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INTERVIEW OF: JANET WOODCOCK, M.D.

Monday, May 13, 2024

U.S. HOUSE OF REPRESENTATIVES,

COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY,

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC,

WASHINGTON, D.C.

The Interview Commenced at 10:03 a.m.

Appearances

For the SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC:

MITCH BENZINE, Majority Staff Director

PETER SPECTRE, Majority Professional Staff Member

ERIC OSTERHUES, Majority Counsel

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For HHS:

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For FDA:

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P R O C E E D I N G S

Mr. Spectre. Go ahead and go on the record.

BY MR. SPECTRE.

Q This is a transcribed interview of Dr. Janet Woodcock conducted by the House Select Subcommittee on the Coronavirus Pandemic under the authority granted to it by House Resolution 5 and the rules of the Committee on Oversight and Accountability. This interview was requested by Chairman Brad Wenstrup, as part of the Select Subcommittee's oversight of the federal government's response to the coronavirus pandemic.

Further, pursuant to House Resolution 5, the Select Subcommittee has wide ranging jurisdiction, but specifically to investigate the development of vaccines and treatments, and the development and implementation of vaccination policies for federal employees and members of the Armed Forces, and executive branch policies, deliberations, decisions, activities, and internal and external communications related to the coronavirus pandemic.

Can the witness please state her name and spell her last name for the record?

A Janet Woodcock, W-O-O-D-C-O-C-K.

Q Thank you. Dr. Woodcock, my name is Peter Spectre, and I am a professional staff member for the Majority staff of the Select Subcommittee. I want to thank you for coming in today for this interview. The Select Subcommittee recognizes that you are here voluntarily and we appreciate that.

Under the Select Subcommittee and Committee on Oversight and Accountability's rules, you are allowed to have an attorney present to advise you during this interview.

Do you have an attorney representing you in a personal capacity with you today?

A No, I do not.

Q Is there an attorney present representing the Department with you today?

A My understanding --

Mr. Cooke. Yes.

Mr. Spectre. Will counsel please identify themselves for the record?

Mr. Cooke. Perrin Cooke, senior counsel at HHS.

Mr. Spectre. For the record, starting with the Majority staff, can the additional staff members please introduce themselves with their name, title, and affiliation?

Mr. Benzine. Mitch Benzine, staff director for the Majority staff.

Mr. Osterhues. Eric Osterhues, chief counsel for the Majority staff.

[redacted]. [redacted], chief counsel for the Minority staff.

[redacted]. [redacted], Democratic staff director.

Ms. Tsilker. Yelena Tsilker, senior adviser for oversight at HHS.

Ms. Raveendran. Manasi Raveendran, senior adviser for oversight at FDA.

Mr. Spectre. Thank you.

BY MR. SPECTRE.

Q Dr. Woodcock, before we begin, I would like to go over some of the ground rules for this interview.

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

If either side is in the middle of a specific line of questions, they may choose to end a few minutes past an hour to ensure completion of that specific line of questioning, including any pertinent follow-ups. In this interview, while one member of staff from each side may lead the questioning, additional staff may ask questions.

There is a court reporter taking down everything I say and everything you say to make a written record of the interview. For the record to be clear, please wait until the staffer questioning you finishes before you begin your answer, and the staffer will wait until you finish your responses before proceeding to the next question.

Further, to ensure the court reporter can properly record this interview, please speak clearly, concisely, and slowly, and I will try

to do that as well.

Also, the court reporter cannot record any nonverbal answers, such as nodding or shaking your head, so it is important that you answer each question with an audible verbal answer.

Exhibits may be entered into the record. Majority exhibits will be identified numerically and Minority exhibits will be alphabetically.

Do you understand?

A Yes, sir.

Q We want you to answer in the most complete and truthful manner possible, so we will take our time. If you have any questions or do not fully understand the question, please let us know and we will attempt to clarify, add context to, or rephrase our questions.

Do you understand?

A Yes.

Q If we ask about specific conversations or events in the past, and you are 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 the 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 Although you are here voluntarily and we will not swear you in, you are required, pursuant to Title 18, Section 1001 of the United States Code, to answer questions from Congress truthfully. This

also applies to questions posed by Congressional staff in this 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 you are unable to provide truthful testimony in today's interview?

A No.

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

Pursuant to that, 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 and the reason for the assertion on or before the scheduled date of testimony or appearance."

Do you understand?

A Yes.

Q Ordinarily, we take a five-minute break at the end of each hour of questioning. But if you need a longer break or a break

before that, please let us know and we are happy to accommodate. However, to the extent there is a pending question, we ask that you finish answering the question before we take the break.

Do you understand?

A Yes.

Q Do you have any follow-up questions before we get started?

A No.

Q All right.

First, I just want to talk a little bit about your education and experience. And I thank you for your long career in public health. Just briefly, where did you attend undergraduate school and what degree did you graduate with?

A Bucknell University. I received a bachelor of science in chemistry.

Q And what year was that?

A 1970.

Q Thank you. Did you receive any further degrees, and if so, from where and in what?

A I received an MD from Northwestern University in 1977.

Q Who is your current employer, and what is your current job title?

A I'm a private citizen.

Q Congratulations. And briefly, can you run through your career prior to joining the FDA? We will get into your FDA experience

after that.

A Well, subsequent to graduating from medical school, I pursued a residency in internal medicine at Penn State University. And subsequent to that, I stayed on as a junior faculty member for a short period of time.

Then I went to UCSF, and I pursued a fellowship in rheumatology, which I completed that fellowship. And then I stayed at UCSF for perhaps a year as, again, a junior faculty member.

Subsequent to that, I moved back to Maryland and I had an infant at the time. And so in 1986, I joined FDA, the Center for Drugs and Biologics, it was called at that time. I joined the biologics part as a part-time medical reviewer.

Q Thank you. And we'll get into a little bit more of your FDA experience, but do you currently hold honorary positions?

A I have an honorary degree.

Q Okay. From where?

A From University of Maryland.

Q Thank you. Do you currently hold or have you previously held any positions on boards of companies, nonprofits, or otherwise?

A I'm on the board of PCORI, Patient-Centered -- I forget what it stands for. Patient-Centered research group. That is -- I was appointed by the Comptroller General of the United States. It is a nonprofit, but it has an unusual status. But that's the board I'm on.

Q Thank you. Now, if we can elaborate a little bit more.

A I also -- for many years, I served on the editorial board

of the New England Journal of Medicine.

Q Okay. Thank you.

A Mm-hmm.

Q Now, we can elaborate more on your roles at FDA. I understand you had a long career and wore a few different hats. I know you started out as a drug reviewer -- part-time drug reviewer?

A Biologics.

Q Biologics reviewer. Can you explain where your path led from there?

A Yes. Well, I started out as a part-time reviewer in the I&D division in the biologics part of the agency. Subsequently, I became director of that unit. Subsequent to that, I became acting deputy director of the Center for Biologics.

Q That's CBER?

A Yes, it had split at that time, and then was the Center for Biologics Evaluation and Research.

Q How long were you director of CBER?

A I was acting deputy.

Q Acting deputy.

A I don't know. Subsequent to that, I was the head of the Office of Therapeutics of CBER, a newly formed office that was dealing with the new biotech drugs that came online. I did that until 1994 when I was appointed director of the Center for Drugs at FDA.

Do you want me to continue?

Q Yes, please.

A I have sort of a disability or something, I can't remember dates.

Q That's okay.

A I always had that.

Q Just to the best of your recollection.

A This is going to be roughly. I can provide you my CV.

Then I worked for Mark McClellan, when he was Commissioner. And then I stayed on -- he left and I became Deputy Commissioner, chief operating officer of the agency. I did that for a while. Then I went back and took -- I think that was 2007, I went back and took over the Center for Drugs again for another stint. And I remained head of the Center for Drugs until I became Acting Commissioner.

Q And do you recall exactly when you became Acting Commissioner?

A Well, that was right at the transition of the administration, so it would have been 2021.

Q And when did you finish up in that role?

A February of that following year. So I did it for about 13 months.

Q And you went back to another role for a brief stint after that?

A Well, for several years until I retired, I was Principal Deputy Commissioner.

Q Thank you very much. And forgive me, when exactly did you retire? That was this year at some point?

A January 31st.

Q Congratulations.

A Finally.

Q Now, transition to talking a little bit about relationships you may have had over the course of the pandemic. Specifically, I want to go down a list of people, and ask if you communicated with any of them regarding COVID-19 vaccination authorizations, approvals, recommendations, or other vaccine and policy. Does that make sense?

Mr. Cooke. And this is all to the best of your recollection, of course.

BY MR. SPECTRE.

Q President Biden.

A No.

Q Dr. Francis Collins?

A Yes.

Q Any other NIH officials?

A Dr. Fauci. And possibly other individuals who I can't remember their names at NIH.

Q Okay. Any other NIAID officials besides Dr. Fauci?

A No, I don't believe so.

Q Secretary Xavier Becerra?

A Yes.

Q Dr. Rochelle Walensky?

A Yes.

Q Any other CDC officials that you can remember specifically?

A I may have occasionally spoken to the chief of staff there, Sherri. I don't remember her name.

Mr. Benzine. Sherri Berger?

The Witness. Potentially.

BY MR. SPECTRE.

Q Dr. Tom Shimabukuro?

A No.

Q Secretary Lloyd Austin?

A No.

Q Any other DoD official?

A Could you restate your question?

Q I can. So these are communications regarding COVID-19 vaccination authorizations, approvals, recommendations, or other vaccine policy. So the name we were on was Secretary Lloyd Austin or any other DoD official.

A Is there a timeframe you're asking about here?

Q From December 2020 or -- over the course of the pandemic until you left FDA.

Mr. Cooke. If you're talking about -- you're talking about during her tenure when she would have been involved in the approval process?

Mr. Spectre. COVID-19 vaccination authorization or approvals.

Mr. Cooke. But just so we are all on the same page, is that

referring to when she was part of that process as Acting Commissioner?

Mr. Spectre. As any role she had in the FDA, any conversations she had about vaccine policy.

Mr. Benzine. For Secretary Austin, it would be after Secretary Austin was sworn in.

Mr. Cooke. So now we're talking early 2021? Okay.

The Witness. Well, I am a little confused.

Mr. Cooke. Sorry, just so we're all on the same page. Are you asking on those topics any conversations with anyone at DoD, beginning in early 2021, when she was actually involved in the approval process; is that right?

Mr. Spectre. It --

Mr. Benzine. Let's separate the questions.

BY MR. BENZINE.

Q So January 2020 to December 2020, any conversations with any DoD officials that you remember?

A During that time, I was detailed or whatever to Operation Warp Speed, I was the therapeutic lead for Operation Warp Speed, not vaccine lead.

Q So the conversations during the time, to the best of your recollection, would have been centered around Operation Warp Speed?

A Could you repeat?

Q So the conversations with DoD officials, probably General Perna and a couple others, from January 2020 to December 2020, would have been centered more around your detail to Operation Ward Speed?

A Yes.

Q Than your FDA position; is that correct?

A That's correct.

Q Okay.

A That's why I was having trouble.

Q And then for Secretary Austin, the timeframe would be when he was sworn in, so I don't know the exact date, but January-ish, 2021 to when you left?

A I did not have conversations, to my recollection, with Secretary Austin.

BY MR. SPECTRE.

Q Or how about any other DoD officials?

A Between when I was Acting Commissioner?

Q Yes.

A Not to my recollection.

Q Okay, thank you.

[redacted]. If you can keep the volume up a little, so we can hear. We've got a fan going back here. Thank you. Appreciate it.

The Witness. Sure.

BY MR. SPECTRE.

Q I am going to go through a few more. Dr. Deborah Birx, the same questions.

A Could you restate the question very clearly?

Q Any conversations regarding COVID-19 vaccination authorizations, approvals, recommendations, or other vaccine policy.

Mr. Cooke. And are we subdividing? So there's Operation Warp Speed --

Mr. Benzine. So we'll put Operation Warp Speed to the side. Any conversations specific to vaccines.

The Witness. After I was Acting Commissioner?

Mr. Benzine. Well, Dr. Birx would have been before.

The Witness. Oh.

Mr. Cooke. But not related to Operation Warp Speed.

Mr. Benzine. But not related to Operation Warp Speed.

Mr. Cooke. So outside that context any conversations with Dr. Birx regarding those topics.

The Witness. No.

BY MR. SPECTRE.

Q So same stipulations --

A I had a complicated time.

Q And we understand that. So same stipulations for Dr. Ashish Jha?

Mr. Benzine. This would have been January 2021 to retirement.

The Witness. I had conversations with Dr. Jha as part of group conversations, yes.

BY MR. SPECTRE.

Q Dr. Jeffrey Zients?

A I had conversations with him, yes.

Q Dr. Rick Bright?

A No.

Q Dr. Stephen Hahn?

A When are we talking about here?

Mr. Benzine. This would have been --

The Witness. After he was gone?

BY MR. BENZINE.

Q No, January 2020 to December 2020, conversations regarding vaccine authorizations, approvals, or policies with Dr. Hahn?

Mr. Cooke. Not a part of Warp Speed.

Mr. Benzine. Correct.

The Witness. Not to my recollection.

BY MR. SPECTRE.

Q Dr. Peter Marks?

A Yes.

Q Dr. Marion Gruber?

A To my recollection, I had one or two conversations with Dr. Gruber.

Q Dr. Philip Krause?

A Yes, one conversation.

Q Dr. Albert Bourla?

A Not to my knowledge.

Q Stephanie Bancel?

A Not to my knowledge.

Q Kiran Ahuja or any other Office of Personnel Management official?

A No.

Q Denis McDonough, or any other VA official?

A Can we restate the question? When was this?

Mr. Benzine. This would be January 2021 to your retirement.

Mr. Cooke. So during the current administration, any discussions with McDonough in his capacity—

The Witness. Regarding vaccines?

Mr. Benzine. Yes.

The Witness. No.

BY MR. SPECTRE.

Q Dr. Bernadine Futrell, or any other Office of Head Start official?

A No.

Q Douglas Parker, or any other OSHA official?

A No.

Q We'll go back through a couple of these. And just some of the ones you said yes to, we'll talk a little bit more.

You said you spoke with Dr. Collins about vaccine authorizations, approvals, recommendations, or other vaccine policy. Do you remember any particular conversations that stand out with her?

A Certainly. For emergency use authorizations, the regulations stipulate that we should consult with CDC -- FDA, when I say we, should consult with NIH, CDC, and relevant agency parties about issues.

So for example, I recall a conversation NIH and CDC about the AstraZeneca vaccine and the thrombotic diatheses that we were

experiencing and how that should be managed. We also held those appropriate consultations during various potential actions, labeling actions or other potential changes that might be related to the vaccine.

Q Any specific conversations about vaccine recommendations or vaccine policy, like vaccine mandates, for example?

Mr. Cooke. Can we be more precise? Specifically about vaccine mandates now or policies?

BY MR. SPECTRE.

Q Vaccine mandates or any other vaccine policy outside of authorizing and approving vaccines, if that makes sense.

A Yes, I did have conversations with Dr. Collins about policies related to vaccinating FDA and NIH employees. And we tried to have some uniformity about the exceptions, and how we would handle those matters.

Q And was that after the federal employee vaccine mandate was issued or was that prior to that?

Mr. Cooke. If you remember.

The Witness. I can't recall.

BY MR. SPECTRE.

Q Thank you. You also said you spoke with Dr. Fauci. Are those the same conversations as with Dr. Collins or different ones?

A To my recollection, the conversations with Dr. Fauci were also taken in a group consultation around, say, adverse event or labeling decisions around the EUA, in accordance with the regulations.

Q And no specific conversations about vaccine mandates?

A Not to my recollection.

Q Secretary Xavier Becerra, do any specific conversations jump out, to your recollection?

A Secretary Becerra received every two weeks or so, I don't recall exactly how frequently, briefings from the involved agency heads about the progress of multiple different activities that were going on with regard to COVID vaccine, and I was a part of those.

Q Okay. Were your conversations with him strictly about the authorization and approval process, or did it delve into the mandate policies as well?

Mr. Cooke. Sorry, just so I know we're keeping on the right side of the line here, obviously, to the extent you're asking about details with respect to these internal conversations, we have an Executive Branch interest in maintaining the confidentiality of those. We're not going to be able to go into details of all those conversations. I guess, just so I know what you're asking -- -

Mr. Benzine. That was a yes or no. If the conversations with Secretary Becerra also involved mandated policies.

Mr. Cooke. I want to be sure the yes or no was clear. So did those conversations with Secretary Becerra involve discussion abut mandate policy?

Mr. Benzine. Yes.

The Witness. My conversations?

BY MR. BENZINE.

Q Yes.

A To my knowledge, no.

Q You said it was like a group biweekly meeting. Did vaccine mandate policies come up with other people in that meeting?

A I don't recall.

BY MR. SPECTRE.

Q You touched on your meetings with CDC. But more specifically with Dr. Rochelle Walensky, do you remember any specific conversations that jump out about these issues?

A Can you describe these issues?

Q COVID-19 vaccination and authorizations approvals, recommendations, or vaccine policy?

A Yes, the CDC has a dual role with FDA on these matters. And the ACIP, which is the, again, acronym about immunization policies or the Advisory Committee on Immunization Policy of the CDC would meet and opine and make general immunization recommendations after the FDA had done an action on a vaccine.

And that occurs for most vaccines that CDC would have an interest in. And so we would frequently meet with Rochelle and her staff, and discuss what action FDA would potentially be taking. They would often present at our Advisory Committee, which would be first, and then they have an ACIP.

So we would discuss this whole process. We didn't want any -- we certainly wanted to be open to different scientific points of view, but didn't want any sort of unseemly different agency -- differences of

opinion to -- you know, we would like to work those out in advance.

Q Sure. And in those advanced conversations before meetings or other conversations, did FDA provide forewarning, advanced warning or notice that an approval or regulatory action was going to occur?

A Yes, because they would need to schedule a meeting with multiple scientific advisers soon afterwards.

Q Sure.

A We couldn't ever -- FDA can't ever, you know, guarantee that an action is going to happen, but we could certainly give sort of a ballpark, so they could do planning.

Q And roughly, how much in advance were you able to give that ballpark, a couple of weeks, months?

Mr. Cooke. You mean in general?

BY MR. SPECTRE.

Q In general.

A And you're, again, talking about the various COVID vaccines.

Q Yes, that's right.

A The way FDA does its review process, it's planned. It's very complicated. Very many pieces have to come together. So generally speaking -- if I could step back away from COVID and just talk about review.

So generally speaking, project managers lay out a timeframe and work -- generally speaking, the timeframe is set by PDUFA goals, and

then you work backwards. And when does the labeling review have to be done? When do the inspections have to be done? Inspection reports have to be filed? And when does the safety review have to be done?

And so you work backward. Here, you kind of work forward. When is filing expected. And as you know, the companies would frequently tell the world they were going to file something. They would frequently -- this is true all the time for all products -- they would frequently be wrong, too optimistic, right? And so -- but then what needs to happen -- what would need to happen is a timeframe, a project plan would need to be laid out, okay?

So for this filing, do we need to do inspections? Do we -- how much -- how big is the safety review going to be? All this kind of stuff. So generally speaking, you get a target date, like a best case scenario date, and then you refine that.

So FDA was able to tell -- the filing would be public and tell the CDC, we think it would take this long. And refine that as we move forward. And you never -- you find stuff as you're doing a review, and more problems. And it might take longer, or it might be able to get done quicker.

Is that helpful?

Q Yes. So as you refine that, that due date, it's called an action due date, I believe?

A Yes.

Q So as the ADD gets moved around, are you providing updates to CDC about that?

A Yes.

Q Do you typically provide -- or does FDA typically provide updates about the ADD to other agencies besides CDC?

A FDA typically does not do that, because that's market moving information, right? And we ask anybody that -- we generally wouldn't tell people that, right? But this relationship with CDC is very special, because they have an action to take as well.

Q So outside of CDC, it's generally private information?

A Absolutely.

BY MR. BENZINE.

Q You said typically. I don't mean to nitpick on words, but during the COVID vaccine approval process, was the ADD shared with any other agencies?

A Not to my -- not by me.

BY MR. SPECTRE.

Q To your knowledge, did somebody else?

A Well, it often would appear in the papers. But that might have been from the companies, because we tell the company, so they can prepare. They have to -- the company has to do a lot of work. It's a very frenetic activity toward the end of that, as you approach that final date.

And so the companies would be told. So it's hard to know who would -- but the dates might start floating around out there. You know, companies are talking about that.

BY MR. BENZINE.

Q Do you know if anyone within the FDA shared the ADD with the Department of Defense?

A I do not know.

BY MR. SPECTRE.

Q Thank you. I think we'll talk a little bit more about the shifting ADDs and this topic a little later, but just to get through a few more of these names here.

You said you have spoken with groups -- and I can say the categories again for you -- with Dr. Ashish Jha about COVID-19 vaccination authorizations, approvals, recommendations, or other vaccine policy. Do you remember any specific conversations that jump out to you?

Mr. Cooke. I know we went over this, but let me make sure I understood. You're now talking specifically in the context of Operation Warp Speed.

BY MR. SPECTRE.

Q Unless -- I understand your role in Operation Warp Speed was therapeutics. Did you have any role in vaccines with Operation Warp Speed?

A I did not have any direct decisional role.

Q Okay. So, yes, outside of Operation Warp Speed. All of these will be outside --

BY MR. BENZINE.

Q And while Dr. Jha was a member --

A Pardon me?

Q Dr. Jha was a private citizen involved in public health, but just became part of the administration in 2021. So the time scope on this would be January 2021 until he left -- I think he left before you.

A And I beg your pardon, but could you rephrase the question?

BY MR. SPECTRE.

Q Absolutely. How about this? Did you have any specific conversations about vaccine mandates with Dr. Jha while he was a government employee, outside of Operation Warp Speed?

A Not to my knowledge.

Q So the same for Dr. Jeffrey Zients. Did you have any conversation about vaccine mandates?

A No.

Q Dr. Peter Marks, I'm sure you had lots of conversations about some of those other topics with Dr. Marks; is that right?

A I was Dr. Marks' supervisor during that period when I was Acting Commissioner, and I had many conversations with Dr. Marks about the vaccines.

Q Did any conversations ever touch on vaccine mandates or mandatory vaccination policies, broadly?

A I believe Dr. Marks brought it up a couple times.

Q A couple of times?

A Yes.

Q Do you remember specific times?

A No.

Q Thank you.

BY MR. BENZINE.

Q What did he bring up?

A The fact that different groups were considering vaccine mandates. It was widely being discussed in the press and so forth. And the fact that some of that was tied to status, the status of the vaccine was also being discussed, and he commented on that.

BY MR. SPECTRE.

Q So if I'm understanding correctly, he mentioned the fact that FDA may need to take regulatory action in order for vaccine mandates to be possible. Is that what you're saying?

Mr. Cooke. Again, I think we're getting into some fairly high level details here. If you can keep things general, then I think we're on the right side of the line. But to the extent that you're getting into details of conversations with Dr. Marks, we're not going to --

Mr. Benzine. I can rephrase it, so it's a yes or no, too.

BY MR. BENZINE.

Q Did Dr. Marks ever speak to you about the need for full Biologics approval in order for groups to institute vaccine mandates?

A Dr. Marks commented on the fact that mandates for some populations would be tied to their FDA status.

Q It was his opinion or was he just commenting on the press?

A He was commenting on the press, and that this was being

talked about, to my recollection, yes.

Mr. Spectre. Thank you.

BY MR. SPECTRE.

Q You said you spoke with Dr. Marion Gruber one or two times. We'll talk about one of those times a little bit later, July 19, 2021. But is there another time specifically that you can remember?

A No.

Q So you said one or two. Just -- you think there may have been another time at some point, but you're not sure when?

A I may have said good-bye to her when she went off to Germany.

Q Okay. Thank you. And Dr. Krause, you said you spoke with him one time. Was that the July 19th meeting?

A I believe so.

Q Thank you. All right. Do you recall ever communicating with any of the officials who we spoke with -- and I can go back through, if you would like me to -- via a personal email or personal cell phone?

A No.

Q Not on your end or on theirs?

A I didn't have a personal cell phone.

Q Okay. Good for you.

BY MR. BENZINE.

Q Does FDA have Teams or another messaging app on your

desktop or laptop?

Mr. Cooke. If you know.

The Witness. I don't know.

BY MR. SPECTRE.

Q When was the last time you communicated with Dr. Marks?

A In his official capacity?

Q Right.

A In my official capacity.

BY MR. BENZINE:

Q Did you ever communicate with Dr. Marks about any testimony before Congress, yours or his?

A I spoke to Dr. Marks about ten days ago about my garden, and mentioned -- he's a fellow gardener. And I mentioned that I might be talking to Congress about this.

Q Did he mention that he just had?

A I believe he told me he had a hearing.

BY MR. SPECTRE.

Q Did he mention any other testimony he had given before Congress besides the hearing?

A No.

Q Thank you.

A Not to my knowledge.

Q Okay, last little section here on the relationships part. Did you regularly communicate with organizations or entities outside of the FDA as a part of your job as Acting Commissioner?

A Yes.

Q With pharmaceutical companies?

A My job as Commissioner did not involve inserting myself into discussions between the FDA and pharmaceutical companies unless there was a problem that had been escalated to my level.

Q And did that happen within the context of COVID-19 vaccines during your time as Acting Commissioner? Was it elevated to your level, such that you had to get in between those conversations?

A You're talking about approvals, and between pharmaceutical companies and the FDA?

Q Authorizations or approvals between the FDA and a pharmaceutical company for COVID-19 vaccines.

A For vaccines. I cannot recall any, but it might be possible.

Q Okay. So did you have any particular conversations with the WHO as part of your duties?

A No.

Q Advocacy groups?

A Many.

Q And I assume within advocacy groups, probably patient groups as well?

A Yes, I've always spoken to many patient groups.

Q Thank you. I want to move on, talking a little bit more about the vaccine process and the COVID-19 vaccine itself a little bit more.

Just as a couple of baseline questions, could you explain a little bit what the FDA's typical role is in vaccine development?

A FDA does several things. Number one, FDA sets the standards for the safety evaluation of a product as well as its efficacy evaluation.

Ideally, that's done quite early, so that the development program's going in the right direction, and there's not a lot of waste of time. Once -- and that might include toxicological evaluation before clinic, but those would be recommendations by the agency which are often published as guidance.

Once a company is planning to go into people and agency gets involved, and that's the IND process. So a company must file an IND, and wait 30 days. And the agency evaluates the plan, as well as the safety information to make sure that first in-human, experiment is safe. And then the agency will be overseeing the development -- clinical development program all along.

At some point, probably pretty early for vaccines, part of the safety evaluation is looking at the construct, whether it's a drug or a vaccine, or whatever. How it's made, what the chemistry is. Make sure not only that it's safe, but it's controlled.

And as you get later in the development process, you want to make sure that the product is able to be manufactured reproducibly, so the data from this person actually applies to the next group because the product is the same.

So they are more -- as things go along in the development, there

are more and more stringent chemistry and manufacturing controls, standards, as well as clinical evaluation.

Q Thank you. So we touched on this a little bit, I think, but where within the FDA are vaccines, in particular, regulated?

A They're regulated by the Center for Biologics Evaluation and Research.

Q And is there a sub-office of CBER that works particularly on vaccines?

A Yes, I believe it's Office of Vaccines.

Q Thank you. Who was in charge of CBER while you were Commissioner?

A Dr. Peter Marks.

Q And who was in charge of the Office of Vaccines?

A Dr. Marion Gruber.

Q And I understand the Office of Vaccines also has some sub-offices; is that right?

A Likely.

Q More than one?

A I am not very well-versed in the sub-organization. I believe it has changed over time.

Q Okay, thank you. As Acting Commissioner, what was your role in the COVID-19 vaccine development, authorization, or approval process?

A As I said, my job was to make sure that all the activities of the agency continued legally, scientifically valid,

appropriate, and so forth. And to deal with problems as they arose.

Q Thank you. We touched on this already, but I understand you had a formal role in Operation Warp Speed regarding therapeutics. I think I already asked you this, but just, again, you didn't have a specific role related to vaccines; is that right?

A That's correct.

Q In your opinion, do you believe Operation Warp Speed was a success?

A Yes.

Q Do you think anything should be done differently in a future pandemic, with regard to Operation Warp Speed?

A I am certainly on record saying that it has more to do with the clinical trial infrastructure. In fact, that we really don't have a sort of -- warm base for clinical trials in the United States. This was very evident for therapeutics. And there were hundreds and hundreds of trials that went on, I published on this, none of which were able to -- would yield any actionable data.

On the vaccine side, the companies ended up running the trials because they had the infrastructure to get that done, you know, with the help of the government and participation of government sites as well.

Q So you're saying we need a little bit more infrastructure on the therapeutic side to generate good data?

A On both sides. And I have certainly, as I said, published on this and been very vocal about it.

Q Thank you. We're going to talk a little bit more about authorizations and approvals. And just for the record, I think I can delineate EUA, I'll refer to as authorizations. And full biologics approval, I'll calls it approvals, if that's okay?

A Certainly.

Q Could you please explain the difference between an emergency authorization and the full biologics approval?

A EUAs were conceived as a way to get products out there before the entire general process had been conducted. The standard for an EUA is -- it's in the regulations. It's basically that the foreseeable benefits and so forth outweigh the expected harm.

And so that's a different standard, okay, than the safe and effective, what have you. Then there are other parts that can be conducted more quickly or perhaps executed more quickly, especially some of the bureaucratic parts, than a full -- you know, a licensed -- a biologic license.

Q So are pharmaceutical companies generally permitted to advertise for authorized products?

A Yes.

Q And they can promote them under an authorized status?

A That's my understanding.

Q Does an EUA necessitate informed consent from individuals?

A My understanding is it does not.

Q And could you explain a little bit about what that means?

A What what means, informed consent or --

Q Sure, let's start there. What is informed consent?

A Informed consent has turned into, in the United States, a very long legal document, right? That nobody can understand, practically. That -- but the principle behind it is that the individual has to understand the parameters. That what -- and typically, used in clinical trials, that people understand they're volunteering for an experiment. And that the outcome isn't known, and that's why they're doing the experiment.

And so that they can sign something that they were made aware of this, and not just given something and not known about it, right?

Q Right. So within the context of a COVID-19 vaccine under emergency use authorization, since it didn't necessitate informed consent, does that mean that individuals may not have been fully informed by their physicians about the potential risks?

A There were information sheets that were given that spelled out, to my understanding, both for therapeutics and for the vaccines, what the parameters were.

Q And that's called a fact sheet, from what I understand, in the EUA?

A Maybe.

Q As opposed to a package insert, is that what it's called, for a full approval?

A The package insert for full approval for a product that isn't a direct consumer product, is intended for the learned

intermediary, not for the -- there may be a patient sheet, which I fully endorse, that can be given to patients, or it might be the end of the package insert. But generally speaking, the package insert is intended for somebody with a very high degree of medical understanding.

Q Okay. But to be clear, the EUA vaccines had a document, but it was not a package insert; is that right?

A That's correct. To my understanding, there was information for prescribers, there was information for patients.

Q And my understanding, correct me if I'm wrong, is that package inserts are continually updated as the administration finds new information. Are fact sheets in the EUA, those are also continually updated?

A Yes.

Q Thank you. COVID-19 vaccines were very widely distributed first under EUA. Had that ever been done before?

A Not to my knowledge.

Q Do you know, and I understand if not, but do you have a rough understanding of how many doses were distributed or administered under EUA?

A I do not, no.

Q Is it fair to say that it was millions?

A Yes.

Q Once the license was approved and issued on August 23rd, 2021, to your knowledge, were the EUA doses pulled off the shelves?

A I do not recollect what happened with that. There was a

discussion about it.

BY MR. BENZINE:

Q Discussion between whom?

A Within the agency.

BY MR. SPECTRE.

Q To your knowledge, were the approved doses widely available quickly after approval?

A I do not recall.

Q And we'll dive into this a little bit more later, but just quickly, were COVID-19 vaccines approved more rapidly than normal?

Ms. Raveendran. To clarify the question, more rapidly than what?

BY MR. SPECTRE.

Q My understanding is when a BLA is submitted from a company, it's usually about a 12-month timeline for a vaccine. Is that about right?

A The approval of a product, whatever it might be, first of all, it's dictated partly by PDUFA, right, which it gives a ten-month timeframe for general approvals, and a shorter one for priority review.

The agency may decide -- the clinicians, in overseeing the file, may decide that due to the urgency of the need, an unmet medical need, that the product should be approved as quickly as possible, and may accelerate that further. And there are a number of examples, some of them biologics, obviously, that were gotten out much quicker.

Vaccines, typically, you know, take -- may have a priority review or a standard review, but given that they are a preventive

intervention, right, it's more likely they would have a standard review.

Q And just for clarity for the record, COVID-19 vaccines were under a priority review; is that accurate?

A I do not know.

Q Okay. Thank you. So to your recollection or knowledge, are authorized doses manufactured in facilities that are subject to the same FDA oversight as approved doses?

A Can you clarify the question?

Q Sure. When you were talking a little bit earlier about the FDA's role in development of vaccines, you talked a little bit about ensuring that each dose, that it is what it says it is, that it was manufactured properly, safely, all that.

Does the FDA have the same oversight of the facilities who are producing EUA authorized doses as it does oversight of fully approved dose manufacturing facilities?

A It's hard to respond to that question. There is no, like, rigorous algorithm about what the oversight might be. If the facility has been inspected recently for other reasons, and then is participating in some phase of the manufacture of a vaccine, for example, then the agency may decide not to look at that facility, whether it's for an emergency use authorization or for an approval.

So I honestly can't answer your question. I feel that the FDA oversight is what it needs to be at any given stage.

Q So to your knowledge, there is no difference between what

the FDA does to regulate facilities that are producing EUA vaccines, as opposed to what FDA does to regulate facilities that produce approved vaccines?

A There might be legal requirement differences. But scientifically, this is one thing I'm pretty much of an expert in, all right? You know, as far as the quality of the production, ensuring quality production, I think the oversight is very similar. However, there might be different legal requirements for a BLA than there might be for an EUA.

Q So there may be different legal -- there might be legal distinctions between the two, but in your view, they are on par, as far as safety?

A Well, for an EUA, that -- where you're planning to administer a product, whatever that product may be, to a large number of people, FDA wants to guarantee standard quality assurance., pharmaceutical quality. And so FDA will do what it needs to do to have that.

Q Thank you. And this will be my last question before we finish up this hour here. Do you think the government generally did a good job communicating what differences there may be between authorized and approved doses?

A I think it's very hard to communicate, as we have just been demonstrating, these differences.

Q Okay.

Mr. Spectre. Thank you very much. We can go off the record.

[Recess.]

[redacted]. We can go on the record.

BY [redacted].

Q Dr. Woodcock, good morning. Thank you for being here. My name is [redacted]. I am the Democratic staff director for the Select Subcommittee.

I would like to take a step back and ask you a few questions, some of which may be redundant. To the extent these questions are redundant, I would appreciate you providing a full answer. And I would like to begin by discussing the emergency use authorization process that the FDA follows for the consideration of vaccine products.

As an initial matter, would you mind just briefly walking us through the FDA's emergency use authorization process for vaccine products, including the circumstances under which FDA can issue EUAs?

A Well, certainly the FDA has to -- follows the regulations regarding emergency use authorizations. And these -- generally speaking, there will be an application for an emergency use authorization, it will be submitted to the agency. That will have the usual relevant information in it, or should, right, which would include manufacturing controls information, any other kinds of relevant safety toxicology information, clinical experience to date, rationale for using it -- using the product in an emergency.

Then the FDA will review this against the standards, okay, where foreseeable benefits -- and I'm very much paraphrasing the regulations. I am not a lawyer, and I can't remember all these things very well.

But where the foreseeable benefits outweigh the potential harms. And obviously, that also includes the pharmaceutical quality of the product and so forth in that package. And then we'll make a decision based on that.

And then that has to be forwarded. During that time, these emergency use -- during the time that you're referring to, 2021, these emergency use authorizations were signed off by the chief scientist of the agency, whose office -- so it would be signed off by the relevant center, and then reviewed by the chief scientist's office, who generally do a procedural review.

And that EUA approval would include the relevant documentation that would be given to patients, the fact sheets, or what have you, the other relevant information about the product, the rationale for the decision, and so forth.

There would be a whole package that would be put together. And then that product would be enabled to be used for an EUA until which time those conditions no longer applied. And of course, the EUAs were withdrawn by the agency as well.

Q So focusing on your scientific perspective, we'll set aside the legal sort of aspects for a moment. I was hoping you could offer me your view on the mechanisms that are in place through the EUA process to maximize consumer safety, specifically for vaccine products.

A Well, first of all, the agency has complete discretion on deciding to what extent they will verify or validate the pharmaceutical quality. So how many inspections they wish to do, whatever testing

they wish to do of the product, or require additional testing to be done.

That, for example, to mention another one, hydroxychloroquine that has been imported from somewhere in Asia and brought to the United States, full testing of that product was done before, for pharmaceutical quality before it would be put -- be made available. So that's an example.

With the vaccines, with the COVID vaccines, which I assume is what you're referring to here.

Q Sure.

A Okay. They had come -- been tested in very large clinical trials, larger than most vaccine programs -- development programs would have contemplated, right?

And so there was a tremendous amount of information on performance characteristics of these vaccines in the subjects in the trials. So that would be very carefully reviewed by the FDA, as well as ensuring by looking to pharmaceutical quality that the product that would be authorized under the EUA would be the same product that was tested within the clinical trials.

So that would give you an assurance of safety, as well as the efficacy from -- that was derived from clinical trials.

Q So you just mentioned, there was a tremendous amount of data that was produced relevant to the clinical trials. You also mentioned, I believe in the preceding hour, that there was a process by which known and potential benefits are weighed against known and

potential risks through the EUA process.

Can you share a little bit about how that process takes place, and specifically how it occurred for the COVID-19 vaccine EUAs?

A To my recollection -- and please remember, this is somewhat of a blur to me, because I was doing a very large number of things at once.

Q Okay.

A The agency had put forth standards which, as I already said in my prior discussion, that frequently do put standards for how effective -- how something should perform as far as effectiveness. So the agency had put forward an effectiveness standard, right, a threshold or bar that a vaccine should theoretically have, to be considered an effective vaccine, okay?

That threshold was quite well exceeded, to my recollection, by the various candidate vaccines that were tested in trials. Certainly the ones that received emergency use authorizations. And that is a typical process for all products as the agency puts out guidance for information about what standard should be met, and that was the standard for efficacy, okay?

So that -- to my recollection, that standard was well exceeded by the vaccines, as far as preventing infection and different things like that, things that were tested in the trial.

The safety evaluation is more a judgment call. However, as I said, these vaccines had had far more human exposure than most any products that FDA typically would approve. I think many, many, many

years ago, under -- it wasn't called EUA at the time, it was called compassionate use, there were -- for a cardiovascular drug, I think there were tens of thousands of people who got that drug before approval. That was many, many decades ago, okay?

But again, that's a huge amount of human experience, relevant, safety experience, but it wasn't in trial, whereas these vaccines were tested in trial, whereby there was a systematic collection of safety information and comparison groups -- randomized comparison groups for safety.

So that information, I think, would far exceed almost any package -- any approval package that the agency would get normally, as far as human experience. And that information was thoroughly reviewed prior to granting an EUA.

Q Taking a step back, just on to the efficacy and effectiveness side. In epidemiology, those are distinct terms. Just to clarify, when you say efficacy and effectiveness, are you using them synonymously or like a breakdown of the epidemiologic concepts?

A Right. I am using it with respect to the Food, Drug, and Cosmetics Act, the statutory standard which calls for safety and effectiveness. Now, granted that was passed in 1962, and they didn't probably, the lawmakers, appreciate these distinctions. And many people -- agencies use that terminology routinely, safe and effective.

Now, I am fully aware of the distinctions that are made, but let's just talk about what the primary end point was. That's what FDA considered effectiveness, right? And those exceeded -- those vaccines

all exceeded the threshold that had been set by the agency for that performance, okay? And so they had met that threshold.

Q And of course, as it relates to evaluating the efficacy or effectiveness of a product, there are some limitations by which that can occur. For example, from a temporal standpoint, if there were certain variants of COVID-19 in place at the time, that is the metric by which you are measuring effectiveness or efficacy -- the benchmark by which you are measuring effectiveness and efficacy. New variants, for example, are not something that can be immediately considered discretely through existing processes because they, in fact, do not exist yet; is that correct?

A That's correct.

Q Continuing in the same vein, relating to the EUA process as a whole for vaccine products, to the extent you would like to comment specifically on COVID-19 vaccines, that is welcome.

What mechanisms are in place to insulate the emergency use authorization product -- process for vaccine products from political interference?

A If I may step back. Generally speaking, one of the roles of the senior management of the agency is to insulate the professional review staff from any type of outside influence. The agency is lobbied all the time by patient groups, by industry, by advocacy groups, who have one position or another on a very wide variety of different topics. And the goal is to allow staff to conduct their reviews without considering -- without being subject to those kind of

pressures.

Q So then as the acting FDA Commissioner at the time, as an expert on these matters, do you feel that consumers should feel confident in the safety of products that are authorized under emergency use, even if they have not gone through the full approval process of the FDA?

A Yes.

Q Would you like to elaborate on that any more or --

A As I said earlier, the FDA tries to ensure that those products, as well as they do for an approval -- approved product, that any product under an EUA might be fit for its purpose. In other words, its benefits -- its foreseeable and known benefits outweigh its known and foreseeable risks, and it's appropriate. This is basically medical judgment that FDA makes every day with all the products it regulates.

Q Of course. So as I understand it, based on the regulations you're referencing, the laws that govern the operation of the Food and Drug Administration, it is necessary for the Secretary of Health and Human Services to declare that circumstances are necessary, justifying use of emergency use authorization for products; is that correct?

A That's my understanding.

Q For the COVID-19 vaccine products, would you be able to remind me at what point the Secretary of Health and Human Services declared that there were circumstances that existed justifying the EUA process for COVID-19 vaccines?

A No, I can't recall that.

Q Okay. As I understand it, there was a February 4th, 2020 declaration from Secretary Azar that took effect March 27, 2020. Does that sound roughly correct to you?

A It does.

Q And so then just to clarify, it was actually the former administration's Secretary of Health and Human Services, President Trump's HHS Secretary, Dr. Azar, who declared that circumstances were appropriate for an EUA to be considered for COVID-19 vaccines; is that correct?

A That's my understanding, yes.

Q And just taking us back to February or March of 2020, sort of that late winter, early spring 2020 period, could you remind us what circumstances were like for our society and for public health in that early point in the COVID-19 outbreak?

Mr. Cooke. Sorry. Just as a reminder, as we talked about with your colleagues, at this point, Dr. Woodcock didn't have a decisionmaking role with respect to the approval process. So this is speaking as a general scientist.

[redacted]. Of course. Thank you.

The Witness. Well, during that time, there were outbreaks in large cities such as New York. There were huge number of fatalities. The hospitals were overwhelmed in certain areas. That was definitely a crisis, a medical crisis situation.

BY [redacted].

Q And that point in time, am I correct that the options we had to go prevent and also treat COVID-19 were severely limited?

A That is correct.

Q So the Pfizer booster was authorized in 2021, as I understand. Am I correct in my interpretation that that emergency use authorization occurred under an amendment to the EUA that was issued during the previous administration by Secretary Azar?

A I believe that is the case.

Q And similar question, again, sort of late summer, early fall of 2021, could you remind us of the circumstances that we, as a society, were navigating vis-a-vis the COVID-19 pandemic at the time when FDA was evaluating booster products for emergency use authorization?

A Well, scientifically, the pandemic had gone through several different stages. There were various variants that came and went. And the concern was that with waning immunity, which we knew was the case from -- waning immunity either from infection with COVID or actually being vaccinated with the regimen, the neutralizing titers were dropping across the population, particularly as you get older, with the older people.

And the concern -- and if you get a variant, then the neutralizing titers which may have been more effective against the original strain it was raised against would be even less effective against a variant, and then with remaining titers even less effective.

And this is a situation we see with a number of types of

immunizations and viruses that tend to undergo a lot of mutations. The virus is circulating broadly all over the world, and therefore, lots of variants were coming up. They were scary. Sometimes they would go back down again. There was concern that a more infectious and potentially more virulent variant would occur, and we would be faced with a population with waning immunity.

Q And as you alluded to earlier, the emergence of new variants in the COVID-19 pandemic and other public health circumstances oftentimes merits the updating of products or the release of new products to maintain current levels of protection for populations; is that correct?

A Yes. When I started as Acting Commissioner, I had all three centers -- I called for scenario planning, which we did. And we went through various scenarios that might occur. You know, perhaps the virus would just sort of go away, perhaps we get variants to which we were not protected against, and so forth. And we did that.

And then we also issued guidance for diagnostics, because you could get a variant that wouldn't be detected with current diagnostics, okay?

If it's a PCR, the primer pairs wouldn't be correct. If it's a monoclonal, it maybe wouldn't be grabbing on to the right, you know, virus because the virus had changed.

So we said what we would do in those situations with the diagnostics. We issued what we would do with the therapeutics. And indeed, we had to withdraw, if you recall, a number of the monoclonal

antibodies because they no longer were effective. But what we did is we published that and told everybody what would happen under different scenarios.

The same with the vaccines. We said how we would try to pick -- and you know, we put this out there scientifically to get input in the discussion. How we would try to pick a booster, or whatever you want to call it, to kind of forecast if there was a rise in a variant that wasn't well covered by current vaccination. However, the background was that titers were falling for everybody.

Q And so focusing specifically on the data that Pfizer submitted to FDA for the emergency use authorization and evaluation of its booster product, did that data, from your scientific perspective, demonstrate that the booster product that Pfizer had proposed was both safe and effective?

A Yes.

Q I would like to ask you a similar set of questions as it relates to the approval process that's in place. So full BLA approval. Briefly, again, would you just be able to quickly walk us through the approval process that is in place for vaccine products at the Food and Drug Administration?

A It's hard to be brief.

Q Fair.

A The companies must submit -- and for a long time, we have standardized a lot of this under the ICH, International Council for Harmonization of, you know, medicines. They have to submit a very

large application that has multiple sections. There's a section on manufacturing and how they control the product, and how its quality is maintained. A toxicology section, clinical and statistical.

There's information on all the facilities where the product, or parts of the product could be manufactured and their status and their role and so forth. And they submit a draft label or package insert. That is the technical term for that, so they submit a draft package insert.

Generally speaking, once that's submitted, you know, the agency holds a meeting or series of meetings to develop a rigorous plan. And as I said earlier, that will include what has to be reviewed, who -- which experts should review each part, when those parts should be completed.

For example, if inspections are needed, when the inspections would be done. Some of them might be all around the globe. Then when could the reports be back. And then when could all the information be synthesized.

There's also post-market commitments. For example, if there are adverse events you're concerned about, you'll want to develop a plan for monitoring them afterwards, and have the company commit to that. There's also often a plan for younger age groups called the pediatric plan that has to do with the Best Pharmaceuticals for Children Act, and so forth.

So all these things, it's too complicated for a person just to do in the back of their brain. They -- you know, a project plan should be

created, typically, and charts and so forth. All this information would be put together. So a huge cadre of experts would be recruited and assigned different parts of the work. And then when those people all come together, and this whole thing comes together, and then you have a proposed or best guess date for completion.

Q So as part of the robust process you just described, it sounds as though there are mechanisms in place to maximize consumer safety, again, that are built into this FDA approval process for vaccine products. Could you elaborate on those mechanisms to maximize consumer safety?

A Certainly. Well, there would be -- and particularly with the vaccines, since there was emergency use authorization, a separate group would look at the safety information. That would be, like, the post-market group would be looking at all the safety information that was submitted from spontaneous reports or from the company, from the experience of tens of thousands of individuals who had received the product under an emergency use authorization.

That would be separate from the group that, again, would look at -- and of course, that had already been reviewed, the clinical trial safety data. But those two data sets need to be put together to learn anything new from this broad exposure of people. And if so, what? And how does that modify our safety assessment?

And then there would be supervisors of all these folks who, at various points during this review process, would review and sign off on the safety findings.

Q Am I correct in my understanding that that process you just described was the process that was followed for Pfizer's COVID-19 primary series vaccine product?

A To my knowledge, yes.

Q And in the process you just described, again, similar question, what mechanisms are in place to insulate that approval process from political interference?

A FDA's regulations state that a person should sign their part of their review. A number of years ago, I tried to get a combined review done, so that everybody worked together better. And one of the difficult parts was getting -- how could people sign off on combined review.

So people -- what the regulations say is, when you sign as a scientist, you're signing that you concur, right? That you -- that's your work and you agree with it, right? Not that you were pressured into it or whatever. People can write dissenting memos, and we have that ability and a process for dissent on approvals, and so forth.

And as I said, the review staff themselves are not exposed to any pressures, like, from the advocacy groups or whatever, generally, directly. That would be taken by the center directors or Commissioner's staff, and so forth.

Q So as the acting FDA Commissioner at the time, did you have any concern that the mechanisms that you described to maximize consumer safety, as well as the mechanisms to insulate approvals from political interference, were insufficient or ineffective when the

Pfizer COVID-19's BLA was being considered?

A When I heard about the issues related to the review, I was concerned that the staff, Marion and her people, could not immediately cough up a very detailed Gantt chart about what they were doing.

And I had raised several times that this is a complicated review with all this EUA safety data, and suggested that they take some resources from CDER, computational science people, and also pediatric cardiology to look at myocarditis, and how that would be followed over time.

Because I feel like I -- I felt that pediatric cardiology was the correct discipline to evaluate adolescent myocarditis, right, and sequelae -- potential sequelae, if any, of that.

So when Dr. Marks talked to me about the review, I repeatedly raised these issues. Otherwise, I feel like, you know, a very thorough and complete assessment was being conducted.

Q So at the end of the day, and I imagine there will be subsequent questions related to the discrete evidence you discussed, but the processes that were in place, the mechanisms that were in place to maximize consumer safety, to insulate the approval process, the BLA for the COVID-19 vaccine from political interference resulted in a product that you felt was safe and effective?

A Absolutely.

Q I would also like to shift gears slightly, and now look at sort of the back end of what occurs when products have been deployed

to market. And specifically, the process that is in place for evaluating and acting in response to vaccine-related adverse events.

Am I correct that FDA's role in this process is informed by data that is generated from multi-tiered surveillance systems that are operated both by the Food and Drug Administration and the CDC?

A Yes.

Q So when signals of adverse events are detected through these surveillance systems, what actions does the FDA take in response?

A Well, first of all, technically, a signal is just a signal. It doesn't necessarily mean causal relationship. So there are multiple -- and these signals may arise from reporting. In other words, a clinician or a patient may report an adverse experience to the agency. And that's encouraged. Or CDC may, from their surveillance systems, they may see some imbalance or signal, okay? It doesn't mean it's related, causally related.

So what happens is a workup of that, to evaluate whether or not there is a link. And the Center for Biologics have established the BEST system -- BEST medical records-based system where they can do signal evaluation, and they can see if they can find it anywhere.

They also -- as I said, the CDC has a smaller number of people, but they have active surveillance. And the FDA has access to, say, the Medicare database. They have access and cooperate with the international authorities who have hundreds of millions of experiences also.

And if I dare say so, they have better acquisition of

information, because their health care system is not as fragmented as in the United States. So those groups that have national health care systems have pretty full data on people, and the FDA has access to that.

So what happens when a signal arises either from a drug or vaccine, or whatever, is this type of look is done across all these databases to see if the signal is actually related.

Q And so to be clear, it is your view that the federal government does have in place a comprehensive, robust, multi-tiered system to evaluate and determine signals and trends of potential vaccine-related adverse events; is that correct?

A Yes.

Q And these systems were operating to detect possible signals or trends of adverse events for Pfizer's COVID-19 vaccine products; is that correct?

A Oh, yes.

Q Did these systems generate any data that warranted concern for you sufficient to remove these vaccine products from the market?

A No.

Q And what role, in your estimation, does continued comprehensive investment in these surveillance systems have to ensure that only the safest products are available to American consumers?

A These are -- the systems are critical. I built the first FAERS, FDA Adverse Event Reporting System, in the '90s. Subsequently,

we also built an active surveillance system for CDER. And BEST is the sort of echo of that for the vaccines, okay?

So these are critical, and it's critical for us to use the electronic health record data and all digital data to try to follow up all regulated products and make sure their performance characteristics stay positive for the country.

Q And to be clear, when there are instances of adverse events, signals, or trends that are detected, that warrant or sort of merit the removal of a product from the market, FDA would act to do so; is that correct?

A Correct.

Q And just to put a finer point on that, that did not occur with Pfizer's COVID-19 products?

A That's correct.

[redacted] We can go off the record.

[Recess.]

Mr. Spectre. Back on the record.

BY MR. SPECTRE.

Q We finished talking a little bit about authorized versus approved doses at the end of our last hour, but I am going to switch a little bit now to some questions about the general public's understanding of sort of these complicated issues we're talking about today.

First, do COVID-19 vaccines prevent the spread of the virus?

A Most likely, to some extent.

Q But not entirely?

A Not entirely.

Q Do COVID-19 vaccines prevent illness?

A Yes.

Q Were COVID-19 vaccines designed to prevent transmission?

Mr. Cooke. If you know.

The Witness. I don't understand the question. Technically speaking, you try to get the immune system to eradicate the virus and prevent its replication, right? So vaccines are designed to prevent transmission, to some extent.

However, different viruses, depending on their mode of transmission, whether they're respiratory -- like, for example, norovirus, okay, you can get norovirus on a cruise and you can get it again six to eight weeks later, okay? Lovely thought, huh? And that's because it's intestinal. You need intestinal immunity.

So the answer to the question is, yes, vaccines are designed, in my opinion, to prevent transmission, but you don't normally succeed in everything. In fact, during development, you often don't succeed.

Q And specifically within COVID-19 vaccines, were those clinical trials designed to assess whether the vaccine was preventing the spread of the illness?

A To my understanding, the primary end point was to prevent illness.

Q Rather than --

A Correct.

Q -- spread?

A Mm-hmm.

Q Was the FDA's issuance of EUAs for COVID-19 vaccines dependent on that vaccine's ability to prevent the spread?

A No.

Q Similarly, were the biologics licenses for COVID-19 vaccines dependent on the vaccine's ability to prevent the spread?

A No.

Q Thank you. Moving on a little bit now. Sort of the last hour covered some of the questions I had in this section, so I think we can be brief. I won't introduce the document unless that's easier, but the first FDA emergency use authorization for a COVID-19 vaccine was on December 11th, 2020. Is that accurate?

A To my knowledge. I was not at the agency at that time.

Q That's right. So you played no direct role in the consideration or authorization of that EUA?

A That is correct.

Q You mentioned during the last hour that within the FDA, the evaluation of the safety side of the equation is somewhat of a judgment call, I think was how you phrased it. Whose judgment is it to make that call?

A It is the generally combined judgment of the clinical staff of the agency, the medical people looking at frequency, severity of adverse events, and weighing that against the benefits.

Q So when you say the clinical staff, would that be

Dr. Gruber and her team, or someone --

A The clinical side, correct, of that.

Q Okay.

A As well as the center directors also play a role.

Q So who has the final decisionmaking authority on any EUA? Is it somebody within the Office of Vaccines?

A At the time, the final decisionmaking authority was the chief scientist of the FDA, who signed off, finally signed off on the EUAs.

Q Thank you. I'll move a little bit to the full approval. The minority covered some of these. I'll try not to double efforts too much here, but forgive me if that happens a little bit.

Do you recall when the first biologics license application was submitted for a COVID-19 vaccine, roughly?

A No.

Q Does about May 2021 sound about right?

A Yes.

Q And we touched on this a little bit earlier, but how long does the entire process take under normal circumstances usually? When would the action due date typically be targeted for if the application was sent in May?

A As I said, I think at the time of the PDUFA agreements, the agency agreed that most standard applications would be completed in eight months or ten months, and six months for priority. That's what I recall.

Q And I think that might include, and correct me if I'm wrong, two months on the front end for, like, the rolling application. Does that sound right? Is it ten months, total, but eight months with the two months at the beginning?

A I don't recall. This has changed multiple times with the different PDUFA negotiations, but that's in the ballpark.

Q I understand. So COVID-19 vaccines were under accelerated approval. So my understanding, if you look at some of the documents, the initial action deadline -- action due date, ADD, appeared to be January 2022. But is it accurate to say that there was a general understanding that that was too late?

A First of all, accelerated approval as a technical term doesn't apply here, okay? So you might say they were -- made the review faster.

Q Priority review, is that more accurate?

A They were -- to my understanding, they were under priority review, all right?

Q Thank you.

A Can you rephrase the rest of your question?

Q Yes. So under typical priority review, if the application was submitted in May, that was supposed to land the action due date sometime around January of the next year.

A Okay. As I said earlier, those are the user fee due dates that are agreed to by the agency to meet as a target. So the agency said, we'll meet 90 percent of the standard, I think. Again,

this has changed, those percentages, over time.

And we agreed to try to meet 90 percent of the priority reviews within that timeframe, all right? Where there are medical circumstances, the urgency, the agency will review products faster, especially if they have a huge impact. For example, cystic fibrosis drugs, where people with cystic fibrosis die in their 20s and they get very sick in their teens and so forth.

These were life-changing and they were -- I think the first one we might have reviewed in six weeks, I'm not sure about that, is Gleevec. If you recall Gleevec, that was 20 years ago, but it was a game changer for chronic myelogenous leukemia, and some other, and that was reviewed very quick. So it depends on the circumstances.

Those dates that you're talking about are what are agreed to under the user fee agreements with the industry and with Congress.

Q I understand. So with that context in mind, when -- around May or June of 2021 -- 2021, when, to the best of your recollection, was the FDA's target date to finish the review of Pfizer's BLA?

A Again, I'm sorry, I can't remember that.

Q I understand. I'll try to use the word priority. Do priority reviews have different standards than typical reviews?

A No.

Q So how is the priority or the accelerated timeline achieved typically?

A It will differ, depending on the circumstances. More

staff can be put on the review, so that the pieces can be done more quickly on a different basis.

Very frequently the agency will have known about the findings from the trial well before the filing, and so they will have reviewed pieces in advance and much of the work could be done in advance before the actual application comes in. This is very typical.

When, say, Gleevec or some trial result like that, some incredibly life-changing result occurs, then everyone knows. And start talking -- the staff will start talking to the company about, what can you send us now? What can we get done? So that when the application comes in, we just have to do a label and final safety review, and so forth.

Q That makes sense. So my understanding is that some of the data that the FDA may, or likely does request from a pharmaceutical company is follow-up data after the vaccine's been administered. Is that true, safety data?

A Absolutely.

Q Does a priority review change the length of time of follow-up that is able to be collected, as far as data?

A Again, this is very particular to whatever the application is. For the COVID vaccines, they had been given to an unprecedented number of people for a very -- since the time you mentioned the EUA for that particular vaccine had been granted, there had been a huge amount of exposure.

There were spontaneous report and other surveillance data, safety

data coming in all along. And of course, the agency would be looking at that all along.

Now, for 50 years -- well, since PDUFA was passed, okay, the left wing has been saying, oh, you're reviewing things too fast, right, and therefore, they're not safe anymore.

And I will tell you, it has been profoundly irritating to me, okay? The real issue is how competent the review is. And frankly, some of our older medical officers, I had intervened in this a long time ago. It would take them months to go through a data file because they were geezers, like me, okay?

An 18-year-old could have looked at this in two days, and had a much more comprehensive understanding that this person who had never used a dataset before, you know, is trying to do an analysis on. So it's more technical competence, in my very experienced opinion, than it is speed.

To answer your question, though, of course, the longer you wait, the more experience you accumulate. The question is, how much experience do you need to make a conclusion.

Q Thank you. Again, we touched --

A And my apologies if the left wing is in the room.

Q We may have touched on this a little bit. But is it fair to say, it is the Office of Vaccines that leads review of a BLA, is that accurate? Does the Office of Vaccines lead the review of the BLA?

A Yes.

Q And I sort of asked this about the EUAs, but who has the

final decisionmaking authority on BLA?

A My understanding that that signatory at the time, because this has to do with the delegations of authority within the agency, that signatory was the office director in the Office of Vaccines.

Q Thank you. Did you play any role in the decision to approve the Pfizer BLA?

Ms. Raveendran. Do you need a clarification of the question?

The Witness. It's complicated. I did not play a direct role in deciding if, scientifically, it was ready, okay? What I did was ask that certain -- make sure certain experts were involved in the review process.

BY MR. SPECTRE.

Q Thank you.

A That was my contribution to it.

Q So it's fair to say you didn't provide any scientific expertise, it was more directing the employees on how to do that scientific valuation?

A Mm-hmm. That's correct.

Q Maybe I'll just be a little more specific. I think we touched on this at the very beginning, went through a list of names. But did you communicate with any federal government entities regarding the Pfizer BLA for COVID-19 vaccine prior to it being issued?

Mr. Cooke. If it's a yes or no question, did you communicate with anyone?

The Witness. Yes.

BY MR. SPECTRE.

Q Did you communicate with anyone at the Department of Defense prior to the BLA being issued regarding the BLA?

A No.

Q The same question for the White House. Did you communicate with anybody at the White House regarding the Pfizer BLA prior to being issued?

Mr. Cooke. Again, if it's just --

Mr. Osterhues. A yes or no question.

Mr. Cooke. The topic, that it wasn't discussed, then you can answer.

The Witness. Yes.

BY MR. SPECTRE.

Q Did you discuss with the White House the expected ADD as it evolved over time for the Pfizer BLA?

Mr. Cooke. Now we're getting more into the substance, and at that point, we're not going to be able to answer.

Mr. Spectre. You're instructing the witness not to answer?

Mr. Cooke. Yes.

Mr. Spectre. Thank you.

BY MR. SPECTRE.

Q So we talked about these names a little bit earlier, but Dr. Philip Krause and Dr. Marion Gruber, who are they?

A Marion Gruber was the head of the Office of Vaccine, Dr. Krause was her deputy.

Q Do you recall Dr. Krause or Dr. Gruber raising any concerns with the pace that the FDA was taking regarding the review of the Pfizer BLA?

A Yes. I was told of that by Dr. Marks and I spoke to them directly.

[Majority Exhibit No. 1 was identified for the record.]

BY MR. SPECTRE.

Q I'm going to introduce Majority Exhibit 1. This is an email sent on July 8 from Dr. Marks to Dr. Gruber. It's just one piece of paper, so you can take one and pass it along.

A I see. I was worried how thick that was.

Q Have you seen this email before? I'll give you a second to look at it.

A I don't know.

Q You are not on the email, so you may not have.

A Possibly I saw this before. I don't know.

Q So if you look sort of in the middle of that paragraph, Dr. Marks writes, "I need to be able to demonstrate to Janet that we are diligently pursuing the process, and this would be very helpful."

Is it fair to say that Janet would be you, Dr. Woodcock?

A That's correct.

Q What do you think Dr. Marks means here?

A Well, I was interrogating him on the process of the review, what experts -- I knew there was a very large amount of

post-market data, a very large safety database. We had this pediatric cardiology concern, and I wanted to see the project plan for completing the review, who was on there.

My goal partly is to help usually in, for example -- like in some other parts of the agency during my tenure, I brought other people in to assist and get things done. I wanted to make sure. This is a small office in CBER, I wanted to make sure they were adequately staffing this and they had enough people and so forth.

Q Did you direct Dr. Marks to accelerate the review of the BLA?

A I did not.

Q As of this email on July 8, 2021, do you recall when the ADD would be?

A I do not.

Q Is it fair to say Dr. Marks says, I need to be able to -- excuse me.

In the previous sentence, Dr. Marks writes, "Regarding the Pfizer review timeline, by early next week, would it be possible to get a high level listing of review activities sorted by week over the course over next two and a half months."

Is it fair to say that he is indicating here, and there are some other documents that show this data as well, that there was a September 15th ADD that came along at some point, is it fair to say that's what Dr. Marks is referring to there?

A I don't know.

Q Thank you. At this point, do you recall any conversations about moving the ADD earlier than January 2022?

A I recall that the center told me that they would likely get this done in the early fall.

Q Early fall?

A Mm-hmm.

Q But you don't remember any specific dates?

A Well, based on at this point, no. Based on later discussions.

Q That's fair, thank you. I would like to introduce Majority Exhibit 2. This is a much longer email chain, a couple different email chains, there's some forwarding happening within it. So I'll pass this around as well.

[Majority Exhibit No. 2 was identified for the record.]

BY MR. SPECTRE.

Q I'll tell you which pages we're referring to at each time here.

Mr. Cooke. There's a lot here, so we want to be sure she has a chance to get a sense of what she's looking at.

Mr. Spectre. Absolutely. And each question will likely refer to a very, very small section of these emails. I will point you to those.

BY MR. SPECTRE.

Q First, if you could flip to the page marked SSCPVaccine000069. So that should be an email that Dr. Marks forwarded

to you on Thursday, July 15th, around 10:00 a.m. I will give you a second to look at that.

Do you recall this email?

A I do not. But I get -- at the time, I was getting hundreds and hundreds of emails every day.

Q Absolutely. Well, I will read a part of it here. "Dear Janet, Perhaps we can have a brief call tomorrow? I can fill you in on the conversation that I had with Marion and Phil subsequent to their sending me this document. I have asked them to provide me with a timeline of milestones, and they are meeting with the review team today to be able to do so tomorrow morning. That said, they are intransigent at this time on the September 15 date."

So firstly, do you recall having a phone call with Dr. Marks as he suggests --

A I do.

Q -- happened in this email?

A Yes.

Q And do you recall talking about concerns from Dr. Gruber and Dr. Krause regarding the timeline on that call?

Mr. Cooke. So we have something of a reflection of what would have been discussed on the call. But to the extent you're asking for something beyond the document, I would have to draw the line here.

Mr. Spectre. You're instructing the witness not to answer the question?

Mr. Osterhues. What privilege is being asserted?

Mr. Cooke. As I mentioned, these are deliberative conversations in which the Executive Branch has a confidentiality interest.

Mr. Osterhues. So what do you think are the deliberative nature of these conversations?

Mr. Cooke. I think it's fairly clear, this is about deliberations regarding the BLA, and in any event, we're here voluntarily.

Mr. Osterhues. Is it about recommendations on policy?

Mr. Cooke. Look, I'm not going to sit here and litigate this issue. But to the extent we're getting into the details of deliberative conversations, we're not going to get into that here. But, look, ask the question and we can see if we can answer it, but I just want to put that on the record, to the extent we're getting into the details of deliberations of the documents, we're not going to get into those here.

Mr. Spectre. Just for the record, you're instructing the witness not to answer the question?

Mr. Cooke. Why don't you ask the question again? Sorry.

BY MR. SPECTRE.

Q So on the call that -- you just testified that you had a call with Dr. Marks following this email, did you discuss concerns from Dr. Gruber and Dr. Krause about moving the ADD?

Mr. Cooke. Yes, so if you can answer by reference to this document and the attachment, I think that's fine. But anything beyond that, I direct you not to answer.

The Witness. Okay.

Yes, we discussed that. My concern was not about the timing of the -- as I've already said, about the timing of the action, but about the fact that they had not produced the Gantt chart. This is supposedly a complex BLA. You need to have a project plan, a whole project management sheet.

And I could have seen who was on there, how many people were staffing this part of the application, who was doing that. I was particularly concerned about the clinical review and that there was the appropriate and adequate staff on that.

So that was most of the conversation I had with Peter, although he reported on, he felt that all the action -- all the activities could be completed in a certain timeline.

BY MR. SPECTRE.

Q You already testified earlier that you had not instructed anyone to accelerate the review. But did Dr. Marks tell you that he had instructed them to accelerate the review?

Mr. Cooke. Again, if it's not reflected here, we're not going to be able to go --

Mr. Spectre. In the email, I will point you to the part where he says they are intransigent at this time on the September 15th date.

BY MR. SPECTRE.

Q I don't see the word intransigent very often, but my understanding of that is that Dr. Krause and Dr. Gruber told Dr. Marks that they were unwilling to move on the September 15th deadline.

Is it fair to say just looking at this email that Dr. Marks is indicating that he had asked them to move the date earlier?

A Yes, I believe this came up in the context of Marion saying she was going to take a month off and go to different country, and you know, attend family matters, which was totally appropriate. But that would remove the senior clinician from this activity.

Q So the potential moving of the deadline was, in your view, related to Dr. Gruber's leave that she may be taking?

A I was not in a position to know that. However, I was concerned that I did not have in hand a project plan and a Gantt chart on how this was going to be done. And, yes, having one of the principal leads -- the lead person be absent during the review process is always very disruptive to an application.

Q Before this email, were you aware that anyone had concerns about the approval timeline? The date of the email is July 15th.

A July 15th. Not to my knowledge.

Q Okay. So in the same exhibit, if you flip to the page ending with 74.

A Mm-hmm.

Q This is an email from Dr. Marks to a Deirdre Hussey. Do you know who Deirdre Hussey is?

A I do.

Q What is her position, if you can recall specifically?

A She is the -- she was the executive officer of CBER.

Q Is she someone that would be in charge of HR issues for CBER?

A HR is a centralized function. She would be someone who would be assisting in that -- potentially in HR matters.

Q Okay. So if we look at the email, and I will give you a second to read the whole thing. I won't read the whole thing into the record here. But at the beginning, Dr. Marks says, "Dear Deirdre, I am copying this to you because I think that it is important to document that despite repeated verbal attempts, and as documented in the attached email, I have asked Marion for a timeline that would help justify the September 15 data that she provides for completion of the review."

Why do you think Dr. Marks might be documenting his interactions with Dr. Gruber to someone who works with HR?

A Well, first of all, Deirdre does not work in HR. She was exec officer. It’s an administrative position. I do not know why Dr. Marks would do that.

Q By this point, and this email is July 16, 2021, to the best of your recollection, had the idea of relieving Dr. Gruber and Dr. Krause of their duties been discussed?

A I can't recall.

Q To reiterate, was Dr. Marks pressuring Dr. Gruber and Dr. Krause to accelerate the deadline?

A My understanding is that Dr. Marks' professional opinion -- and he's a very accomplished scientist with industry

experience, as well as deep regulatory experience. He believed that activities could be accomplished more quickly, and he was seeking the Gantt chart or the timeline that the Vaccine Office had to understand why they thought it would take longer.

Q You mentioned a little earlier that one of the roles -- in the last hour when the Democrats were asking questions, one of the roles of the senior FDA leadership is to insulate FDA reviewers, staff, from political pressure.

A Mm-hmm.

Q Would that duty also fall to someone like Dr. Marks?

A Yes.

Q As far as you are aware, was Dr. Marks pressured by anybody? You said not yourself. But are you aware of any pressure that may have been exerted on Dr. Marks to accelerate the timeline?

A I do not, no. Dr. Marks told me that, in his professional opinion, this could be completed more expeditiously with the appropriate plan and oversight.

Q Was anybody pressuring you to accelerate the deadline, even if you hadn't passed that pressure along?

A No.

Q So it's a little confusing, because I think later on in the chain, as earlier on in document -- let me confirm that I have the right number for you here. So on the page ending in 58.

A If I could make a slight amendment to my previous statement.

Q Absolutely.

A Members of the public wrote me, many of them, about many things, including that I would be tried at Nuremburg for being involved in the vaccine. But many of them said that they wanted an approved vaccine before they would take vaccination.

So some of them said they would not take an mRNA vaccine, but they only wanted an approved vaccine and that we had to approve one of the other vaccines quickly.

So to be totally correct in my answer, yes, there were people writing me and trying to call me and so forth saying, we have got to have an approval because I won't -- my family won't take the vaccine unless it's approved -- a vaccine unless it's approved by FDA. So sorry for that.

Mr. Osterhues. That's helpful.

The Witness. You asked me if anybody. Not if anybody political, you asked me anybody. Well, yeah, there were members of the public who were very torqued about this and there was a whole campaign about younger children. People wrote in. There were many campaigns, pro and con, the whole time. So there was a flood of groups and individuals advocating on the outside for various positions.

BY MR. SPECTRE.

Q Thank you for the clarity on that.

A Yeah.

Q So I think it's perfectly understandable that you were receiving pressure from the public, and you've already testified that

you didn't pass that pressure along to Dr. Marks or to any of the employees; is that correct?

A That is correct.

Q Do you think that they probably felt similar pressures?

A I'm sure Dr. Marks got emails, because he was one of the faces of the agency in this regard. But we always, also got, as I said, we got all kinds of accusations, that we were criminals and so forth as well. So that was on the other side.

Q Thank you. So as I mentioned, this email I'm going to reference now is on the page ending in 58, which is a little confusing, later on in the same chain.

So it appears to be you responding to Dr. Marks, that email where he mentioned that Dr. Gruber and Krause were intransigent on the September 15th date.

You replied about an hour later and said, "Well, they seem open to additional support on other vaccine efforts, and are already working with CDER Office of Computational Science, which is a good thing. Peter, you can find out more when you take over. JW."

A Mm-hmm.

Q I think you mentioned earlier sort of the computational science resources that you were hoping to reallocate from CDER to CBER. Is that what you were talking about there?

A That's what I was talking about.

Q And you said, "Peter, you can find out more when you take over." Are you referring to Dr. Marks taking over the review from

Dr. Gruber?

A Yes, I believe I was.

Q So is it fair to say that --

A July 16th.

Q By July 16th, you had decided that Dr. Marks would be taking over?

A That's fair.

Q Did you talk about that on the call we were discussing a little bit earlier? Is it possible that's when you told Dr. Marks he would be taking over for Dr. Gruber?

A I don't know.

Q So you don't recall exactly when you told Dr. Marks?

A Clearly within this timeframe.

Q Did you make that decision on your own?

A Yes.

Q And did Dr. Marks request that, or was it your idea?

A It was my idea.

Q And you made it unilaterally? No one else was involved in that decision?

A I was the person responsible.

Q Thank you. Could you explain why? You said earlier Dr. Krause was Dr. Gruber's deputy. Why didn't Dr. Krause take over?

A Several reasons. Number one, they had made quite an issue, and I think it was true they had multiple other vaccines under review at various stages, including other COVID vaccines.

So the office was very busy at that time. My experience is that at the very end of a review cycle, especially if you have to transition from one lead to another, it's a very tense time. So I thought the Vaccine Office should keep going and get all this work done, and Peter, who is very involved in this and was very aware of everything, would be the best person to get this one over the finish line.

I was also concerned that they weren't bringing all the appropriate resources to bear. And it's very concerning here that Peter said that he is trying to get a Gantt chart together. Why didn't they have one? You should have all that laid out.

I mean, CDER had hundreds of applications at one time. Every single one of them, you know who was working on each piece, when that deliverable was expected, and how it was supposed to come together at the end.

And here you have this extraordinarily complex application because of all the people who had been exposed because of the EUA and so forth. And I was just concerned that it didn't have the appropriate resources put against it. And I talked to Peter about that.

BY MR. OSTERHUES.

Q Just to clarify, because toward the beginning of your answer there, you said they weren't bringing the appropriate resources to bear. So is it CDER?

A No, no.

Q Who?

A The review committee.

Q I'm sorry. Thank you.

A Yeah, I was concerned that, and I had been for -- since I heard about the status of this review. You said it was submitted in May?

Q Yes.

A So this was July. So all of that should have been in place, and, you know, pediatric cardiology working on a follow-up plan for myocarditis and so forth.

BY MR. SPECTRE.

Q So is it fair to say that you had concerns with Dr. Gruber's performance? Is that fair?

A I was concerned they were treating this sort of business as usual, that they had not experienced something this big before, and that these -- certain of these side effects were very unusual for -- vaccinologists don't usually have pediatric cardiologists as a member of their team, for example.

And so that's what I was concerned about, is that they had just been treating this more like they would an ordinary -- and leaving aside what you think about the vaccine and all that, you have to admit, this is a complicated application that needed a lot of attention. That's why I had been on their case about the computational science people who are data scientists, so they can get in the database, so they know how to do the analyses very quickly and so forth.

So that was basically -- and then when they couldn't cough up a project plan, my level of concern was raised, too. So it wouldn't be a

performance issue in the sense of like bad performance. It was like maybe they did not raise their level up to where they should have.

BY MR. SPECTRE.

Q Thank you. Now I would like to introduce a CNN article also from July 16th.

[Majority Exhibit No. 3 was identified for the record.]

BY MR. SPECTRE.

Q I'll give you a second to look at it. But just on first glance, have you seen this article before?

A No, I didn't read all this stuff during this time. I was too busy.

Q That is understandable. So we talked a little bit about this issue before, but I will just point you to the first two paragraphs on the front page there. And it says that an FDA official said a decision on full approval was coming, quote, soon. It also says that "The FDA official told CNN on Friday that a decision on full approval is likely to come within two months."

I know you testified earlier that you have to share these expected deadlines with the drugmakers.

A Correct.

Q But that generally this is private information.

A That's correct.

Q And it shouldn't be in the public.

A That's right.

Q Were you the FDA official that shared that with CNN?

A No.

Q Do you know who that may have been?

A No.

Q If you knew who they were, would they have received disapproval from you?

A Likely.

Q Is that an offense that would result in some kind of punishment within the FDA, or is that just a, don't do it next time?

A I think it depends on the kind of leak. But I have very little experience with punishment, because you never -- the reporters won't tell their sources, so you don't know who said that.

Q Certainly. So just for clarity for the record, it is abnormal and not in the interest of the FDA to have a deadline -- to have a quote like this about a deadline be shared publicly in an article?

A Well, this is still kind of vague, likely comes within two months. So it's desirable for us not to do these things because we don't know what we're going to find when we -- but I don't think this would necessarily -- the decision, it could be an adverse decision. So I think this is more mild than sometimes we see.

Q Is it possible that this being shared publicly, this data being shared publicly in the CNN article put undue pressure on the Office of Vaccines or other clinical personnel who are responsible for ensuring the review?

A I cannot say that, one way or another.

Q Okay. Thank you. We'll set that one aside now.

I believe we'll go back to the long email chain, if you can flip to the page marked with the last two numbers are 78.

Mr. Osterhues. That's Majority Exhibit 2 for the record.

The Witness. Okay.

Mr. Spectre. Thank you.

BY MR. SPECTRE.

Q This is an email Dr. Marks forwarded to you on July 16th as well. The underlying email is from Dr. Gruber and was sent to Dr. Marks. I'll give you a second.

Do you recall this email?

A Well, it obviously -- I was -- it was sent to me, so --

Q But you don't have any particular recollection of it today?

A I have seen this email.

Q Thank you. So if you look to the email which was forwarded to you, so Dr. Gruber's original email says, "See attached our projected timelines for completing currently ongoing reviews, task and responsibilities for the above BLA."

Just quickly, Dr. Gruber also CC'd Mary Malarkey and Steven Anderson. Who are they?

A Mary was the head at the time of the Office of Compliance, and so she would have been overseeing the inspections of the facilities. And Steve Anderson does the post-market safety

evaluation, and so they would have been doing the -- most likely, the review of the safety -- the nonclinical trial safety information.

Q Thank you. So the following pages within the document, within Exhibit 2, are Bates marked with numbers ending in 79 and 80. So this appears to be the timeline that you may have been referring to earlier that hadn't been prepared as of some previous emails.

A Or coughed up.

Q Now it is being provided. Is that fair to say?

A That's -- this is a timeline, yes, this -- it is not complete with staffing. It is more or less a fairly skeletal timeline, but it is a timeline, yes.

Q Could you -- and I know there's a lot here, but maybe just briefly walk us through what this says here, what exactly this timeline is representing?

A What this is representing is the various activities that have to be accomplished before an action can be taken by the FDA, including also when the inspections would be done and the reports and the labeling review, there's a post-market commitment review that has to be done and sent to the company and they have to agree to that.

So some of this, as I noticed Marion said in the previous email here, is contingent on the timely responses from the companies. So it can't necessarily -- that's another reason why the FDA should never talk publicly about timeframes, because you don't know if you're going to find something and the company will submit in a timely way.

So this simply said what has to be done. It doesn't say who is

going to do it and how these are going to be staffed and so forth, but it does go through all different activities. And you can see, as I said previously, that toward the end, there is always a cluster of activities that need to be accomplished.

Q Thank you.

A The action package has to be all finalized and all the different memos and reviews and assessments are all put together.

Q And just for the record, what does it appear that the deadline or when the approval is being targeted for as according to this timeline?

A Pardon me?

Q So just for the record, what date does this timeline indicate the Pfizer BLA will be approved?

A September 15th.

Q Thank you. If you go back to the email on the page ending in 78, Dr. Marks writes in his email to you that he "can already see a number of potential efficiencies." And asks, "Perhaps we can discuss over the weekend in preparation for Monday?"

So a couple questions there. Monday would be July 19th. Is the thing Dr. Marks is saying you need to prepare for on Monday, is that the meeting between you, Dr. Gruber, Dr. Krause, and Julia Tierney that ended up occurring on July 19?

A Most likely, that was when it occurred. I'm sorry about my problem with dates.

Q Understandable, and we'll get to more specifics later.

But fair to say that likely is?

A Yes.

Q And similarly to an earlier email, Dr. Marks is suggesting that you have a call to discuss these issues. Did you end up having a call?

A I don't recall.

Q Did Dr. Marks ever explain to you what "efficiencies" he saw?

A Yes, I believe he did.

Q And do you recall what those were?

A Not in detail. They had to do with the conduct of the review. Some of these activities, you know, could be completed in a more -- faster timeframe.

Q Okay. Now, I would like to talk about your July 19th meeting. We've already talked about it a couple times, and you said you at least vaguely recall having this meeting. Is that true?

A If you're talking about a meeting that occurred amongst Phil Krause, Marion Gruber, Julia Tierney, me, and Peter Marks, yes, I recall that meeting.

Q Yes.

A I do not recall that date.

Q Yes, that is the meeting. And was anyone else there besides those you just listed, Gruber, Krause, Marks, Tierney?

A To my knowledge, no.

Q And on that note, was this an in-person meeting or was

this on a Zoom call?

A My belief is it was on a Zoom call.

Q Thank you. Do you recall roughly how long this meeting went?

A I do not.

Q In your recollection, was it a very long meeting or --

A No, it was not a long meeting.

Q What do you remember discussing during that meeting?

A Well, what I discussed was I said that I was going to have Peter finalize this review because Marion was going to go away, and I felt that the rest of the office work needed to keep going and that this needed full attention to be gotten over the finish line. And Peter was very involved in it.

Q Thank you. And that was the reason you gave in the meeting for why Dr. Marks was taking over, that it was because Dr. Gruber was going on leave?

A Yes.

Q Did you discuss, and we talked about this issue earlier already. But in this meeting, did you discuss why Dr. Krause would not be taking over for Dr. Gruber?

A To my recollection, because this is a long time ago, I said that Phil could -- could continue with the rest of the activities of the office and that this very tense activity of getting this particular application done would be led by Peter, that the lead would transfer to Peter. Dr. Krause had not been the lead. So it's very

typical to transfer the lead to somebody, right, and so I thought this was a very good solution.

Q Did the topic of vaccine mandates or mandatory vaccination policies come up at all during this meeting?

A Not by me.

Q But do you recall that someone else may have brought them up?

A I do not recall.

Q Do you recall, as we've established you said you have not pressured anyone to accelerate the timeline. But did Dr. Mark pressure anyone during this meeting to accelerate the timeline for reviewing the BLA the Pfizer COVID-19 BLA?

A Dr. Marks simply stated he felt it could get done earlier. And of course, they had a massive amount of work in the Vaccine Office, other applications, other important activities needed to be done. It was very important during this emergency to get things completed, but in -- to the highest standard of technical excellence.

Q So is it fair to say that in this meeting, Dr. Gruber was being replaced, and also it was discussed that the timeline could or should be faster than the one that she was working on -- working towards?

A I was not saying that Dr. Gruber was going to be replaced. Dr. Gruber was going on vacation, and I was putting a very senior regulator in charge of this application. My understanding is that when Marion came back, she actually remained involved in the

application, so -- and Dr. Krause was stuck in as managing the rest of the office.

Q Thank you very much. So we have just a couple minutes here, so my last question before we wrap this hour up will be referencing an email on the page marked ending in 83 and 84.

A Uh-huh.

Q So at the bottom of 83, and this is kind of a long email, so I'll give you a second. It is an email from Dr. Gruber to Dr. Marks, yourself, and she CC'd Julia Tierney and Philip Krause. I may have asked you this already, but just for the record, who is Julia Tierney?

A At the time, she was the chief of staff of FDA.

Q Okay. Thank you. So I will give you a second to look over that email because, like I said, it's a bit long. Just let me know when you've had a chance.

A Okay.

Q Thank you. I know that's a long one. And we'll refer back to this email a little bit more when we pick back up in our next hour, but just really quickly, do you generally agree -- let me start over.

Is it fair to say this is an email from Dr. Gruber summarizing what was, in her view, what you all discussed on your July 19th call?

A Yes, she's summarizing that and also arguing her own position, and it's written to Dr. Marks and to me.

Q Thank you. Do you generally agree with her summary of

the meeting?

A She's focusing on the timelines. I did not focus on that in my part of the meeting. I focused on the fact that she would be on vacation, which is perfectly reasonable, some family time, out of the country, not in a position to oversee this very complicated, as she said, review.

Dr. Krause is an expert, he's not a clinician, and I asked that Peter take over the review. That was what -- a lot of sort of extraneous comments in this email about the timeline and other things that I don't think were really the heart of the meeting.

Q So to your recollection, you primarily focused on Dr. Marks' taking over the lead of the review of the Pfizer BLA?

A Yes, that was my intent of having the meeting and explaining that rationale to Marion and to Dr. Krause.

Q But so did Dr. Marks, the things that you did not bring up directly that Dr. Gruber refers to in this email, is her summary a fair summary of what Dr. Marks had said?

A I'm not in a position to remember.

Q Okay.

A I do not remember.

Q Thank you. We'll talk a little bit more about that meeting in just a little bit in our next hour, but we can go off the record for now.

[Lunch recess.]

[redacted]. Back on the record.

BY [redacted]

Q Dr. Woodcock, we had a few clarifying questions about some of the content from the previous hour. One of them is grounded in a document. So if you could find Exhibit -- Majority Exhibit 2 and within that, it's the Bates numbered page 84.

A Okay.

Q So there is a lot of text there. I will just talk about what I'm talking about, and that will spur your recollection. I think you have testified previously today that in this meeting, to the best of your recollection, you did not mention anything related to the linkage between vaccine mandates and BLA approval, that's right?

A That's right.

Q And I think you also said that you are not in a position to recall whether anybody else did say something about that, and if so, who and what, you just don't recall?

A That's right.

Q Okay, great. I only wanted to clarify because it looks like here in Dr. Gruber's write-up of the memo, on page 84, towards the top of that page, maybe two-thirds of the way down in that first big paragraph, Dr. Gruber said that “you” -- the you was a little unclear there. I think she is referring to both yourself and Dr. Marks. I don't know, but she said, "You expressed concern about rising COVID cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized

vaccine would be more inclined to get immunized when the product was licensed."

So consistent with what we just said, as far as you know, whoever said that, that that wasn't you as related to the mandates comment?

A That's right.

Q Great. The other component of that, this idea that there are folks out there who would feel more comfortable getting an immunization if it were the recipient of the full BLA approval, you did talk a little bit earlier that was something you had heard?

A That's correct. And I may have brought that up. I heard that from many members of the public, yes.

Q Great. Is it right to say that at no point in this meeting or this series of conversations about the Pfizer BLA that you did not feel that the safety or efficacy of the vaccine was ever being jeopardized or at risk; is that right?

A That is correct.

Q This is also just a minor factual clarification. Dr. Gruber going out on leave for this extended period, that was already happening for personal reasons, right? That has no linkage to this BLA application?

A That's what precipitated this conversation, when Dr. Marks informed me that the lead for this review was actually going to be absent during that period of intense effort toward the end of the review process.

Q Those were preexisting personal plans?

A That's her plans that she put forward.

Q Right.

A To my understanding.

Q Great. Just one other, it's a minor factual point but on Majority Exhibit 3, the CNN article, if you've got in front of you.

A Yes.

Q As a reader, it felt as if the lead or the source, the FDA official -- the article was in the context of an FDA decision, right? I don't see at any point that the decision is being predicted one way or the other, in terms of approval or denial. It's just a decision in the abstract. I don't know if that is also your perception as a reader.

A People are quoted, which is me and Peter Marks, it appeared, as the FDA usual terminology, that action or a decision, which is the appropriate way to never telegraph what you're going to do.

Q And that would be typical with FDA's usual practice?

A That's correct.

Q Great.

[redacted]. That's all we have for this round. We can go off the record.

[Discussion held.]

Mr. Spectre. We can go back on the record.

BY MR. SPECTRE.

Q Just to pick back up a little bit. The minority's

questions just now covered a couple things here, but we're going to go back over a couple of the same topics.

Just to start out with, during the Select Subcommittee's hearing on February 15th of this year, is that the hearing you mentioned earlier that Dr. Marks had mentioned to you -- Dr. Marks was asked if he recalled "any conversations regarding the need to approve COVID-19 vaccines in order for it to then be mandated." Dr. Marks said, "There was an acknowledgement that an approval could allow vaccine mandates to occur."

And we have touched on this a little bit already, but you said that you were aware of that, you were aware that the decision to approve the vaccine could lead to or allow vaccine mandates. But do you recall any specific conversations discussing that?

A Only that point. This had been widely raised in the press and elsewhere, and I recall people, Peter and others, acknowledging this.

Q Do you remember a specific time that Dr. Marks acknowledged this?

A No, I do not.

Q Thank you. Does the FDA have any role in shaping policies like vaccine mandates?

A No.

Q Were you favorable to the idea of mandatory COVID-19 vaccination in the summer of 2021?

Mr. Cooke. You, meaning, Dr. Woodcock personally?

BY MR. SPECTRE.

Q Dr. Woodcock, in your personal view, were you favorable to the idea of mandatory COVID-19 vaccination as of the summer of 2021?

A I had no opinion on that.

Q Okay. Thank you. I will refer back to that same email that the Minority was just talking about there.

Mr. Osterhues. And this is Majority Exhibit 2.

Mr. Spectre. Majority Exhibit 2, the page ending 83 and 84.

BY MR. SPECTRE.

Q So just to be clear, and again, you testified to this in the last section, but the possibility of mandatory vaccination policies played zero role in the rationale for the actions that were taken during that meeting. Is that true?

A No, not in my rationale.

Q Not in your rationale.

A And I was the decisionmaker.

Q Thank you.

Mr. Spectre. I will now introduce Majority Exhibit 4.

[Majority Exhibit No. 4 was identified for the record.]

BY MR. SPECTRE.

Q This is a one-page document. I will let you take a look, but this is a memo issued by the Secretary of Defense on August 9, 2021. So this obviously would have been prior to the BLA decision. I will give you a second to look at that. You can let me know when

you're ready.

Looks like you're ready. Are you familiar with this document?

A No, this is the first time I've seen it.

Q Okay. So I guess that answers the question whether you recall seeing it between August 9th and August 23rd.

A I do not.

Q I know you just had a brief minute to look at it, and this is the first time you've seen it apparently. But just in your quick look, is it fair to say that this memo indicates that Secretary Austin was planning to mandate COVID-19 vaccination for service members as soon as the vaccines received full approval or as soon as President Biden gave a waiver, whichever came first? Is that fair to say?

A I don't understand about the waiver, but it sounds --

Q I believe that's a legal issue.

A I don't understand, so I can't answer that. I understand what he's saying here is that after -- should there be an FDA licensure, which is the proper term, that he would mandate the vaccines for military.

Q My understanding is that the waiver was a legal matter or a legal issue, where if the vaccine was still under EUA, that the Secretary would have to seek a waiver from the President to mandate it. It sounds like you don't have any familiarity with that issue?

A I do not.

Q Okay. Since you have not seen this memo before today, I assume you were not aware that Secretary Austin was planning to issue a

mandate prior to the mandate being issued on August 24th, or rather -- let me rephrase that.

Were you aware that Secretary Austin was planning to mandate COVID-19 vaccination before August 24th, 2021?

A No.

Q In the interest of time, I won't introduce it as an exhibit, it's here if you would like to see it, but it is just the announcement that the Pfizer vaccine Comirnaty received full BLA approval on August 23rd. I'm sure you recall that announcement. So we'll set that aside, but the next day, and I'll introduce this as Majority Exhibit 5.

[Majority Exhibit No. 5 was identified for the record.]

BY MR. SPECTRE.

Q This is the memo announcing the DoD vaccine mandate written by Secretary Austin on August 24th. I'll give you a second to look at that one as well. It's a single page, double-sided document.

It looks like you're ready. Are you familiar with this document?

A No.

Q So this is the first time you're seeing it as well?

A To my knowledge, yes.

Q You've already answered a couple of these questions here. So I'll skip to -- this memo came out just one day after the FDA announced the -- for approval of Comirnaty. To your knowledge, would DoD have had advanced knowledge that the full approval was imminent?

A Not to my knowledge. He says here about the press talking about it. Public reporting suggests that it could achieve full FDA licensure early next month.

Q You're reading from the August 9th memo?

A Yes. So that's all I know.

Q So you're not aware of any reason why they would have had more specific knowledge of when the BLA would be approved?

A No.

Q Just to round out that section, sorry, I'm trying to decide if it's worth introducing as an exhibit or not here.

In the interest of time, we'll just skip to the next section here. Talk a little bit about COVID-19 vaccine boosters. Do you recall when the first COVID-19 vaccine booster was authorized by the FDA?

A No.

Q Does sometime around September 22nd, 2021, does that sound correct?

A It does.

Q But when this was authorized in September of 2021, it was only authorized for certain individuals; is that right?

A That's my recollection.

Q Does it sound right that it was authorized for people over 65, people between the ages of 18 and 64 with a high risk of COVID-19, and people 18 to 64 whose occupation put them at a high risk of complications from COVID. Does that sound about right?

A That sounds right.

Q And this dose -- this first booster dose was an identical formula as the primary two-dose series; is that correct?

A I don't recall, but I believe so.

Q Thank you. As we discussed, the Pfizer vaccine was given in August of 2021. Do you know when the FDA began consideration of the first booster emergency authorization?

A To my recollection, it was in the previous spring.

Q In the previous spring. Did Pfizer have or any other company have to proactively request this, or does the FDA prompt them?

Ms. Raveendran. Could you clarify what "this" is.

BY MR. SPECTRE.

Q Did Pfizer have to proactively request that the FDA assess the same doses as being a booster dose?

A Companies have to submit an application for a change to their BLA or for an EUA, as like earlier discussed. So, yes, any company that wished to have a booster or something like that would have to submit an application that had manufacturing control data if it were different, as well as clinical data or other data.

As I said earlier, we had put out guidance about what kinds of information we would be interested in should variants change, should they not change, should immunity drop low, et cetera, et cetera.

Q Thank you. Do you recall when the first public announcement was made regarding a plan to authorize a booster dose?

A I do not.

Mr. Spectre. I would like to introduce Majority Exhibit 6.

[Majority Exhibit No. 6 was identified for the record.]

BY MR. SPECTRE.

Q This is a press release from the FDA from August 18th. I'm sorry, I got my documents mixed up here.

This is a press release from August 18 that indicates it was attributable to you as well as CDC Director Walensky, Surgeon General Vivek Murthy, among others, a one page, double-sided document here.

A Thank you.

Q And I will give you a second to review it, but I am going to point to a particular paragraph, that's the fourth paragraph. It should be on the back here. Excuse me, in the last paragraph on the first page. It says, "We are prepared to offer booster shots for all Americans beginning the week of September 20 and starting 8 months after an individual's second dose."

So at this point, on August 18th, 2021, had the EUA for a COVID-19 vaccine booster been -- had the FDA decided on that EUA yet?

A No, the paragraph said, subject to FDA conducting an independent evaluation and ACIP's issuing booster dose recommendations based on a review of the ACIP.

Q Yes, thank you.

A So it was caveated.

Q Okay, thank you. So President Biden made a similar announcement on that same day on August 18, announcing that the

government was planning to offer booster doses the week of September 20th. Is it fair that you are agreeing with that plan as a goal at the very least?

A As a goal.

Q Okay. And within our earlier conversation about sharing these expected deadlines outside of the FDA, would you say that this announcement falls within the general guidelines of what kinds of information can be shared outside the FDA?

A Well, again, as I said, it's caveated about the week of September 20th. It's not about an approval, it's about potentially an approval but not of a new molecular entity. It's about yet another dose, more of the same, so to speak. So it's a little less vague than what usually FDA would do, but yet this is within the public health emergency.

Q So it's a little bit less vague?

A Yes.

Q Do you think that this potentially less vague announcement could put any undue pressure on the scientists who are conducting the review?

A Well, it says subject to independent evaluation and determination. I think our scientists take that very seriously. They have to sign that they agree with it. I certainly never wanted anything other than a thorough and complete evaluation.

[Majority Exhibit No. 7 was identified for the record.]

BY MR. SPECTRE.

Q I would like to introduce Majority Exhibit 7. The date at the bottom left indicates that it's from Volume 398 of the Lancet October 9, 2021. You will have to take my word for the fact that it was published online initially on September 13th, 2021.

And this is a Lancet article which was coauthored by Dr. Krause and Dr. Gruber titled "Considerations in boosting COVID-19 vaccine immune responses." It argues that, "Currently available evidence does not show the need for widespread use of booster vaccination in populations that have received an effective vaccination regimen."

Do you recall this article?

A I knew it was published. I never read it.

Q So I will give you a second to look it over if you would like.

A More than a second.

Q Certainly longer than a second to fulsomely evaluate the entire article. But if we can just focus on that one quote that I read that currently available evidence does not show the need for widespread use of booster vaccination in populations that have received an effective primary dose regimen. Do you disagree with that assessment?

Ms. Raveendran. Could you point to where in the article it is?

The Witness. Third paragraph.

Basically, it says current evidence does not therefore appear to show. It doesn't say does not show. And it would require me to read this article to answer your question.

BY MR. SPECTRE.

Q Okay.

Mr. Osterhues. Just a follow-up question.

BY MR. OSTERHUES.

Q You mentioned you had not read this article. Was there a particular reason you had not read it, or was it just you didn't -- you had a lot to do?

A At the time, I was very well aware of all the data, and including data from other countries about the use of boosters and the impact, and so forth. So I did not feel -- I know these folks, and I did not feel the need to read their argument.

BY MR. SPECTRE.

Q Had you heard this sort of concern raised from within FDA prior to September 13, 2021, when this article was published? Similar, meaning concerns that the evidence may not or does not show the need for widespread use of booster vaccination in populations that have received an effective primary regimen?

A Well, first of all, if I may.

Q Certainly.

A They are talking about general population. This wasn't indicated -- the booster at the time of approval was not indicated in the general population. So you might say they were arguing against something that didn't happen.

Q Do you recall when it was expanded to include all adults?

A I do not recall.

Q Does November 19th, 2021 sound --

A I literally can't remember.

Q Okay.

A As you know, there were many iterations of boosting and other activities during that following year.

Q Certainly. I won't introduce that, but my understanding is that it was the emergency use authorization for a booster for adults was issued on November 19th.

A After more data became available, obviously. But I just -- I simply would say this article, at least as my brief reading of it, is about general population, which isn't -- wasn't the subject of the initial booster recommendation.

Subsequently, of course, there were many, many conversations that went on in the scientific community about this all around the world, not just in the U.S., not just people within the FDA, but all over the scientific community about how to deal with this, how to deal with the evolution of variants, should a booster be engineered to be more forward-looking to cover future variants, how would you predict that.

So this was one of many, many, many. And actually, at least the way this is phrased, they were not talking about what happened initially with boosters.

Q Sure. Do you recall the first time that President Biden publicly said that the booster would be expanded to adults?

A I don't recall when. I know it happened.

Q I'll introduce Majority Exhibit 8.

[Majority Exhibit No. 8 was identified for the record.]

BY MR. SPECTRE.

Q This is a New York Times article from September 24, 2021. On page 2 as we printed it out here, near the bottom the paragraph says, you are going to see that President Biden is quoted as saying, "'You're going to see that in the near term, we're probably going to open this up anyway.'" He also said, "We're also looking to the time when we're going to be able to expand the booster shots, basically across the board."

So just to be clear, when President Biden said this on September 24th, and I know you said you didn't recall it specifically when the booster was expanded, but that was in November. Had the FDA made any determination about authorizing booster doses for more Americans?

A I'm getting really confused here. When was the approval of the booster?

Q So this is President Biden on the same day that the booster was announced for that specific cohort --

A Limited population.

Q Exactly. He is quoted as saying the government was planning to open this up and that "we're going to be able to expand the booster shots, basically across the board." And for the record, that didn't occur until November.

So the question was, when President Biden said this, had the FDA made any determination about authorizing booster doses for all adults?

A No, they had just made a decision that they stand behind for the population that was approved or authorized.

Q Thank you. Could statements like this potentially put undue pressure on the FDA scientists who are conducting the review?

A I think it was vague enough that I don't actually understand what that means, okay, so I wouldn't think it would put too much pressure on. But that's speculation on my part.

Q Okay. And we have asked this sort of question with the initial approval. But did you receive any pressure from any government official to speed up the review of booster doses authorizations?

A Not to my knowledge.

Q Okay. We are going to switch gears a little bit now and talk a little bit about adverse events associated with COVID-19 vaccines. I know my Minority colleagues touched on that a little bit in their last hour.

I will start with introducing this article which is a New York Times article from just this month, which I am sure you may have seen.

[Majority Exhibit No. 9 was identified for the record.]

The Witness. Yeah, Apoorva sent this to me but it was behind the pay wall so I couldn't read it.

BY MR. SPECTRE.

Q Here's a copy for you. It was initially published on May 3rd, and you're quoted a couple times.

Mr. Osterhues. For the record, this is Majority Exhibit 9.

Mr. Spectre. Thank you.

BY MR. SPECTRE.

Q It was published on May 3rd in the New York Times and you're quoted a couple times.

A Mm-hmm.

Q Were these quotes that you gave in an interview you gave directly to The Times?

A Yes.

Q Do you recall when this interview took place?

A It was after I retired, I think, in February or March.

Q Okay. So since it was recent, I am going to assume that it accurately reflects your current belief on these issues generally?

A Yes.

Q I would like to go through each of these quotes and see if you can give me a little more context on what you're saying.

The article indicates that you believe that some recipients of COVID vaccines "experienced uncommon but 'serious' and 'life-changing' reactions beyond those described by federal agencies."

What kinds of reactions are you referring to there?

A I'm referring to reactions that medical science has trouble dealing with. A common problem that occurred before this, before COVID used to be called chronic fatigue syndrome or myalgic encephalitis. And the medical establishment has struggled for 20 years trying to figure out what it is and still have no idea. All right. That's typically a post viral or post infectious illness. However, I

think it could occur post any immune stimulus.

So to answer your question, folks had brain fog, fatigue, prostration, some of them had neurologic symptoms. None of them fit neatly into any diagnostic category.

Q So because they didn't fit neatly inside a diagnostic category, you're saying they're harder to be described or analyzed?

A Well, they're harder to be identified because many of these folk struggled for months and months to even be acknowledged that there was anything wrong with them. Many of them were told, you know, they were just -- it's all in your head. And that's very similar to chronic fatigue syndrome, myalgic encephalitis.

Q Do you think it's all in their head?

A I believe that like anything in the human sphere, okay, some people are going to like 'swing the lead,' as they say, but I think that these are real reactions, many of them, and that the people are suffering. I will say exactly what I think is said here.

Q So you said beyond those described by federal agencies, or at least that's how it's framed in the article. Which in your view have been described by federal agencies?

A Well, certain immune reactions are well known post vaccination. Guillain-Barre syndrome, idiopathic thrombocytopenia, and in some people say that other neuropathies. But these others are not acknowledged to be vaccine adverse events because they don't have a medical definition, nobody knows what they are. And so -- and if somebody comes in and complains of brain fog, what are you going to do

with that?

So I think there are well-known reactions to vaccines and to viruses that occur and are easily categorized because they have distinctive syndromic characterizations. But this isn't one of them.

Q You were also quoted as saying that you "feel bad for those people" and you "believe their suffering should be acknowledged, that they have real problems, and they should be taken seriously."

I think we just talked about that a little bit, but is there anything further you wanted to share on that topic?

A Well, I tried, I harassed the people at CBER to certainly search worldwide databases repeatedly at my insistence to look for this. They could not find a signal. So that means scientifically it wasn't there, all right?

They got these reports, too. I talked to many of the people who had this, many times. I even talked to NIH, I talked to even see if they would add an arm, because this is very similar to some of the things that people get with long COVID. You get-- people get long COVID much more frequently after getting COVID than they do getting this after vaccination. But it does seem to happen.

So I wanted to get it studied because I think what the first thing we need is study. And the NIH study on long COVID is looking for syndromic definitions. That's mainly what they're doing, they're trying to find syndromic clusters so they can name these conditions in the same way that people get POTS, postural orthostatic tachycardic syndrome, which is another probably autonomic neuropathy, okay?

So my goal was to try and, number one, get the people studied so they can be acknowledged, that they were having a problem, and also start working up ideas of treatment. Now, I wasn't really that hopeful because CFS ME has gone so long without effective interventions.

But Dr. Nath over at NIH had done some work with some people and given them IVIG early in their -- they had more, he's a neurologist. They had more predominant neurologic symptoms and those people got better.

That doesn't really mean anything, because some people get better, right? But at least to define these syndromes, so that they would show up in the databases. So if somebody had this and they went in to a doctor, they wouldn't just send them home and say that the -- just send them home and say you need to rest more.

Which is similar with people with long COVID at first, right, you know, you had a bad virus infection, you need to rest, take vitamins, right?

Q You said that the symptoms are at least somewhat similar between long COVID and some of these other neuropathies you're describing.

A Yes.

Q Does it seem to you that long COVID has been taken more seriously by many than these neuropathies associated with COVID vaccines?

A Well, I would say when long COVID happened at very first, there weren't that many people who had it, so it wasn't taken that

seriously, right? There were other things to worry about, like people dying in hospitals on ventilators and ECMO and everything.

Eventually, there was such a huge number of people who got this post viral syndrome that it couldn't be ignored, whereas it's still not that many people who have this.

Q You mentioned that you were -- I forget the exact language you used, but that you were trying really hard to get CBER to look into some of these things.

A They did.

Q And you do believe that they did?

A They looked into it. As I said, they went and searched international databases, they asked our international regulatory colleagues to look. But where are the search terms, you know? Even POTS. Some of these patients told me or some of maybe the physicians told me that POTS—there were only a few centers in the United States that actually can definitively diagnose it.

So how are you going to get a person like in Iowa or something, they go to their general practitioner and say, I can't stand up anymore. I mean, how are they going to get into the system and get properly diagnosed? And that was -- these are like still my concerns about this.

Q You also say in the article that you are, quote, disappointed in yourself and that you, quote, did a lot of things you feel very good about, but this is one of the few things that you feel you just didn't bring home.

What did you mean by that?

A Well, I wished I could have gotten an arm of the study over at NIH started, for example, but it was really hard. I talked to the companies, but how are you going to get them to do it unless you actually have scientific data?

Q A study on?

A Well, there's a study called Recover at NIH and it's on post COVID, and they're studying all different phenotypes, they're called different clusters of symptoms of COVID, post COVID, long COVID, whatever you want to call it.

And they are trying to categorize them, and then they are going to try to look at interventions. What if you took an antiviral for a long time or what if you took an immunosuppressant, would you get better? And so forth.

I was thinking at a norm of post vaccine, post COVID like syndrome, and get them characterized. And then hopefully maybe they could get treated. But I failed to get that done. I feel bad about it. I feel bad for these people.

Q Why do you think that that stalled?

A Well, I had too many things to do. And I think the main reason is without a signal, you know, like we get a lot of signals in our real--, like I was telling you earlier. You have to work them up and they aren't causally related. That requires some strong causality -- Potentially causally related signals hardly get the companies to pay for it. They would have had to pay for a study like

that at NIH.

Q So do you feel that others within FDA took this as seriously as you did?

A No.

Q Where within FDA should have taken this more seriously?

A Well, it isn't that. They tried. CBER, it was their responsibility and the post-market safety people I talked to them numerous times, had emails with them and they tried, they looked. But they're data driven. I talked to all these people because I'm a doctor, okay, so I talk to them.

And I was convinced many of them were like very pro-vaccine type people, you know, but their lives have just been wrecked. And I was convinced -- as I told you earlier, I'm a rheumatologist or trained in rheumatology and immunology. So I've seen a lot of these odd immune reaction type of things, and that's what I think this probably is.

Q But you said you have spoken with lots of patients, and we talked earlier, you talked with advocacy groups. Was one of these groups React 19 or Brianne Dressen of React 19?

A I spoke to Bri Dressen. I don't know if she was part of React 19 or not. This was quite a while ago, yes.

Q And do you feel that -- you already talked about this a good bit, but do you feel that you've adequately -- you shared those concerns that were brought to you by patient groups or individual patients within the FDA or outside of the FDA?

A I'm sure people thought I overshared them. I was very

vociferous. You know, as you probably know, I'm very outspoken. I said I think these are real reactions, I think it's very difficult to categorize them medically. I think we need to do a better job, blah, blah, blah. I did.

Q And did you share those thoughts outside of FDA as well?

A Well, yeah, certainly I talked to the advocates. Yeah, I was not silent about this. I talked to NIH about getting a trial arm going. But they only had a certain amount of money. They had already dedicated that to the post COVID trial. They would have needed somebody to finance another arm.

Q That makes sense. Did you ever share these thoughts publicly, I guess, other than in this New York Times article that we're discussing?

A Yes, I did. I wasn't perhaps as -- here, I was honest that I felt I had not gotten this done because I have gotten many things done in my career.

Q Okay.

A Many pieces of legislation, many this, that, and the other thing. I just feel I couldn't get this to a place where I felt good about it.

Q Just skipping ahead a little bit, because you have shared a lot that covers some of the other questions I've asked here. But what role does the FDA play in surveilling for or assessing possible safety signals associated with the vaccine? What is FDA's role in that?

A The FDA's primary role in the United States is-- CDC shares that role whereas for pharmaceuticals, for example, it's strictly FDA. So FDA, I would say, is the primary post-market surveillance vaccine entity.

Q This New York Times articles mentioned that the European Medicines Agency has linked the Pfizer and Moderna vaccines to facial paralysis, tingling sensations and numbness, and also considers tinnitus as a side effect of the Johnson & Johnson vaccine. Were these issues, those conditions I just said, assessed by the FDA?

A I don't have direct knowledge of that, but I am sure they were.

Q Shingles, facial paralysis, tingling, numbness?

A Bell's palsy is a post -- can be a post-viral syndrome. So whether or not it's elevated, I'm sure these were assessed by the FDA based on signals that were received and determined to be or not be worthy of being put in the label.

Q And so since the European Medicines Agency linked some of these and the U.S. has not, I understand you don't have direct knowledge of the assessment of those conversations, but just in your view, why do you think the U.S. is seeing different results than other countries?

A Well, that doesn't occur uncommonly with drug regulation. These are, to some extent, as I've said, a matter of judgment. The FDA looks very carefully, does the signal evaluation of every signal and they decide which ones they feel might be causally related. And those

are the ones that are usually put in here.

So that -- it's a difference of opinion about whether they were causally related. Because these events that we were talking about here, tinnitus, facial, Bell's palsy, and so forth, occur spontaneously as well. So you have to try to distinguish those.

Q Do you believe FDA's systems or procedures to identify causal links are robust enough?

A Well, as I said earlier, I feel that because U.S. has a fragmented health care system that it is more difficult to consolidate the records. That was complicated in the case of COVID vaccines because it was very difficult to link vaccination recipients with their medical records because they would get a vaccine at some big, you know, stadium or anywhere. And then that record wouldn't necessarily go with their other health records. So the FDA -- and these events that we're talking about here are rare enough you don't see them in clinical trials, right? Generally speaking.

So the FDA also, and CBER also, as I said, relies upon the data and gets data from the other regulators. So those data are by no means mysterious or secret. The agency gets to see those as well. So they would know the basis upon which the EMA or other regulator decided if Bell's palsy was linked and would overtly decide whether or not they agreed with that.

Q Thank you. The New York Times article also mentions the U.S. officials were not the first to identify myocarditis in young people, that Israeli officials first raised the alarm in 2021, but U.S.

officials hadn't seen the link. Why do you think the U.S. was behind in identifying the link with myocarditis?

A Because Israel had a national health care system.

Q I guess that answers -- what could be done to fix that, in your view?

A Better linkage of vaccination records with medical health records.

Q Okay. Thank you very much. I am going to introduce Majority Exhibit 10.

[Majority Exhibit No. 10 was identified for the record.]

BY MR. SPECTRE.

Q This is a document that the FDA produced to the Select Subcommittee, CBER Sentinel Program Sufficiency Memorandum, and it indicates that on May 18th, it's for a product that was submitted on May 18th, also action due date is January 16, just the bottom left of the page indicates that the document was last updated January 29, 2019. I believe that is inaccurate, or at the very least, it's just a reflection of when the template was updated.

A I see.

Q Is that your view?

A Probably -- I don't know.

Q Just for the record, it's referring to a biologics license application that did not exist as of January 2019. So just for the record.

A Yes.

Q It appears that that is a different date. Are these memorandums standard?

A I do not know.

Q Have you seen this one before?

A I have not.

Q The second page defines the objectives and scope of the memo, which it says is, "reviews the capability and sufficiency of the CBER active post-market risk identification and analysis system referred to as the CBER Sentinel Program to evaluate the serious risk for myocarditis and pericarditis following receipt of BNT162b2."

At the top of page 6, there is a block of blue text, it's vaguely blue here on my printout, which begins with "Available data sources in the CBER Sentinel Program are NOT sufficient to identify the outcomes of myocarditis and pericarditis due to reasons identified in 2.3.1," and so on.

What does that mean?

A My understanding is that, first of all, Sentinel was a CDER-driven -- is a CDER-driven program. I set this up, which is an active surveillance program to monitor -- and as they say here, at the time it was under contract, activities conducted through the contract of Harvard Pilgrim Health Care Institute, the current and future contracts through BEST, interagency agreement with Medicare and Medicaid.

Okay, so it's all of those, okay? So go ahead and ask me that

again, please?

Q Sure. Certainly. It says at the top of page 6, there is a block of blue text that says, "Available data sources in the CBER Sentinel Program are NOT sufficient to identify the outcomes of myocarditis and pericarditis due to reasons identified" -- the chart identifying those reasons is on page 5, if you want to take a look.

But what does that mean, that CBER Sentinel is not sufficient to identify the outcomes of myocarditis and pericarditis?

A Well, what they're saying is the data elements or sources that they currently have available or collect cannot adequately characterize that risk, okay? And mainly -- and you're making me do this really fast.

But mainly, if you look at 2.3.1, right, in the chart there, and why is that. First of all, they say there aren't any biomarkers that are very reliable. That's element 2 there.

But mainly element 5, the algorithm for, as I was saying, research definition. And they say no, okay? That's very similar to what I was talking about with this adverse, the adverse event of brain fog, and if there's no algorithm here.

Of course, myocarditis is a much better defined entity, but they're saying that it's not in the literature, there isn't a really good algorithm, they can’t search all these claims data and so forth and reliably identify myocarditis.

Is that helpful?

Q That is. And it's not clear to me given the date on the

bottom left appears to be inaccurate when this memorandum was filled out. But clearly at some point between May 18th, 2021 and January 16, 2022, given the timeline of the BLA which is also on the front.

Does this memo indicate that the FDA's Sentinel Program was not sufficiently capable to assess the risk of myo and pericarditis?

A I think -- can I answer your question in a larger context?

Q Certainly.

A I believe when Sentinel was authorized by Congress, we were told you had to look at Sentinel first before you put in post-market convention and so forth, to see if it were adequate alone, if active surveillance alone would be adequate to further characterize the risk.

So just -- this is my take on this, having very briefly looked at this memo. My assessment of this is that, no, you need additional -- the answer is no, you can't just rely on Sentinel. The whole -- and BEST and so forth, the Medicare database. You need to put in place other specific post-market requirements for this because just use of generic active surveillance won't get you the answers.

Q So in your view, did FDA sufficiently analyze the risk of myo and pericarditis?

A Yeah, this isn't related to analyzing it. It's related more or less to follow it up. I think cases that were identified were very carefully looked into and also that although our population's not identical to other populations, the incidence in other countries that

again had national health care systems, so they did -- they knew everyone who was vaccinated between the ages of 15 and 40 or whatever, and they were able to catch all the cases of myocarditis.

So the incidence of myocarditis following first vaccination and follow up second vaccine and so forth could be characterized better by those -- by those data sets than by the U.S. experience. However, I think that what they say here -- this is what they say, which is what I said.

The Sentinel Program, this is number 3 in the second box. "Sentinel Program is NOT sufficient to assess the serious risks," "in lieu of PMR safety studies under FDA Amendments Act."

So the FDA Amendments Act said you have to look and see if Sentinel would work first, and that's what this is about.

Q Okay.

A And this is saying this didn't work, we need a post-market study or registry or whatever type of thing, which is what I was saying about pediatric cardiologists, all right?

Q Thank you. That's helpful context. Do you recall any conversations discussing the downplaying of the risk of myo or pericarditis?

A With whom? What are you talking about?

Q Do you recall any conversations within the FDA about downplaying the risks that the vaccines have of myo and pericarditis?

A No, I mean, there was intense interest in figuring out who got it, who was at risk, how common was it, what were the sequelae,

how quickly did people recover and so forth.

Q Thank you. I will show you Majority Exhibit 11.

[Majority Exhibit No. 11 was identified for the record.]

BY MR. SPECTRE.

Q This is a National Academies report titled Evidence Review of the Adverse Effects of COVID-19 Vaccination and Intramuscular Vaccine Administration. It was issued in April of this year.

Have you seen this before?

A No, I have not.

Q I'll give you a second. This is just a summary of a longer report, from what I understand. So it's not super long if you want to give it a brief look-at, but it indicates that the evidence was insufficient to establish, favor acceptance of, favor rejection of the 65 potential relationships between vaccines and possible harms.

Mr. Cooke. That's the bottom of the first page?

Mr. Spectre. Yes.

The Witness. Okay.

BY MR. SPECTRE.

Q As I mentioned, the report indicates that the evidence was insufficient to establish, favor acceptance of, or favor rejection of 65 potential relationships between vaccines and possible harms.

What does that mean?

A Well, when you give an intervention, and I'm talking generally, a drug, give it to millions of people, they're going to have

everything. They're going to get hit by a bus, they're going to have hair loss, they're going to get illnesses, they're going to have gallbladder attacks, gout. So you have to figure out, right, are any of these causally related? Sometimes it really surprises you. We've had relationships that really surprised us for drugs, right?

So you vaccinate hundreds of millions of people, they're going to have everything under the sun happen to them, okay? If you gave them saline, the same thing would occur, generally, except those that are causally related. And it's picking a needle out of the haystack. The rarer they are and the harder they are to define medically, the less likely you are to be able to tell whether they are causally related or not. If they're extremely common and there's a very small increase caused by the vaccination, you may be unlikely to find that, too, except in a randomized study.

So that's what they're saying.

Q So do you believe -- well, you touched on this a little bit already. But do you believe our surveillance systems have blind spots when it comes to data?

A Well, what I said before about the very strange severe post vaccination reaction, some individuals are having, it's a not blind spot on the surveillance system. It's a failure of the medical construct to recognize these syndromes, which is different. You could have tremendous amount of surveillance, you would still miss it because people wouldn't recognize the person in front of them, what they had, because there's no name for it. You may have talked to some of these

people and they have all kind of terms.

So your question about our surveillance system, the answer is it depends on how fine you want to grind the grain, all right? Our surveillance system can obviously pick up and did, according to this, a lot of the major adverse events related to these vaccines because our health care system is so fragmented.

In the U.S., it's much more difficult to find the less likely things. So there's quite a bit of reliance on other health care systems where they know the status of every individual. And frequently the safety staff at FDA have gone to other countries for vaccines to look for those things.

Q Thank you.

Mr. Spectre. We are just about out of time, so we can go off the record.

[Recess.]

[redacted]. Back on the record. One quick question for me and it's a factual question.

BY [redacted].

Q My understanding, is it right that back on the BLA, the Pfizer BLA that Dr. Gruber signed the final BLA for the Pfizer vaccine; is that right?

A That's my understanding.

Q And is it also right that that fact has some sort of regulatory significance, basically an endorsement or something like that? Could you explain your understanding of that?

A That's correct. It's actually in the FDA regulations, and if you don't agree with everything that you're signing to, you have to write a different memo or you should not sign that.

Q Great. Thank you.

BY [redacted].

Q So, Dr. Woodcock, I just wanted to follow on to something that my Majority colleagues were discussing, which is instances of vaccine-related adverse events or vaccine injuries.

Just to clarify for the record, do you agree that adequate and comprehensive compensation for individuals who experience rare but serious adverse events relating to vaccines is an important element of promoting confidence in vaccines?

A I agree with that.

Q Would you care to elaborate on why that is?

A Because any medical intervention will cause some harm as well as some -- as well as major benefit. So the statutes say safe and effective, but safe really means relative to the magnitude of the benefit, not without any harm.

So people who are taking vaccines are not only protecting themselves but doing it to protect others, and so forth. And my understanding is the Vaccine Incentive Compensation Act was passed in order to recognize that people can be harmed and to adequately compensate them and protect them.

Q As you were just alluding to, evaluating products for use is an exercise of looking at the safety of the product versus the

safety of outcome for which the product is seeking to prevent or reduce. At the end of the day, people contracting COVID-19 are experiencing adverse health outcomes including myocarditis and other complications at greater frequency and at greater severity than instances of vaccine-related injuries or adverse events; is that correct?

A That's correct.

Q I briefly want to revisit a few of the exhibits that the Majority introduced in the last round. If we could start with the Lancet paper which is Majority Exhibit 7.

A 'Considerations,' uh-huh.

Q And I actually wanted to focus in on a statement that you had sort of highlighted in the previous round. It is that last paragraph on the first page here. I will read it for the sake of the record. It states, "Current evidence does not, therefore, appear to show a need for boosting in the general population, in which efficacy against severe disease remains high."

Now, in our first round of questioning from the Minority side, we discussed the various processes that were in place through the FDA approval and authorization processes relating to maximizing consumer safety and insulating these processes from political interference.

As I understand it, one aspect of these processes is the convening of the advisory committees, and in this instance that was the Vaccines and Related Biological Advisory Committee or VRBPAC. Is that correct?

A Yes, that's correct.

Q So when VRBPAC was convened to evaluate the EUA for the booster, ultimately VRBPAC did not recommend that the booster be applied or administered across general populations. Rather, it recommended that the booster be recommended for a narrower set of populations, elderly individuals and people with immunocompromised status or immune complications; is that correct?

A That's correct.

Q So, functionally, what we are seeing here in the Lancet paper by Dr. Krause, Dr. Gruber, and others, that suggestion is not what FDA ultimately proceeded with, consistent with VRBPAC's advisement?

A That's correct.

Q Thank you. I also wanted to briefly revisit Majority Exhibit 10. This is the Sentinel document.

A Yes.

Q And I actually wanted to quickly go back to the paragraph that my Majority colleague was focused on, which is in a slight shade of blue on page 6.

A Okay.

Q If you would like to take a moment just to sort of refamiliarize yourself with this paragraph, please do, and let me know when you're ready.

A I'm ready.

Q So four or five lines into this paragraph, there is a

clause that reads, "the CBER Sentinel data sources are not sufficiently powered to assess the magnitude of risk for the 12-30 years old" population "that has been reported in VAERS in an epidemiology study."

So to paraphrase that, but would you agree that is what that statement says?

A Yes.

Q So in epidemiology and in statistics, when we are discussing power, we are discussing the ability of a methodology working with a dataset to detect an adverse outcome or an incident, basically to reject a known hypothesis.

A Yes.

Q Is that correct?

A That's correct.

Q So we see later in this paragraph, there are a few different sentences, one of which is referencing, I'll quote here, "CBER Sentinel data sources do not have sufficient longitudinal data on patients to conduct this type of analysis."

In the preceding sentence, it's referencing that a minimum follow-up time of three to six months is required to assess and adequately capture long-term sequelae. Do you agree with that characterization of this paragraph?

A Yes.

Q So when we're talking about the power of a data source and a statistical analysis to detect an adverse outcome, of course longitudinal data, adequate data is necessary to have a powerful enough

statistical exercise to reach a conclusion; is that correct?

A Well, it's more like the number of events.

Q Right.

A To reach a conclusion.

Q Right. And so at the end of the day, the fact that the myocarditis outcome may not be detected or the CBER Sentinel Program is not sufficient to identify outcomes of myocarditis and pericarditis due to the reasons identified on the preceding page, that is not necessarily a commentary on the Sentinel Program as an apparatus. Rather, it is a commentary on the data that is available, the frequency and the outcomes and the combination at which those two phenomenon will allow the Sentinel Program to detect rare but serious adverse outcomes like myocarditis and pericarditis?

A Yes. The Congress told FDA in the FDA Amendments Act that they had to assess the ability of Sentinel Program writ large to adequately monitor an adverse event prior to putting in place a requirement on the company that they have a registry or some other type of post-market study, feeling that the active surveillance, you know, taxpayers have paid for that, and it will be sufficient for certain things.

So this was assessing the sufficiency of an active surveillance system to detect and monitor these adverse event outcomes and determine that Sentinel alone would not be sufficient.

Q And then just on the point about long-term data necessary to evaluate, detect, and react to long-term sequelae. We heard in the

previous round that other nations had greater success in identifying more early -- or earlier some of these adverse health outcomes. For example, in Israel, you had nodded to the fact that nationalized health insurance or a less fragmented health care program in the United States would facilitate that.

Would you also agree that issues relating to collecting sufficient longitudinal data to assess sequelae outcomes like serious myocarditis and pericarditis were delayed by the fact that we at initial points in deploying the vaccine did not have the rapid infrastructure to get it out immediately to people, such that in the opening months of the vaccine being available, there were some delays in people getting appointments, getting their first doses and second doses?

A I can't comment on that.

Q Okay.

[redacted]. I think we can go off the record.

[Pause.]

BY MR. SPECTRE.

Q Back on the record. We are going to pick up with a few more questions about adverse events associated with COVID-19 vaccines.

Firstly, you are quite familiar with the VAERS system of adverse reporting system; is that right?

A I'm familiar with it.

Q I am going to introduce 12 Majority Exhibit 12.

[Majority Exhibit No. 12 was

identified for the record.]

BY MR. SPECTRE.

Q This is a British Medical Journal investigation published in November 2023. It is titled, "Is the US's Vaccine Adverse Event Reporting System broken?"

Have you seen this article before?

A I have not.

Q Then I will give you a second to take a look at it. But I would first point you to the first heading, Understaffed, where it says that VAERS is comanaged by the US Centers for Disease Control and Prevention and the Food and Drug Administration.

What is the FDA's role in managing VAERS, as far as you're aware?

A I'm not exactly sure of the relationship between CDC and FDA in managing VAERS, I'll be honest.

Q That’s okay.

A I set up FAERS, but I never actually deeply involved myself in VAERS.

Q Okay. Under the next header, which is at the bottom of the back of the first page, The User Experience. It discusses an instance where a doctor submitted a VAERS report in 2022 for a seven-year-old boy who had a cardiac arrest after COVID vaccination, the boy died a week later, but the doctor was unable to update the report in VAERS.

Why don't you just look at that for a second.

I can give you additional time to read it, but just for context,

Dr. Whelan appeared at the Select Subcommittee's hearing on March 21st, and testified that nobody at CDC or FDA followed up about this instance of this 7-year-old boy until he brought it to Dr. Marks' attention directly and then was ultimately able to meet with staff members at the FDA.

Are you familiar with that case with Dr. Whelan?

A I am not.

Q So I assume you are not involved with that meeting; is that correct?

A No, I was not.

Q Dr. Whelan also testified that VAERS indicates that the boy's injury was a cardiac arrest and gives no clue to the ultimate outcome and VAERS is not set up to acknowledge a change in outcomes like this.

And you mentioned already that you were involved in the creation of FAERS, is that right?

A Yes.

Q And FAERS is set up to acknowledge changes in an individual report; is that correct?

A Yes, serial reports is my understanding, but yes.

Q Are you aware whether -- are you able to verify that VAERS is not able to set up --

A I am not.

Q If it is not, as Dr. Whelan has reported and as this article from the BMJ indicates, should VAERS be set up to acknowledge

changing outcomes the way that FAERS is?

A Ideally, any adverse -- any spontaneous reporting system should be able to keep up to date on the status of the case, and help people report and provide updates.

Q Do you know how many FDA staff are responsible for following up on serious VAERS reports?

A No.

Q Dr. Daniel Jernigan, CDC's director of the National Center for Emergency and Zoonotic Infectious Diseases, testified to the Select Subcommittee that, "Every serious adverse event in VAERS is followed up, medical records are collected and autopsy records are collected to identify that."

To your knowledge, is every serious adverse event in VAERS followed up on?

A Sorry, I don't have knowledge of that.

Q Thank you. If you look back on the BMJ investigation, the heading that says Two VAERS - only one public. It's on page 4.

A Mm-hmm.

Q I will give you a second after I read this quote, but it explains that, "FDA and CDC essentially maintain two separate VAERS databases: a public facing database, containing only initial reports; and a private, back end system containing all updates and corrections - such as formal diagnosis, recovery, or death."

A Okay.

Q And as you mentioned, you don't have a lot of direct

knowledge of VAERS, but do you know if that is accurate?

A Honestly, I don't know the administrative aspects of VAERS. I just don't.

Q Okay. Thank you. And then the third paragraph from the bottom. Let me read this quote to you, and then I will find the actual document here.

A Okay.

Q But a physician called Helen, for the purpose of the article, argues that there is a "negative feedback group" whereby "the FDA is not naming additional adverse reactions to vaccines because the passive surveillance systems aren't displaying it. But the passive surveillance systems aren't displaying it because physicians are blinded to the adverse reactions in their patients, and thus aren't reporting them."

Are you familiar with this negative feedback loop idea?

A I don't understand this statement. Physicians are blinded to the adverse reactions in their patients?

Q I was curious, and the reason I bring it up to you is because I'm curious of your thoughts about this topic. And you mentioned a little bit earlier, where physicians are having a hard time identifying conditions because the symptoms are not strongly associated with a particular disease or outcome, right? Is that maybe what this doctor called Helen is referring to there?

A I have no idea what she is referring to. That's why I said, it's a very confusing sentence to me. I don't know what that

means.

Q Okay. Just switching gears a little bit, are you familiar with the case of Maddie de Garay?

A I know about it.

Q Who is she, to your recollection?

A A minor who was in a trial of the COVID -- Pfizer COVID vaccine.

Q And do you remember when you were first made aware of her condition?

A No.

Q I will introduce Majority Exhibit 13.

[Majority Exhibit No. 13 was identified for the record.]

BY MR. SPECTRE.

Q If you would flip to the page marked FDA 2022, 4101, it ends with 133. I believe that's a little hard to read also because it's red on black, but it's the first page that looks like an email.

A Okay. All right.

Q You'll see an email from Patrick de Garay which was forwarded to you on June 25, 2021 by Steve Kirsch regarding Maddie de Garay condition. The email from Patrick de Garay to Steve says, "Steve, been a little crazy here since Maddie's last MRI, she's struggling to hold her head up and can't stand on her own. Stephanie will resend the folder today."

Do you recall receiving this email?

A I don't.

Q You replied, "I forwarded the last email you sent to the team, and of course, FDA evaluates every serious adverse event related to a clinical trial, and intensively if in a healthy population."

I assume that by "in a healthy population," a minor who was otherwise healthy.

A Preventive, yeah.

Q Is that what you meant by that?

A I meant, generally speaking, clinical trials of people are treating an illness, they're sick. Here, you're treating generally healthy -- intervening to prevent something.

Q That makes sense. So you said "FDA evaluates every serious adverse event." What kind of evaluation was done in this case, if you can recall?

A My question is, to what extent am I allowed to talk about this due to HIPAA?

Q These emails were released under FOIA.

A But you're asking me to expand on that.

Mr. Cooke. If you're not sure that you can answer the question --

The Witness. Just very generally.

Mr. Cooke. I think ultimately, if you know that you can't speak to things that are covered by HIPAA, I think you should not speak to those things.

The Witness. I would say I forwarded this. So people were aware

of this case. They had intensively investigated it. They had been in contact with the treating physician, which is the typical way, and been having conversations.

As usual, I stayed out of it in the sense that it was being handled in the ordinary way that these types of things would be handled.

BY MR. SPECTRE.

Q Thank you. On the next page, down to 134, this email from Doran Fink at 9:32. My apologies, that email is on the following page that ends in 135. That is an email at 9:32 a.m. from Doran Fink.

Mr. Cooke. Bottom of the page.

The Witness. Okay.

BY MR. SPECTRE.

Q Dr. Fink asks for an update on where things stand on Maddie de Garay case, so he can "get back to Peter Marks and Janet Woodcock."

Donna Boyce replies at 9:49 a.m., confirming that Maddie was a participant in the Pfizer group COVID-19 trial. She also said that, "Dr. Alejandra Gurtman spoke with Dr. Frenck who is the Principal Investigator at Cincinnati's Children's today and confirmed that this case is not related to the vaccine, and that the participant had extensive work up with consultations with various specialties, including pulmonary, neurology, pain management, and psychiatry with no findings of anything organic."

Dr. Fink eventually forwards the information from Pfizer to

Dr. Marks who forwards it to you. You reply, "Thanks," at the top of the page there.

Do you happen to recall these emails?

A Yes, I recall that they got back to me that there had been this activity, mm-hmm.

Q Thank you. Did FDA conduct any further evaluation of this case?

A I can't say specifically.

Q Because you don't know?

A I asked them to also talk to the investigator themselves. I do not know the follow-up from that. I received verbal follow-up, I think, from Peter that this had been evaluated further.

Q And generally speaking, the FDA would want to evaluate further than just taking this email at face value; is that correct?

A Yes, for something serious in a clinical trial.

Q And you believe that that occurred in this case?

A Yes. Well, it says, "It was also presented to the ACIP working group and many other recommending bodies," yeah. But, yeah, usually we would get the records ourselves or we talk to the investigator. I believe that occurred.

Q So you do believe that FDA sufficiently evaluated this case?

A To the extent that FDA could. FDA cannot go and do scans themselves and so forth. We have to take the -- I saw more records, okay, of this. We have to take the assessment of the treating

clinicians.

Q Can you say what the FDA's official determination was in this case?

A No, I can't.

Q But it made an official determination?

A I don't know what an official determination is. I think they evaluated the -- they evaluated the workup that had been done by the treating clinicians in this case.

Q So the FDA did, in some way, evaluate whether there was a causal relationship between the vaccine and Maddie de Garay condition?

A Yes.

Q And you're just not able to share that because you don't recall or because it's private?

A Based on the workup that was done by the patient's doctors.

Q I think you've already said that it was common for you to interact with members of the public regarding vaccines; is that correct?

A Yes.

Q So this isn't an uncommon interaction you had here?

A Not uncommon at all.

Q Can you remember other specific instances that you spoke with people about?

A Certainly. I had many, many people who had various concerns or reactions. I usually would send them to the team. I would

follow up with Doran Fink or with other members, depending on what the case was, Steve Anderson or whatever, make sure they had followed up on what I sent them, so I could get back to the people who had written in to me, and say, I looked into this, it's being evaluated or worked up or handled.

Q Okay. Thank you very much.

A That was part of my job, I think.

Q Certainly.

Mr. Spectre. Well, thank you. We can go off the record with that.

[Whereupon, at 3:20 p.m., the taking of the instant interview ceased.]