anyone other HHS officials?

A I might have mentioned it to Dr. Redfield; but this really wasn't his area of oversight.

Q Do you recall what you discussed with Dr. Redfield?

A I don't, other than maybe just relating the circumstances to him.

Q During your conversations with Secretary Azar over the decision to make the change with respect to the LDT authority, did you ever threaten to resign?

A No.

Q After you were interviewed by CNN for a special last year, Secretary Azar released a statement which said, "Dr. Hahn's recitation of this call is incorrect. The only intemperate conduct was Dr. Hahn's threat to resign."

So was Secretary Azar's statement incorrect?

A I believe it was incorrect, yes.

Q You mentioned that HHS announced the policy change and FDA did not put it on its website. Why was that decision made?

A Why was which decision made?

Q That it would be announced on HHS's website and not on FDA's.

A All I can tell you is what I was involved in, which is I made it clear that FDA would not publish that on

its website. That we did not agree with it. It was against a longstanding legal opinion that we had. I personally did not feel it was related to public health.

Q To be clear, did you express those concerns to Secretary Azar?

A Yes.

Q Did a similar disagreement ever occur during your tenure as FDA commissioner where HHS desired to make a change that you disagreed with?

A Yes.

Q What else?

A There was a memorandum of understanding around Ag-Biotech with the Department of Agriculture.

Q Okay. And what was the outcome of that disagreement?

A Ultimately, in late January, another official signed a memorandum of understanding because I refused to do so.

Q Apart from that, were there any other similar incidents?

A Not that I remember.

Q Did FDA ever update its website while you were FDA Commissioner to reflect the change in authority with respect to LDTs?

A Yes. We updated our website, I believe -- we

at least updated our guidance and perhaps our website. We'd have to check versions. But what we decided to do at that point, given the legal determination by HHS, was that we decided that even if individual LDT makers submitted applications to us, we would not review them unless the impact of those LDTs was -- I believe the number, [Majority Counsel], was 150,000 per week or more.

We wanted to be able to prioritize our resources so that we could have the biggest impact. And obviously, also for point of care and at-home testing. That was another big one. And I believe that we updated that on our website.

Q Did you raise concerns about this change in guidance to anyone outside of HHS?

A Yes.

Q Who?

A The head of the Domestic Policy Council at the White House and Dr. Birx.

Q What did you discuss with Dr. Birx?

A Just my concerns on this issue and how it might affect testing.

Q What was Dr. Birx's reaction?

A I don't remember the specifics of her reaction; but I think, in general, she agreed with our position.

Q Did she suggest any possible proposal or way forward on this issue?

A Not that I remember.

Q What did you discuss with the head of the Domestic Policy Council?

A Again, the general approach to this, what our stance was, and why we thought it was important.

Q On September 15, 2020, HHS issued a memorandum stating that all departmental rules must now be signed by the Secretary.

Was it your understanding that this applied to FDA?

A Yes.

Q Was it your understanding that this prohibited FDA from signing any new rules regarding medicines, medical devices, and other products unless Secretary Azar agreed?

A Yes.

Q What was your reaction to this memo?

A I thought it would be a significant bottleneck. And while I would not characterize FDA's issuance of guidance and rules to be quick, I thought that this would further slow that down.

Q Did you speak with anyone in HHS about the memo before it was released publicly?

A I was unaware.

Q So was the first time that you learned about

the memorandum when it was actually issued on September 15th?

A I believe so, [Majority Counsel].

Q Did you speak any --

A Our folks internally might have heard a day or two before. I just don't remember, and again I want to be accurate with you.

Q I appreciate that. Thank you. Did you speak with anyone at HHS after the memo was released?

A Yes, Administrator Verma and Dr. Redfield to see if they were aware, had been aware of it.

Q What did you discuss with them?

A Just what the memo was about, and did it affect them, and had that been discussed with them before it was issued.

Q And what did they say?

A It did affect them, probably not as much as us, and it had not been discussed.

Q Did you speak with anyone else at HHS?

A Our team did.

Q What was discussed?

A Just the rationale for it. Why, you know, that sort of thing.

Q What were they told?

A You know, [Majority Counsel], I don't remember

all the details of those conversations. But it was discussed, and there wasn't really an opportunity for us to effect a change.

Q What do you mean by that?

A In terms of not having it go forward. Basically, it seemed and my remembrance of it is that it was a done deal.

Q Did you raise your concerns to Secretary Azar?

A I did not.

Q Why not?

A At that time, my regular one-on-ones had halted, and there just wasn't the means or opportunity to do anything.

Q Who had halted those meetings?

A I'm not exactly sure, but typically those meetings would be scheduled through the Secretary's office.

Q When did those regular meetings cease?

A Sometime in October, November, I believe.

Q You said that you were concerned that this rule could have created a bottleneck. Did it in fact create a bottleneck or slow anything down?

A Well, these things take a while to be implemented. So during my tenure, I don't think that we specifically saw that.

Q Did you learn the rationale for making this

change?

A No.

Q Did you believe that this change was made to specifically limit FDA's rulemaking power?

A I can't speculate to that. I don't know.

Q The White House and CDC released a number of public health guidance documents in 2020 related to the pandemic. Did you have any role or responsibility with respect to that guidance?

A Our -- there's an interagency review process, and typically our agency would review. That would not typically go to the Commissioner's office. So I can't remember a circumstance where I would have looked at it ahead of time unless Dr. Redfield specifically asked me, and I don't remember that at this point.

Q Okay. You don't remember them being discussed at the task force meetings?

A We discussed guidances, but it was typically through a late stage in the review process. But there was always opportunities to change guidances, and so that was one of the reasons to discuss with the task force.

Q What was your role in that process at the task force? Would you actually review and provide comments?

A If it was something that was related to FDA's purview where I felt that I had expertise related to that,

yeah, I provided comments. And often it was informally with Dr. Redfield, but typically it was formally through the interagency review process.

Q Do you recall specific pieces of guidance that you provided comments on?

A At one point, Dr. Redfield was contemplating changes to testing guidance and there were some technical issues related to FDA's oversight that we had a conversation about. I don't remember the details. It may have been related to asymptomatic testing, the same issue we brought up before, and whether a guidance was consistent with the intended use in the emergency use authorizations.

Q Do you recall if -- strike that.

The testing guidance was updated in August of 2020 and then again in September of 2020. Was that what you were referring to, one of those changes?

A Or both of them, [Majority Counsel]. We had a lot of discussions about it. And what I would always do is internally relate them to Jeff Shuren and his team so that we could have the experts weigh in on them, because we really wanted to make sure that whatever guidance we provided was both practical and impactful but also consistent with what the data supported.

Q I'd like to briefly turn to your interactions with Dr. Scott Atlas, who was appointed to serve as special

adviser to President Trump in late July 2020. Did you have interactions with Dr. Scott Atlas?

A One time at the task force.

Q What do you recall?

A It was an introduction.

Q Did you have any substantive discussions with Dr. Atlas?

A We had a substantive discussion at the task force that day about issues related to herd immunity, related to, you know, masking, and issues of whether natural infection could be a way of increasing herd immunity.

Q Was that something that Dr. Atlas was advocating for?

A I believe so.

Q What was your reaction to that?

A Well, I'm not sure if it was that meeting or subsequent meetings we had a discussion about it, and from our own individual perspectives the doctors on the group commented on it.

And my personal reaction was that, particularly being a cancer doctor, the problem with that approach, although in some situations that's not an unreasonable policy and something that at least needed to be discussed. Because of the particular effect of COVID on the immunosuppressed and

its lethality in that setting, we don't know who's walking down the street and could be immunosuppressed, for example, getting chemotherapy. Thank God we've progressed to the point where that's not always apparent. And, therefore, those people could be at risk without prior knowledge of it.

Q So is it fair to say that you disagreed with the herd immunity strategy that Dr. Atlas was advocating for?

A I think it's fair to say that I disagreed with it, yes.

Q Did you have concerns about it?

A Well, those were the concerns that I just raised to you, [Majority Counsel].

Q Did you ever discuss those concerns with other members of the task force?

A Yes. I remember having that discussion with Mr. Short.

Q What do you recall discussing with Mr. Short?

A The same issue that I brought up. And listen, you know, the problem with 2020, maybe now, is that not having an environment that allows you to have a discussion about a legitimate medical issue is problematic.

And so the tenor of the conversation needed to be that we respect people's opinion, but that we can have

reasonable disagreements based upon the science and the data. And that was where I stood, that I did not think that that was an appropriate response to this particular pandemic because of that.

Q Did you think it was a legitimate response?

A You know, during an emergency, doctors will give and take on ideas all the time. You may decide that it's a bad idea, a stupid idea, whatever you want to call it, but one thing you don't do is ridicule the production of ideas and the discussion of them. And that's the way that I approached this.

Q Got it. Did Mr. Short have any reaction to that conversation?

A He wanted my opinion about it, to his credit, and I gave him my opinion.

Q And did you have any further discussions with Mr. Short about it?

A We might have had other discussions about it. It was along the same lines, it was very respectful, really seeking my opinion about it.

Q Did the administration ultimately adopt any of the policies that Dr. Atlas was advocating for?

A Not that I am aware of.

Q Are you aware whether others on the task force had concerns about the strategies that Dr. Atlas was

advocating for?

A Yes. Sorry.

Q Of course.

A I know that Dr. Redfield, Dr. Fauci, and Dr. Birx, and I had similar feelings about it.

Q What did you discuss with them?

A Just in general the proposal and, you know, highlighting the issue around the immunosuppressed and the vulnerable, and the practical aspects of implementing such a policy.

Again, this was a doctor discussion about a suggestion, and I think it's important to remember that some countries actually had done that. I think it was a Scandinavian country that had done this early on in the pandemic. So it's not so outlandish that a country didn't decide to do it. You could argue about whether that was an effective strategy or not, but in our country given the heterogeneity and the number of immunosuppressed, it's an issue.

Q Very briefly, the testing guidance that was changed in August of 2020, you mentioned that you discussed it with Dr. Redfield. Do you recall who was involved in updating the guidance beyond just Dr. Redfield?

A I believe Dr. Birx, Dr. Fauci, Admiral Giroir. Those are the folks I can remember.

Q It was widely reported that the White House blocked Dr. Birx and Dr. Fauci and possibly other task force members from appearing on television news programs in 2020. Were you ever blocked from appearance on TV news programs by the White House?

A There were times when I was invited, and I was told that it was not going to be allowed.

Q Were you told why?

A No.

Q It's been publicly reported, in early November that Dr. Birx delivered a private warning to White House officials that the country was entering a concerning and most deadly phase of the pandemic, and that a more aggressive approach was needed to be implemented.

Do you recall that?

A I don't have specific recollection around that, [Majority Counsel].

Q Did you agree with the assessment that the country needed to -- that the country was potentially entering a severe winter surge and more aggressive action was needed?

A I did agree that we were anticipating and seeing signs of a surge at that time, yes.

Q Did you make any proposals to mitigate that surge?

A The doctors group and -- through Dr. Birx had discussed it, and I know that Dr. Birx had made several proposals.

Q Were those proposals implemented?

A I don't know.

Q According to the Washington Post, you and the other doctors on the task force decided to stage an intervention as cases started to tick upward in mid-November; is that correct?

A I'm not sure what they mean by intervention, but we decided to have conversations at the task force and with the Vice President's office about this.

Q What did you discuss with the Vice President's office?

A Just what Dr. Birx -- what you reported Dr. Birx said, that we were anticipating a surge, and that we really felt that we need to be prepared to deal with that and what efforts could potentially be put in place for that.

Q What was the response from the Vice President's office?

A Consideration of it.

Q Were those strategies or proposals implemented?

A I believe some of them were, [Majority

Counsel].

Q Do you recall which?

A I don't.

Q Do you recall which strategies were not implemented?

A I don't, sorry.

Q Of course. The Washington Post article reported that you and the other doctors also met with Mr. Meadows, and that he told you he did not believe the troubling assessment about the pandemic and accused you of outlining problems without prescribing solutions. Is that accurate?

A I don't remember a specific meeting with Mr. Meadows with that particular issue related. I just don't remember, [Majority Counsel]. It might have been in a task force meeting as opposed to a specific meeting, but I just don't remember those circumstances.

Q By late November, early December, was the task force meeting as regularly as it had previously in the year?

A Certainly not as regularly as the spring of 2020 and even earlier in the fall, but it was meeting regularly.

Q Was there concern that -- did you have any concern that the White House was not paying sufficient

attention to the pandemic during that period?

A I think we all had concerns that given the results of the election and the potential transition, that we wanted to make sure that we kept our eye on the ball as much as possible. I don't remember conversations where someone specifically said the White House isn't paying enough attention to it, but I do remember the conversations about concern given the sort of state of the political environment.

Q What do you mean that there was conversations about concern of the political environment?

A Just, again, we all as doctors have to keep our eye on the ball as far as what's going on. So the FDA doing its job regardless of what happened on the political side, CDC, the same with the task force. And that included communicating with states addressing testing issues, et cetera.

Q What steps do you think could be taken to maintain the independence of scientific work at the FDA?

A Well, I've been on the record, so I'll just go for it. I think strong consideration needs to be made for the independence of FDA from Health and Human Services. That ultimately, at the end of the day, an agency that is in a situation where scientific decisions can be reversed, I've always been -- it's problematic to me.

And I also have been very clear about the fact that we cannot have rogue agencies in government, that there has to be appropriate oversight of that. So could a model be developed where there's appropriate oversight, but at the same time scientific independence.

This is a great country. There isn't any reason that we can't come up with such a model.

Q Do you believe that having an independent FDA would have helped ensure a better, stronger response in 2020 to the pandemic?

A I can't speculate to that. I don't know.

Q Apart from the independence of the FDA, are there any policies and procedures that you wish you would have had in place to protect FDA from pressure during 2020?

A I can't think of a specific policy to put in place for the protection of the agency. I do think that our review of our response and the prep document is a useful commentary about what should be made permanent; inspections, communication, transparency, rolling review, et cetera.

Q Okay. I am nearly done. Thank you so much for sticking with us today. I would just very briefly like to discuss document issues.

We have discussed previously that you had printed out certain records and took them with you when you left FDA.

How did you decide which documents to print and take with you?

A I chose documents over issues that I thought there would be questions that were raised, and I wanted to make sure I had as accurate a recollection as possible and be consistent with. And I had, as I told you, multiple conversations with folks at the agency about what the rules of the road were.

So I wanted to be certainly consistent with the law, but also make sure I had in my mind documents that could help refresh my memory.

Q Have all of those documents been turned over to HHS in connection with --

A Yes.

Q -- this process?

A Yes.

Q Okay. Thank you. What devices did you use to communicate regarding official business while working for FDA and on the task force?

A My FDA computer and my FDA phone. I did have text messages with individuals on my personal phone, typically with people who I was in touch with before becoming Commissioner, and I turned those all over to the agency when I left. I handed my phone over for them to extract those.

Q So apart from texting on a personal cell phone, did you use any other messaging applications on your personal cell phone or your computer to discuss official business?

A To discuss official business, I did have Signal on my phone. Those messages disappear. And, in general, I received messages from people who I met preceding my tenure and typically when the messages were regarding setting up meetings, and also the press sometimes communicated that way.

Q Did you have any substantive communications with individuals on Signal beyond just setting up meetings?

A Typically not, no. And I'm saying typically just because I don't remember every one. But I really tried to steer policy decisions to -- official FDA documents to actual conversations that someone would be a witness to.

Q Do you recall who you communicated with on Signal?

A Not everybody. Almost every one of my contacts is on and is in there. But, again, there would be people in the agency, outside of the agency who were part of that.

Q Who were those people? And I only want you to focus on any communications that were related to the

pandemic response work.

A Okay. So one of my deputies, Dr. Shah, used Signal. As I said, the press used Signal a lot. Whether you consider that to be related or not, they always had questions and typically I would say, I'm happy to have a conversation with you, those sorts of things.

I am having trouble remembering anybody else but, as I said, almost my entire contact was on Signal. I just don't remember having anything substantive relating to the pandemic response.

Q And is it your understanding that those messages are not retained or stored anywhere?

A Correct, yes.

Q Apart from Signal, did you use any other messaging applications to communicate with individuals about official business?

A Official business? No.

Q Did you use any personal email accounts?

A No.

Q Did you use any personal computers, iPads, or other devices for official business?

A Not personal. I did have an iPad for the agency.

Q And did you return that at the end of your employment?

A Yes.
Q Did you save any files to a personal hard drive, cloud storage, or other location?
A No.
Q Without discussing any communications that you had with your counsel, what steps did you take to search for any documents that were potentially responsive to the select subcommittee's request?
A I looked at what I had kept and remembered what I had kept from the agency.
Q Apart from Signal, did you ever hear of others in the government that used personal devices or email accounts to communicate related to official business?
A Not that I'm aware of.
Q Did you ever hear of anyone using ProtonMail?
A Yes, I have a ProtonMail account, but I did not use it for official business.
Q Are you aware of whether others used ProtonMail for official business?
A I'm not aware of people using ProtonMail for official business, but I wouldn't have had those discussions with people.
Q You mentioned the people that you communicated with on Signal. Were you aware of others in the federal government that used Signal to communicate for official

business?

A I was not aware.

(Recess.)

[Majority Counsel]. We can go back on the record.

Ms. Klock. Can we please correct the record when we spoke about -- or when Dr. Hahn spoke about the oleandrin issue. He suggested or stated that FDA had issued a 483 to the companies. It was actually a warning letter, not a 483. Or there may be a 483, but it was a warning letter he was referencing.

[Majority Counsel]. We can briefly go off the record.

[Minority Counsel]. We have a few quick questions. We can go back on the record.

BY [MINORITY COUNSEL].

Q Dr. Hahn, you were having discussion with [Majority Counsel] about open, scientific dialogue, I think it was related to herd immunity. And recently some emails have come to light, I think through FOIA.

In particular on April 16th, 2020, Dr. Collins sent an email to some virologists that said. "Wondering if there's something NIH can do to help put down this very destructive conspiracy with what seems to be growing."

And he's talking about the lab leak conspiracy.

Do you agree that that's a conspiracy, the theory

that the virus leaked from a lab?

A I mean, I am no expert about what defines a conspiracy, but I do think that it's relevant for future pandemics that we take a one-health approach and that we understand what happened to prevent something like this in the future, if possible.

Q So you think that the lab leak theory should be examined, it sounds like?

A Oh, yes.

Q Okay. Thank you. And then on October 8th, 2020, in reference to -- are you familiar with the Great Barrington Declaration?

A Yes.

Q In reference to that, Dr. Collins wrote to Dr. Fauci and Cliff Lane -- is he a doctor?

A NIH, yes.

Q And Dr. Lawrence Tabak. He said, "This proposal from three fringe epidemiologists who met with the Secretary seems to be getting a lot of attention - and even a co-signature from Nobel Prize winner Mike Levitt at Stanford. There needs to be a quick and devastating published takedown of its premises. I don't see anything like that online yet. Is it under way? Francis."

Do you agree with this sort of what -- would you agree that this is stifling scientific dialogue, a swift

takedown of the authors of the Great Barrington Declaration?

A As characterized in that email, I would be concerned that that would be stifling scientific dialogue.

Q Do you agree that the authors of the Great Barrington Declaration are three fringe epidemiologists?

A I would not have used that term to characterize them. And as I mentioned in my testimony, I believe that what should occur during a public health emergency is a respectful and open discussion of all options.

Q Thank you. Is it your understanding that the President did not -- it's my understanding that the President did not follow the advice of the authors of the Great Barrington Declaration. Is that also your understanding?

A My understanding as well.

Q And I believe that Dr. Bhattacharya actually testified to that fact. Do you have any awareness of Dr. Bhattacharya's testimony on this?

A No, I'm not aware of it.

Q Thank you. Do you agree -- so in the buildup to the Delta spike, surge, the President and Dr. Walensky said that this is, quote, "a pandemic of the unvaccinated."

Do you find that narrative productive?

A I do not find that narrative productive.
Q Would you care to elaborate on that?
A I mean, it's a complicated situation. And while I've been very public about the fact that I think people should get vaccinated, I think that's a really important and strong public health message, I do believe that this is a discussion that should occur between providers and patients and people about the risks and benefits associated with it. And I think we should have a respectful discussion with people about their fears and concerns and try to convince people to get vaccinated. I have said that repeatedly, and I continue to feel that way.
Q Dr. Birx spent two days with us, much like you have today, and she testified that she thinks you need to meet people where they are and understand their concerns and have a dialogue and address their concerns. Would you agree with that?
A Absolutely. Listen, my perspective as a cancer doctor, if I made a recommendation for someone to a treatment and they were afraid and didn't want to do it, but I felt strongly it was the right thing to do, I wouldn't ridicule, I wouldn't push. What I would say is, let's have a discussion about it. Let me respect where you are and have a discussion about why I think it's important and let's review the information. But ultimately, patients

have autonomy and they can make those decisions.

[Minority Counsel]. Thank you.

[Minority Counsel]. I have two quick questions.

BY [MINORITY COUNSEL].

Q Does COVID-19 infect and kill people based on political affiliation?

A No, it does not.

Q What about based on their vote for a presidential candidate?

A Not to my knowledge.

[Minority Counsel]. Thank you.

[Majority Counsel]. We are off the record.

(Whereupon, at 4:31 p.m., the taking of the instance interview ceased.)