COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY,

SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC,

U.S. HOUSE OF REPRESENTATIVES,

WASHINGTON, D.C.

INTERVIEW OF: ERIK STEMMY

Monday, November 13, 2023

Washington, D.C.

The interview in the above matter was held in Room 3400, O'Neill House Office Building, commencing at 10:01 a.m.

Present: Representative Wenstrup.

Appearances:

For the SELECT SUBCOMMITTEE ON THE CORONAVIRUS PANDEMIC:

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MARTA COOK, SENIOR ADVISOR FOR OVERSIGHT,
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Mr. Benzine. This is a transcribed interview of Dr. Erik Stemmy conducted by the House Select Subcommittee on the Coronavirus Pandemic, the Committee on Oversight and Accountability, and the Committee on Energy and Commerce, under the authority granted to them by House Resolution 5, House Rule X, and the rules of the Committee on Oversight and Accountability and Committee on Energy and Commerce.

This interview was requested by Chairman Brad Wenstrup, Chairman James Comer, Chair Cathy McMorris Rodgers, Chairman Morgan Griffith, and Chairman Brett Guthrie as part of the committee's oversight of the Federal Government's response to the coronavirus pandemic.

Pursuant to House Resolution 5, the select committee has wide-ranging jurisdiction, but specifically to investigate the origins of the coronavirus pandemic, including but not limited to the Federal Government's funding of gain-of-function research.

Pursuant to House Rule X, the Committee on Oversight and Accountability has jurisdiction to investigate any matter at any time, and pursuant to House Rule X and XI, the Committee on Energy and Commerce has jurisdiction for Public Health Service agencies, including the National Institutes of Health and the entities it funds, as well as Federal biomedical research and development.

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

Dr. Stemmy. Yes. Dr. Erik Joseph Stemmy. S-t-e-m-m-y.

Mr. Benzine. Thank you.

Dr. Stemmy, my name is Mitch Benzine, and I am the staff director for the majority staff of the select subcommittee, and 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 present with you today?

Dr. Stemmy. I do not.

Mr. Benzine. Is there an attorney present representing your employer?

Dr. Stemmy. Yes.

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

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

Mr. Benzine. For the record, starting with the remainder of the majority staff, can the additional staff members please introduce themselves with their name title and affiliation? And we'll just try to go in a circle.

Mr. Strom. John Strom, senior counsel, Energy and Commerce, Oversight and Investigations Subcommittee.

Mr. Osterhues. Eric Osterhues, chief senior counsel, majority, select subcommittee.

Dr. Wenstrup. Brad Wenstrup, chair of the Select Subcommittee on the Coronavirus Pandemic.

Ms. Brewer. Madeline Brewer, counsel for the majority, Subcommittee on Coronavirus.

Mr. Cipollone. Joseph Cipollone, counsel for the majority, Select Subcommittee on the Coronavirus Pandemic.

[redacted], [redacted], select subcommittee, minority counsel.

[redacted], [redacted], senior counsel, Oversight and Investigations, Energy and Commerce.

[redacted], [redacted], chief minority counsel for the select

subcommittee.

[redacted]. [redacted] minority senior counsel for the select subcommittee.

[redacted]. [redacted], chief counsel for Energy and Commerce, Oversight and Investigations, minority.

Mr. Slobodin. Alan Slobodin, chief investigative counsel, majority staff, House Energy and Commerce Committee.

Ms. Cook. Marta Cook, senior advisor for oversight at NIH.

Mr. Rechter. Peter Rechter, deputy assistant secretary for legislation at HHS.

Mr. Benzine. Thank you all.

Dr. Stemmy, before we begin, I would like to go over the ground rules for this interview.

The way this interview will proceed is as follows: The majority and minority staff will alternate asking you questions, 1 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 the staff for each side may lead the question, 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 each question before you begin your answer, and the staffer will wait until you finish your response before proceeding to the next question.

Further, to ensure the court reporter can properly record this interview, please speak clearly, concisely, and slowly. Also, the court reporter cannot record 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. Minority exhibits will be identified alphabetically. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. We want you to answer our questions 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. We will attempt to clarify, add context to, or rephrase our questions. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. 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 a conversation or event, you should give us your best recollection of those events or parts of conversations that you do recall. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. 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?

Dr. Stemmy. Yes.

Mr. Benzine. If at any time you knowingly make false statements, you could be

subject to criminal prosecution. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. Is there any reason you are unable to provide truthful testimony in today's interview?

Dr. Stemmy. No.

Mr. Benzine. 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 statement 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 being asserted and the reason for the assertion on or before the scheduled date of testimony or appearance. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. Ordinarily, we take a 5-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 will be happy to accommodate. However, to the extent that there is a pending question, we would ask that you finish answering the question before we take the break. Do you understand?

Dr. Stemmy. Yes.

Mr. Benzine. Do you have any other questions before we begin?

Dr. Stemmy. No.

EXAMINATION

BY MR. BENZINE:

Q All right. Thank you again for being here.

I want to start going through your education and experience up until now. Where did you attend undergraduate school?

A I attended Dickinson College in Carlisle, Pennsylvania.

Q And what degree did you graduate with?

A A bachelor's of science in biology.

Q Have you also received a master's degree, and where, and in what?

A I have. I earned a master's degree in microbiology with a focus on science policy and advocacy at Georgetown University.

Q And where did you receive your doctorate?

A The George Washington University.

Q And in what focus or concentration is your doctorate in?

A Immunology.

Q Who is your current employer?

A The National Institute of Allergy and Infectious Diseases.

Q And your current job title?

A Program officer and team lead for the Centers of Excellence for Influenza Research and Response network.

Q Can you briefly elaborate on what your current role and responsibilities are?

A My main responsibilities are the oversight and management of our Centers of Excellence for Influenza Research and Response, or CEIRR network, which is a global network focusing on understanding how influenza viruses emerge, transmit, and cause disease.

Q And then can you run through your career specifically at NIH up until now?

A Yes. I joined NIH following my doctoral degree in 2011 to the Respiratory Diseases Branch of the Division of Microbiology and Infectious Diseases. I am still in that

same branch today, and I have held several roles over the years beginning with product development specialist, moving into program officer, and then now to team lead for the CEIRR network.

Q For the primary period of time that we're discussing, 2019ish until -- we'll put the end of the pandemic at, like, the end of 2022 or so -- what was your title and responsibilities?

A So my title changed towards, I think, 2021 when I became the team lead.

Q Okay.

A An individual left our group, and I assumed the responsibility of the CEIRR network and transitioned away from the main program officer responsibilities.

Q Can you explain the roles and responsibilities that you had as a program officer?

A Yes. So program officers are responsible for the scientific management of NIH grants and contracts. It involves reviews of annual progress reports, ensuring adequate scientific progress is being made, and interacting with investigators that are interested in receiving NIH funding.

Q In that role, do you make funding decisions?

A I do not.

Q Do you recommend any funding decisions?

A I do -- so we can advocate for specific grants, but program officers do not. The institute leadership and advisory council makes the funding decisions.

Q All right. Do you currently hold or have previously held any honorary positions, including any academic positions?

A No.

Q Do you currently hold or have you previously held any positions on boards of

companies, nonprofits, or otherwise?

A No.

Q How long were you in the program officer role?

A I became a program officer approximately 2013 and was the program -- my main role as program officer continued through, I believe, August of 2021. I maintain the program officer title at the moment because of the management and oversight of this award to EcoHealth.

Q Okay. And, in your role as program officer, you've managed the 2014 EcoHealth award and then its annual renewals --

A Correct.

Q -- up until 2020, and then started managing it again August-ish?

A Correct.

Q All right. In that role, who would you report to?

A In what way?

Q Who was your direct supervisor?

A My direct supervisor is the section chief for the viral respiratory diseases section.

Q And who is that?

A Dr. Diane Post.

Q All right. How much of that job -- so you said it was the scientific management of grants. I don't want to, like, split hairs, but I want to understand kind of how that differs from, like, regular management of grants.

Can you explain that a little bit, how the scientific management differs from maybe the financial management?

A Yes. So the way it works at NIH is there is the business side of the awards

and the scientific side of the awards. The grants management office is in charge of managing all of the business, the budget pages, policy that relate to the financial aspects of the award.

Program officers are responsible for the scientific aspects and tracking the scientific progress and addressing any scientific concerns that may come up with the investigators.

Q Would that include placing scientific-specific award conditions on the grants?

A So placing specific terms of award is the role of grants management.

Q Okay. Would you recommend specific terms of award to the grants management if they were science-driven?

A We would be considered -- consulted and provide input on potential terms of award if they were scientific.

Q Can you really briefly -- because I know it varies a lot and can go from a year to, like, 10 years -- can you walk us through the standard lifecycle of a NIAID grant?

A So the majority of awards are -- I guess I'll just focus on R01s. They are one of the most common.

They are a 5-year award. An investigator prepares an application. It's submitted, for the most part -- except under special circumstances -- it's submitted to the Center of Scientific Review at NIH, which coordinates the peer review of the applications that come in.

Once an application is submitted, program staff are not involved in the peer-review process and generally don't interact with the reviewers, the scientific review officers, or the investigators until a summary statement is issued following a peer review.

Once a peer review is completed, it's assigned -- for R01s, anyway -- it's assigned a

score and a percentile. And at NIAID, our awards are based on percentile pay lines. And so, when a score and percentile are set, you can generally have an idea of the likelihood of a potential award being funded.

Once that happens, there is an administrative process for grants management to go through to the budget office. The grant's funding is then released. Once funding is released by the budget office, program staff then complete administration of checklist reviews and ensures all of the required policy things -- regarding human subjects, for example, or animal subjects -- are met.

And then, once that checklist is completed, grants management then issues an award.

Q And then, as the award goes further, how do you oversee it? Is it strictly through progress reports, or do you have kind of, like, a 6-month check-in? A monthly check-in?

A So, for the most part, it's the annual progress reports or RPPRs that are submitted. That's the main way that program officers monitor scientific progress.

Sometimes, there are problems that arise with different -- you know, for example, human subjects. If there's an issue with an IRB approval, we can help navigate if there's issues for investigators. But, for the most part, progress is through the RPPRs.

Q Are there any policies or standards in what the annual reports have to contain?

A Yes. So the NIH Grants Policy Statement includes the requirements for each of the sections of the RPPR.

Q Does it require they publish every experiment that they conducted during --

A It does not, to my knowledge, no.

Q I'm going to shift gears a little bit and ask you --

Mr. Strom. Can I --

Mr. Benzine. Yeah.

BY MR. STROM:

Q Just so I understand, you made the change from program officer to team lead in August of 2021?

A Yes.

Q And was that a promotion or a lateral move?

A It was a lateral move.

Q Okay. And are you title 42 --

A No.

Q -- special consultant or the other --

A I am not.

Mr. Strom. Okay. That was it.

BY MR. BENZINE:

Q Okay. It's a long list of names, and I just want to ask you, yes or no, if you've spoken to any of these people from December 2019 until present regarding COVID-19, the origins of COVID-19, EcoHealth Alliance, or the Wuhan Institute of Virology.

A So can you clarify? When you say "COVID-19," do you mean anything related to coronavirus?

Q We can stick to, like --

A Do you mean specifically?

Q Specifically origins, but there's some that you might have spoken to about COVID-19 that -- if you want to clarify that when you answer, we can decide if we need to dive any deeper.

Mr. Rechter. We can say "the official business" regarding --

Mr. Benzine. Yes. Official business. Yeah. It's not, you know, texting about whatever. But, yes, official business.

BY MR. BENZINE:

Q Dr. Francis Collins?

A Yes.

Q Dr. Anthony Fauci?

A Yes.

Q Dr. Lawrence Tabak?

A Yes.

Q Dr. Hugh Auchincloss?

A Yes.

Q Dr. Cliff Lane?

A No.

Q Dr. David Morens?

A No.

Q Dr. Ping Chen?

A Yes.

Q Dr. Ian Watson?

A No.

Q Dr. Andrew Pope?

A I'm sorry. Could you repeat that?

Q Andrew Pope.

A No.

Q Dr. Victor Zhao?

A No.

Q Dr. Robert Redfield?

A No.

Q Dr. Michael Lauer?

A Yes.

Q Dr. David Christian Hassell?

A No.

Q Dr. Jeremy Farrar?

A No.

Q Dr. Kristian Andersen?

A No.

Q Dr. Michael Farzan?

A No.

Q Dr. Eddie Holmes?

A No.

Q Dr. Ian Lipkin?

A No.

Q Dr. Andrew Rambaut?

A No.

Q Dr. Christian Drosten?

A No.

Q Dr. Ron Fouchier?

A I have interacted with Dr. Ron Fouchier. I don't recall any interactions about COVID origins.

Q Would it have been about the ferret experiment prior to the gain-of-function

pause?

A So Dr. Fouchier is part of the CEIRR network that I manage. So most of my interactions were in that context.

Q Okay. Dr. Marion Koopmans?

A No.

Q Dr. Peter Daszak?

A Yes.

Q Dr. Aleksei Chmura?

A Yes.

Q Dr. Kevin Olival?

A No.

Q Dr. Michael Worobey?

A Yes.

Q What were those interactions?

A So I organized a -- as part of my coronavirus management responsibilities, I help manage our SARS-CoV-2 assessment of viral evolution program, and Dr. Worobey has been part of those calls.

Q Okay. Dr. Jonathan Pekar?

A No.

Q Dr. Florence Debarre?

A No.

Q Dr. James LeDuc?

A No.

Q Dr. Shi Zhengli?

A No.

Q Dr. George Gao?

A No.

Q Dr. Ralph Baric?

A Yes.

Q Dr. Ben Hu?

A No.

Q Dr. Lanying Du?

A I have interacted with Dr. Du in my coronavirus portfolio management, but I don't recall direct coronavirus or COVID interactions with her.

Q What were the coronavirus portfolio management?

A So she had a few grants that were in my coronavirus portfolio. I think they were vaccine-specific. Developing vaccines for MERS and other coronaviruses.

Q While she was at the Blood Center?

A Yes. I managed her awards.

Q Dr. Zhou Yusen?

A No.

Q Do you remember who -- I'm going to go back to a couple.

Mr. Rechter. And this is real quick.

For the record, that's all to the best of your recollection, correct?

Dr. Stemmy. Correct.

BY MR. BENZINE:

Q I'm going to go back to a couple.

But, on Dr. Du, do you remember who the subawardees were for those vaccine grants?

A I don't recall the exact subawardees. I know she had other collaborators,

but I don't recall if they were official subawards or not.

Q Do you recall any of the collaborators? Were any of them in China?

A I don't recall anyone in China, especially after -- you said 2019?

Q Yeah.

A Yeah. I don't recall anyone after 2019, no.

Q What about before?

A She had a -- when I managed her award, she did have a collaborator in China who had passed away and was no longer involved in the award, but that was quite a while before 2019.

Q Okay. So I'm going to start at the top of the list and ask about what the conversations you worked with certain individuals were.

To the best of your recollection, what did you talk to Dr. Collins about?

A I spoke with Dr. Collins more on sort of briefing calls about the pandemic. I would answer some questions that came up. I wouldn't interact with him one-on-one in any way. It was more just group briefings so he could understand the status of the pandemic response.

Q Can you get a little more specific on what the questions were? Was it EcoHealth-related, or was it pandemic-at-large-related?

A Yeah. So some of them were EcoHealth-related. Potentially -- actually, I think they were mostly related to Dr. Fauci testifying. So there was information I provided about the status of the award.

Q And then Dr. Fauci, same sort of situation?

A Yes. With Dr. Fauci, it was mostly in the process of briefing him for testimonies.

Q Okay. Dr. Tabak?

A The same thing.

Q Dr. Auchincloss?

A The same thing.

Q We'll get to -- I'll ask more specific questions about Dr. Chen.

Can you talk about your conversations with Dr. Lauer?

A So, with Dr. Lauer, it was more peripheral, but he was part of some of these sessions with Dr. Fauci for prepping and also through some of the terms and conditions of the award, but that was much later.

Q Did you have any one-on-one meetings with Dr. Lauer?

A I don't recall any one-on-one meetings with Dr. Lauer.

Q Okay. I'll ask more specifically about Dr. Daszak.

Dr. Chmura, was it just within the oversight of the EcoHealth grant?

A Yes.

Q All right. Same overarching question in your interaction regarding origins of COVID, EcoHealth, or the WIV, but with these entities.

Did you ever have direct communication with the Wuhan Institute of Virology?

A No.

Q The Wuhan Centers for Disease Control and Prevention?

A No.

Q The Chinese Centers for Disease Control and Prevention?

A Not regarding the COVID-19 pandemic, no.

Q All right. Wuhan University?

A No.

Q The Chinese Academy of Sciences?

A Not regarding the COVID-19 pandemic.

Q The Academy of Military Medical Sciences?

A No.

Q Okay.

Mr. Rechter. Sorry.

For the record, to the best of your recollection, those are your answers?

Dr. Stemmy. Correct.

BY MR. BENZINE:

Q Last little group of people, I promise, and then we'll move on.

Mr. Cooke. We'll say preemptively, to the best of your recollection.

Dr. Stemmy. Yes.

BY MR. BENZINE:

Q Some group of names before, but answer, again, to the best of your recollection whether you communicated with these people on a personal email or personal cell phone regarding these issues.

Dr. Collins?

A No.

Q Dr. Fauci?

A No.

Q Dr. Tabak?

A No.

Q Dr. Auchincloss?

A No.

Q Dr. Lane?

A No.

Q Dr. Morens?

A No.

Q Dr. Chen?

A No.

Q Dr. Watson?

A No.

Q Dr. Pope?

A No.

Q Dr. Zhao?

A No.

Q Dr. Redfield?

A No.

Q Dr. Lauer?

A No.

Q All right. Moving -- sticking with kind of communications but getting a little bit more specific, specifically to EcoHealth, who was your primary contact at EcoHealth while you were managing their grant?

A For what aspect?

Q If you had a question about one of the scientific aims in the grant, who would you contact?

A I would contact Dr. Daszak but also copy Dr. Chmura.

Q Okay. How often during the course of overseeing that grant were you in contact with EcoHealth?

A I don't think I could say, you know, an exact number. I would probably say a few times a year.

Q Okay. Have you ever worked with EcoHealth outside of your capacity at

NIAID, like, coauthoring a paper?

A No.

Q Have you met EcoHealth President Dr. Daszak?

A Yes.

Q And in what capacity did you meet him?

A He -- over the course of managing his awards, we've met at scientific meetings. He's been to the NIAID building on Fishers Lane for meetings where we've met there.

Q Okay. How long have you personally known him? Was it just within the scope of the grant?

A Yes.

Q Can you speak very briefly -- and we'll ask more specific questions as we get along.

But, in your experience, is EcoHealth a grantee that's easy to work with? Difficult to work with? Can you kind of characterize their cooperation?

A They are generally a very responsive organization. They are always willing to provide additional information if necessary. And so I've never had any issues interacting with them in that capacity.

[10:26 a.m.]

Mr. Benzine. All right. I'm going to, like I said, talk a little bit more specifically about some of these communications and introduce our first exhibit.

And I know I've asked before. It's not Bates-marked. It's from a FOIA production.

[Stemmy Majority Exhibit No. 1
Was marked for identification.]

BY MR. BENZINE:

Q And it is an email chain between yourself and Dr. Daszak. It begins on January 6, 2020, on an email that starts on the very, very bottom of the second-to-last page.

A Sorry. Just flipping through.

Q Yeah. No problem. Take your time.

A Okay.

Q So the email -- the from line that's on the bottom of the second-to-last page, January 6, at 7:30 in the morning, to Dr. Daszak, and you write to him and ask for -- if he has any more information on, at that point, the novel coronavirus outbreak from any of his colleagues in China.

And the next email up from Dr. Daszak, he responds, "Definitely focusing attention on this, Erik. I spent New Year's Eve talking with our China contacts and with ProMED staff between glasses. I've got more information, but it's all off the record. Could I give you a call tomorrow to fill you in? I've cc'd Alison Andre who can arrange a time that works for a quick call."

Did this call take place?

A Yes.

Q To the best of your recollection, what was discussed on this call?

A So, to the best of my recollection, I don't exactly remember every sentence that was said. But we were interested in understanding if there was any information that he was able to provide about the pneumonia or the coronavirus that was preliminarily identified at that point.

Q Did he provide you any information?

A Generally, yes. It was not -- there weren't a lot of details that I recall being available at the time.

Q Did he ever explain why it had to be off the record?

A He did not.

Q Did you treat it as off the record?

A So we -- internally, we shared it with my branch chief. Alan is the person that's referenced there.

Q Okay.

Mr. Benzine. I want to introduce what will be majority exhibit 2.

[Stemmy Majority Exhibit No. 2
Was marked for identification.]

BY MR. BENZINE:

Q While that's going around, I'll give a second to flip through it.

This is an email chain, and it's Bates-marked SSCP_NIH002924 through 2932. And the primary emails we'll be referencing are on -- the first two pages are from January 9th, 2020. So the day after you had the call with Dr. Daszak.

The bottom email on the first page, I'm going to read to you, even though it's redacted. It's an email from Dr. Chen to you and some others and reads, "If you haven't seen this Wall Street Journal article on the outbreak of the pneumonia in China, here it

is." What's under that redaction is Erik.

And then going on to the second page, she says, "Have you talked to Peter Daszak? His grant funds the coronavirus research in China. Dr. Shi Zhengli in WIV is the expert on coronaviruses. Her work on the coronaviruses in bats in China may allow the quick identification of the virus causing the pneumonia outbreak, assuming Wall Street Journal report is correct."

Do you recall receiving that email?

A Yes.

Q Okay. And then, again, even though it's redacted, you respond and say, "Thanks, Ping. I spoke to Peter yesterday afternoon. He says he doesn't have any new information to share and that his collaborators at Wuhan haven't been sharing any details since Christmas. He did say that the original rumors of a novel coronavirus came from a commercial lab that was used to do initial sequencing leaked the information. Peter said he will let me know if he hears anything else."

Does that summary email accurately characterize your conversation with Dr. Daszak from the day before?

A To the best of my recollection, it does. But specific details, I don't exactly recall.

Q All right. Understanding that China didn't report a case until December 31st but Dr. Daszak said he's been getting information since Christmas, did he provide any more information regarding that delay?

A Not that I recall, no.

Q To the best of your recollection again, did you share everything that Dr. Daszak told you internally?

A I shared the information I received from Dr. Daszak with my branch chief and

section chief.

Q Thank you.

Mr. Benzine. I'm going to introduce majority exhibit 3.

[Stemmy Majority Exhibit No. 3 was marked for identification.]

BY MR. STROM:

Q Just real quick, who were those individuals again? The branch chief and the division chief at the time?

A So the branch chief at the time was Dr. Alan Embry, and my section chief was Dr. Diane Post.

Q Okay. If I understand, your Ph.D. is in immunology. Do you have -- and you spoke about managing mostly the influenza network.

Do you have experience with coronavirus research?

A Yes. So the bulk of my time at NIH, I managed the human basic research coronavirus portfolio.

Q Okay.

BY MR. BENZINE:

Q So this is majority exhibit 3. This is a record of meetings and phone calls produced by Dr. Daszak and Bates-marked EcoHealth Alliance 2 through 3.

In the first 30 days or so of the pandemic, you had three phone calls with Dr. Daszak and a number of others that went on. You had the first one on January 8th that we talked about and another on January 23rd that you can see: 1:45 to 2 o'clock, Erik Stemmy to call.

Do you recall what that phone call was about?

A I don't recall the specific details. At that time early in 2020, NIAID was

really focused on accessing any information that we could on the novel coronavirus, and as an investigator working in that area, Peter was a good contact.

Q And then you had another phone call February 21st, 2020, from 1 to 1:30. The title calendar event is Erik Stemmy, Aleksei, and Hongying.

Do you recall what that phone call was about?

A I don't recall details, no.

Q Throughout your attempts to gain information about the novel pandemic, did Dr. Daszak ever provide any actionable information?

A What do you mean by "actionable information"?

Q The sequence before it was public, any information regarding the outbreak, any information regarding China downplaying cases, downplaying human-to-human transmission, anything that his access in China would have gained that you didn't have.

A I don't recall him providing anything like the sequence or any information like that prior to publication. It was more just things that he was sort of hearing from investigators but not official data or sequences for that information.

Q At the expense of maybe retreading already treaded territory, do you remember any other things that he told you that he was hearing on the ground beyond what was memorialized in the Ping Chen email?

A I don't recall offhand, no.

BY MR. STROM:

Q Do you recall if he talked about the human-to-human transmission?

A I don't recall specifically. I don't recall. I mean, I think if -- it would have come up on the conversations. It sounds likely. But I don't recall specifics.

BY MR. BENZINE:

Q What about asymptomatic transmission?

A Again, I don't recall those specifics from 2020.

Q I'm going to get into some questions, and if you don't know the answer or if it's outside of your expertise, outside of what you feel comfortable answering, just say so, and we'll move on.

In your experience and your education, is investigating the origins of COVID-19 important?

A Sorry. Could you --

Q Using -- you're an immunologist and a biologist. Is investigating the origins of a pandemic important?

A Are you asking my opinion if it's important?

Q Yeah.

A I think it's important to understand where any zoonotic virus has emerged from.

Q Why?

A Because understanding zoonotic emergence is a way to enhance our pandemic preparedness and be prepared for other events.

Q Currently, is the origin of COVID-19 unsettled?

A Are you asking my personal opinion?

Q Uh-huh.

A My personal opinion is that the preponderance of evidence indicates a zoonotic origin.

Q Okay. Speaking to generally how a novel virus may appear, how did the origins of a virus inform preparing for a next possible pandemic?

A What do you mean by "origins of a novel virus"?

Q If it was -- if the index case was from a farmer in a bat cave versus a wet

market versus a laboratory, how does the different possible pathways of emergence help inform preparing for future pandemics?

A So, generally speaking, in preparing for future pandemics, you need to have an understanding of the viruses that are circulating in wild populations, and then also an understanding of the humans that are interacting with those animals. The human-animal interface is what we call it. And so understanding those viruses and characterizing them is sort of the first step in preparedness.

Q So doing kind of mass surveillance testing?

A Surveillance and characterization, yes.

Q Have there been other zoonotic pandemics or epidemics recently?

A Yes. Well, recently --

Q We'll hit the big coronavirus ones.

Have there been other large coronavirus pandemics?

A Well, yes. SARS-CoV-1 and MERS-CoV.

Q To the best that you can recall, how many cases worldwide did SARS-1 have?

A I don't recall. A couple thousand. In that neighborhood, I believe. I don't recall the exact number.

Q What about MERS?

A I haven't seen the most recent MERS numbers, but it's probably on a similar scale. Several thousands.

Q And then do you know the current number for COVID-19?

A Offhand, I do not.

Q Is it larger than SARS and MERS?

A It is.

Q In your experience, why do you think there's such a large difference in cases

between SARS-1 and SARS-2?

A I would have to say the differences in the viruses. Between SARS-1 and MERS and SARS-CoV-2, they are different viruses, and they behave differently in hosts.

Q What are some of the differences between SARS-1 and SARS-2?

A In what way?

Q In their genetic sequence, what are some of the differences?

A So they're pretty different based on their sequences. I don't recall offhand the exact percentage of homology between the two viruses, but they are genetically distinct viruses.

Q Did SARS-1 have a furin site?

A I do not recall.

Q All right. Getting into kind of, like, what prevention strategies would look like. So you said surveillance and characterization is a big part of preventing a future pandemic.

What do some zoonotic spillover prevention strategies look like?

A So zoonotic spillover prevention strategies generally entail managing the interaction between humans and animals at the interface and monitoring those human populations for evidence of a zoonotic spillover event, for example.

Q So regulating the wildlife trade?

A That could be something, yes.

Q Regulating wet markets?

A That could be something.

Q What about laboratory or research-related spillover prevention strategies? What would some of those be?

A So in context of what?

Q How would you prevent a virus from leaking from a laboratory?

A So the biosafety guidelines or the BMBL -- is what we call it at NIH -- is really what governs the biocontainment levels that are required for handling viruses. So those are established by biosafety experts not just at NIH but also at CDC. And so that governs the use and experimentation of viruses.

Q And are subawardees required to follow those guidelines as well?

A To my knowledge, they are.

Q All right. If you know, generally, have lab accidents of coronaviruses happened before?

A I am aware of one.

Q Which one was that?

A A laboratory-acquired infection of SARS-CoV-1. But I don't recall the exact year. 2014.

Q Okay. I want to shift gears and talk generally about the Wuhan Institute of Virology, as they were acting as a subgrantee to EcoHealth, the grant that you manage.

You talked a little bit about the biosafety levels. When you're evaluating or doing a scientific management, do subgrantees have to report what safety level they're doing their experiments at?

A No. As a general rule, the NIH doesn't directly manage grantee subcontracts. The terms of award require them to follow the NIH Grant Policy Statement, and so that flows down, but we don't, as a rule, manage subawards.

Q Did you ever ask or request of EcoHealth to provide what biosafety level the WIV was operating at?

A I did not that I recall.

Q So you kind of just mentioned this. Overseeing grants where the WIV is the

subgrantee. Did you have access to information from the WIV, or was it strictly through EcoHealth as a passthrough?

A All of the interaction I had was through EcoHealth.

Q If you requested documents from EcoHealth, was it your expectation that they would provide them even if it was from the subawardee?

A So, when requesting information, I don't ever recall specifically requesting from a particular -- or excuse me -- particular subawardees. Just, if there was information that was needed, I would ask the prime, and they would provide it if available.

Q But it's your expectation that, when you ask the prime for information, if it's in the possession of the subawardee, that the prime will provide it?

A If it's possible, yes.

Q If it's possible. What do you mean?

A So, as I said, we don't manage their interactions with the subawardees. And so I don't recall any instance where I specifically wanted something from a subawardee or how I would even know, because the data that's provided to us -- for example, in the progress reports -- doesn't really say this comes from this person, this comes from this person. It's a summary of the overall progress of the year.

And so, you know, if, for example, I wanted a clarification point on something I saw in a progress report, I would ask an investigator about that point, not where it came from.

Q But it's your expectation that the prime awardee has access to everything that the subawardee is doing with taxpayer money?

A I would think so, yes.

Q Okay.

BY MR. STROM:

Q Just to elaborate on that a little bit, I mean, you could -- EcoHealth, for example, does not have laboratory facilities. So I assume you could look to see which of the listed subgrantees, collaborators had the BSL-3 and BSL-4 facilities. But that's not something you would typically do? You would just say, "I need information on, you know, the institutional review -- institutional biosafety review board that did this work," and then they -- your turn, EcoHealth, who then goes and gathers it. Is what you're sort of --

A Right. So, for example, the biosafety conditions are generally evaluated by peer review. That's a criteria that's evaluated by the reviewers, the peer reviewers. And they can make comments on the summary sheets about whether something needs to be fixed or used at a different biosafety level. And so those sorts of things are all generally addressed before an award is made. And then, on the annual progress reports, there is a section that says, "are there any changes to those areas?"

Q And the working assumption is that, when a peer reviewer is reading the proposed experiment and proposed biosafety levels, sort of the common language everyone is using is the BMBL?

A Yes.

Mr. Strom. Okay. Thanks.

BY MR. BENZINE:

Q The reason we ask those questions is your expectation -- not, like, your specific expectation, but the expectation that the prime awardee provides the subawardee information was not met in this case. Is that your understanding of the current state of play?

A So in what way? I don't --

Q NIH requested WIV specific information. EcoHealth was unable to provide it.

A So I wasn't involved in any of that direct request of information to WIV, and so -- or what was provided, really, back and forth, I was not directly involved in that, especially once the award was terminated and suspended and then reinstated. I was not involved in any of that direct communication.

Q You were cc'd on the letters. Did you read -- like, were you -- did you have knowledge of what was going on?

A So -- right. I was cc'd on them, but I didn't have any -- I wasn't always copied on everything, to my knowledge, that had been sent out or sent back.

Q In your current knowledge, has EcoHealth provided everything to the NIH that was requested in those letters?

A I think that -- so the NIH has allowed NIAID to renegotiate that award, and so my understanding would be that they have satisfactorily addressed the points that the NIH OD required them to.

Q Okay.

BY MR. SLOBODIN:

Q The NIH regulations state that subaward agreements must have a quoted requirement that the subrecipient permit the passthrough entity and auditors to have access to the subrecipient's records and financial statements as necessary for the passthrough entity to meet the requirements of this part.

The regulations require primary recipients to have effective controls in place to ensure the awards are being carried out in compliance with the terms and conditions. This is citing from 45 CFR 75.303. And they must monitor the activities of subrecipients as necessary to ensure the subaward is used for authorized purposes, which they need to

review and monitor financial and performance reports.

Primary recipients acting as passthrough entities, quote, "must have the right of access to any documents, papers, or other records with a nonfederal entity which are pertinent to the subaward," end quote. That's 45 CFR 75.364.

So, as program officer overseeing or monitoring the progress reports with EcoHealth, what was EcoHealth's responsibility under the NIH grant terms to monitor the WIV?

A So monitoring the subawards is really not something that NIH does directly, right? So we require them to comply with the Grants Policy Statement and to the grants management aspect. So grants management specialists are the ones that would deal with it. We consider that sort of the business aspect of a grant.

Q Right. But, when EcoHealth is reporting something from the WIV, are you -- what is your expectation about EcoHealth's state of knowledge when they are reporting results from work at WIV?

A So, speaking generally, I would say my expectation for any grantee is that information they provide in their progress report is accurate.

Q And how would they -- how would the grantee make sure that the information is accurate?

A So I can't speak to how grantees manage their subawards.

Q But wouldn't they need access if the reporting results --

A Yes. And it's the responsibility of the prime awardee to enforce their subaward agreements.

Mr. Benzine. Can we go off the record for 1 second?

[Discussion off the record.]

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

We have about 10 minutes left. Do you have additional ones?

Dr. Wenstrup. May I jump in?

Mr. Slobodin. Sure, sir. Go ahead.

Dr. Wenstrup. I think what he's trying to ask and what I would like to know is, where's the checks and balances here?

NIH has the obligation when the grant is awarded -- the obligation and the ability to make sure that what is going on with the money that they have put out, with the research that's taking place, the safety of the lab, where it's going -- they should have a process, according to the rules as I just heard it, to be able to have oversight over what's going on in that lab where the research is taking place and verify the safety and the quality of the research.

So what you're saying is that, once it goes out -- I'm asking you. Once it goes out, no more responsibility over that, or it's not taking place, even though it's supposed to be taking place or available?

Dr. Stemmy. No. What I'm saying is -- and based on the Grants Policy Statement -- is that NIH has the right to ask these questions at any time and receive accurate responses back.

Dr. Wenstrup. And, if I heard you correctly, you assume that any response they gave is correct from EcoHealth or whoever is getting the grant? You assume it's correct?

Dr. Stemmy. Assume the response to what?

Dr. Wenstrup. The safety of the lab or the quality of the research. You just assume what they tell you is correct.

I'm just talking about process here. Not necessarily in this specific case, but the process.

Dr. Stemmy. Right. So, as a program officer, we would evaluate what is

submitted in the progress report in particular or the application that's potentially being funded and address any biosafety or biosecurity concerns then.

Dr. Wenstrup. Was that done in this particular case --

Dr. Stemmy. Yes.

Dr. Wenstrup. -- with EcoHealth?

Dr. Stemmy. Yes. It was evaluated by peer review, and anything that needed to be addressed was addressed prior to award.

Dr. Wenstrup. And who is peer review?

Dr. Stemmy. Peer review is arranged by the Center for Scientific Review at NIH.

BY MR. SLOBODIN:

Q But the responsibility of the primary grantee is to monitor the subgrantee?

A Correct.

Q So what does "monitor" mean? That's what I'm trying to get at. What do you understand the responsibility of the grantee to monitor?

A I understand the responsibility of the grantee to monitor and enforce the terms and conditions of whatever subagreement they have in place with their subawardees.

Q And that's an affirmative obligation because they took the grant funds? Would that be your understanding?

A My understanding is that they are required to follow the Grants Policy Statement based on the terms of their award.

Mr. Slobodin. Okay. Thank you. Sorry.

Mr. Benzine. No problem. Thanks, Alan.

BY MR. BENZINE:

Q So you talked about subaward agreements a little bit just now.

Do you review them, or does someone else review the subaward agreements?

A So, generally for awards, NIH does not review. We don't monitor or review the subawards. We interact with the primary, and it's the primary's responsibility to enforce and execute subaward agreements.

Q But NIH dictates what is in -- like, the bare minimum that's in a subaward agreement, correct?

A Based on the Grants Policy Statement.

Q If you don't oversee it, how do you know what's in it?

A So the onus is on the prime awardee to enforce those terms.

Q Okay. So --

A I mean, this is sort of outside the program officer role. So beyond that, I don't --

Q Right. Who is in charge of this aspect of it?

A So the NIH level -- my understanding is the NIH Grants Policy Manual is set at the NIH level, and NIAID, like all the other ICs, follow that.

Q Okay. And I'm asking -- you've done this now for -- I'm going to sell you short, but a decade-ish.

Do you think that is an appropriate level of oversight? Like, to what the chairman and Alan were saying, NIH and NIAID are dictating things on the prime that then you're assuming the prime is carrying out, when it seems relatively simple for you to just request the subaward agreements and be able to review them.

A So, in my experience as a program officer coming up and through, I haven't had any issues with any subawardees or terms that they put on it until I --

Q Until now? Until this one, correct?

A Well, yeah.

Q Yeah.

A So yes.

Q Yeah. I've got a couple more questions, and then we'll stop a few minutes short of the hour to avoid going into a new line.

Have you ever met Dr. Li from the WIV?

A Not to my knowledge.

Mr. Benzine. Okay. I think that's a good place. We can go -- John, do you have anything before we go off?

Mr. Strom. Not for this section, no.

Mr. Benzine. All right. We can go off the record.

[Recess.]

[11:03 a.m.]

EXAMINATION

BY [redacted]:

Q Dr. Stemmy, good morning.

A Good morning.

Q My name is [redacted]. I'm the chief minority counsel of the select subcommittee. We'd just like to ask you a few questions related to the grant that we were discussing in the prior hour.

So in mid-2016, there were a series of communications back and forth between NIAID and EcoHealth about the question of whether or not the work that EcoHealth was proposing was implicated by the 2014 gain-of-function moratorium.

Do you generally recall that back and forth with the grantees?

A Yes.

Q Great. I'd just like to ask some questions about that topic. There were a bunch of scientific arguments being made by them, and you all were looking at it. I'd like to dive into those. I appreciate your patience, because I am not a virologist, nor am I even a scientist. So if I misuse any terms, please, by all means, go ahead and correct me.

I think it makes sense to start just by looking at the moratorium itself, and so I will introduce that as minority exhibit A. And I'll give you a second to look at it.

[Stemmy Minority Exhibit No. A
Was marked for identification.]

BY [redacted]:

Q So it seems as if the operative language of the policy is actually pretty short.

It's just on the first page of the document -- or the first page of text. And I will just read out loud what I think is the pertinent language, which is: New USG -- I assume that's U.S. Government -- funding will not be released for gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses, such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, and SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

Okay. Am I right that, of this, you know, page-and-a-half document, that paragraph is the operative language of the policy?

A Correct.

Q Great. So having that in front of us, if we could start to look at the back and forth from 2016. And so I will introduce what I think was the first step in that exhibit, minority exhibit B.

[Stemmy Minority Exhibit No. B
Was marked for identification.]

BY [redacted]

Q And so that is a May 28th, 2016, letter, and it's from yourself and Jenny Greer, who's a grants management specialist at NIAID, and it's to EcoHealth Alliance. And I think -- so all of this back and forth seemed to include some content related to MERS and SARS-like viruses. I'm just going to focus on the SARS-like part of things.

And with respect to that, I'll read again just the pertinent part. That letter says at the top of the second page of the letter: "In addition, your progress report makes

reference to two chimeric bat SARS-like CoVs constructed on a WIV1 backbone. NIAID requests additional information on these strains of SARS-like CoVs, including the dates the strains were created, whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild-type SARS-CoV, and what research plans you have for these chimeric viruses."

So just a threshold question. The comparison there is described as being to wild-type SARS. How does the gain-of-function moratorium apply in this situation, right? The backbone is not actually SARS. It's WIV1, which I understand to be SARS-like, but the policy -- 2014 policy talks about conferring attributes to SARS.

So how did you all view that policy as applying in this situation?

A So my recollection at the time is that the letter of the policy was influenza, MERS, and SARS-CoV, and these viruses they're proposing to study were not exactly -- these referenced here were not influenza, MERS, or SARS-CoV, but out of an abundance of caution, we thought met the spirit of the policy. SARS-like viruses were something that we should also consider and evaluate.

Q Got it. So not necessarily within the scope of the letter of the policy, but within the spirit of it. And I guess when saying, okay, we're going to apply it in the spirit of it, the comparison that made sense, it looks like to you all, is whether or not we're likely to go above wild-type SARS rather than the backbone -- the WIV1 backbone?

A Correct. And I would say, at this point, we wanted more information generally on what these viruses were to determine whether or not the policy applied.

Q Okay. So if we go to EcoHealth Alliance's response, which I will introduce as minority exhibit C.

[Stemmy Minority Exhibit No. C
was marked for identification.]

BY [redacted]:

Q So this is EcoHealth's June 8th, 2016, response to your inquiry. And Dr. Daszak makes a number of arguments with respect to the SARS-like viruses. We see those on the second page of the document, which is Bates stamped NIH4561.

And there's a lot of text there. I'm not going to read it all out loud, but I guess I'll just start by saying: Are you generally familiar with, do you generally recall this document?

A Yes.

Q Okay. I will try to summarize the arguments that Dr. Daszak seems to be making. You can just tell me if I've mischaracterized any of them.

One distinct argument seems to be essentially that WIV1 is not even subject to the gain-of-function pause, I think more or less what you had just said. Dr. Daszak's logic for that seems to be that, first of all, WIV1 is 10 percent distinct from SARS, it's not SARS. And, secondly, WIV1 has never been shown to infect humans or cause human disease. So that seems to be just his first argument, that it's just not even subject to the pause.

And then, secondly, we're introducing progressively more distant spike proteins into WIV1. I take that to mean more distant from SARS.

A Yes.

Q And so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than SARS.

And his last argument is: Professor Ralph Baric's group basically put out a few publications where they took the WIV1 spike, put it on a SARS backbone and showed reduced pathogenicity in mice with human ACE2. So Dr. Daszak calls that a loss of function rather than gain of function, strongly suggesting even further that we're likely not to see increased pathogenicity here.

But he makes an offer to you all that says: If we see evidence of enhanced virus growth over one log, we will immediately stop and tell you and talk about how to move forward.

Is that -- just for us to work off of, is that a correct description of the argument he was making to you?

A Yes.

Q Okay. Great. And then I think it probably makes sense to look then at the communication back from you all to him. I know there's a lot of paper here. I will introduce that as minority exhibit D. So I'll give you a second to look it over.

[Stemmy Minority Exhibit No. D
was marked for identification.]

BY [redacted]:

Q This is a letter from yourself and Jenny Greer back to EcoHealth Alliance, and I think this is sort of giving the answer to the initial question. And I will read the pertinent part, which is on the first page, Bates stamped NIH516. This is a lot shorter, but next to that first bullet: "NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses is not subject to the gain-of-function research funding pause. This determination is based on the following: One, the chimeras will contain only S" -- which I take to mean spike – "glycoprotein genes from phylogenetically distant bat CoVs, and, two, recently published work demonstrating that similar chimeric viruses exhibit reduced pathogenicity. Therefore, it's not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route."

Great. Like, I think it's not difficult to keep track of what was being argued to you and then what you all communicated back as making sense to you.

Can we talk in more detail about both these arguments? So the first one: Chimeras will contain only spike genes from phylogenetically distant bat CoVs. Could you just explain a little bit about the premise and the logic of that argument?

A Right. So they are proposing here to investigate animal coronaviruses, right, with the goal of trying to understand if they are possibly able to use a human receptor. And so what they are proposing to do here is put the spike proteins from these animal viruses onto this WIV1 backbone, which is also an animal virus, and test whether or not it can infect initially cells in cell culture.

Q All right. But the premise specifically, as I understand it, seems to be -- everybody understands the genome of SARS, SARS-1, and there seems to be a sense that, as we move further away from that, that the assumption, I guess, or the view is that that is progressively less and less pathogenic or transmissible.

Am I sensing correctly that that's a --

A So it's -- the further -- the more phylogenetically distant you are, right, from SARS-1, the less you would expect that distant virus to behave like SARS-1.

Q And I guess that's what I would like to understand a little bit better. It makes sense that you could say, as you go further away from SARS, we expect it not to be exactly like SARS. But for the question of whether or not we expect it to be more or less pathogenic, the view seems to be, well, we reasonably expect it to be less pathogenic as we move away from SARS.

Now, I guess I'm just wondering why that would be.

A So SARS-1 was a coronavirus that made a zoonotic jump and became more adapted to infect people -- or mammals and then people, right. So you're starting at an end point with this SARS-1 virus that can cause disease in people, right. And so you are studying distant viruses that are, you would assume since they're sampled from animal

populations, more adapted to an animal population versus a human population. And so that's why you would expect these animal viruses to not exhibit the same characteristics or the characteristics in the same way as a SARS-1.

Q Okay. These particular novel bat coronaviruses at this point have not been sort of shown to infect humans, unlike SARS-1?

A Correct.

Q Okay. As it relates to mice, does that analysis change at all or is it the same logic?

A In what way?

Q Well, the 2014 policy relates to mammals, of which mice are. I understand that premise that you just described as it relates to what you would expect to see in humans. I'm just wondering, is it the same thinking for mice experiments?

A Right. So that was one of the reasons why we evaluated this, right, because the gain-of-function research funding pause policy specified transmissibility or pathogenicity in mammals via the respiratory route, right. So mice are not humans, but they are mammals, as you said.

So when you're moving these genes around, if you don't know what the outcome is going to be, that was one of the reasons why we investigated this, is to review whether or not it seemed likely that it would increase pathogenicity in the mice.

Q Okay. But the assumption that they are not likely to be more pathogenic if they are distant from SARS -- as you pointed out, SARS is already in a state where it can infect humans -- that is not known to be the case for WIV1.

A Correct.

Q As it relates to mice, would it be -- I mean, would it have been known at this point whether or not these novel bat coronaviruses -- what their infectivity was for mice?

A No.

Q Okay.

A Yeah. No, these were new viruses that had just been isolated, and so that was what they were trying to understand, was the receptor usage and then whether or not they cause disease.

Q Okay. The second reason here: Recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity.

So Dr. Daszak cited two papers for that line of thinking, and I think it would make sense just to introduce them so we have them in front of us, so I'll do that.

[Stemmy Minority Exhibit No. E
was marked for identification.]

BY [redacted]:

Q First one will be minority exhibit E. And, you know, you do not need to, nor would I expect you to sit here and read this entire paper. Obviously, it's in a few snippets of it. The title of it, for the record, is: SARS-like WIV1-CoV poised for human emergence. And there are a number of coauthors, one of which is Ralph Baric, which is I think how Dr. Daszak referred to it.

[Stemmy Minority Exhibit No. F
was marked for identification.]

BY [redacted]:

Q And then it might make sense, so we also have it available, to introduce the other paper that EcoHealth cited to you, so I will do that as well. And so this one is called: A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence. It is a 2015 paper. Again, a number of coauthors, one of which is Ralph Baric, one of which is also Dr. Zhengli Shi from the Wuhan Institute of Virology.

So as I said, no need to sit and read the whole thing. I'll probably end up directing your attention to a few discrete parts, but we can do that as we go.

Dr. Daszak, just to refresh my own recollection, his argument was Professor Ralph Baric's group took WIV1 spike, inserted it onto a SARS-CoV backbone, and showed reduced pathogenicity in mice with human ACE2. Therefore, this is a loss of function.

And it seemed to me as a reader that one of these two papers did that. The first one that I introduced, minority exhibit E, SARS-like WIV1-CoV poised for human emergence, it did seem -- on the second page of that paper, there's a chart, figure 2, and it seems to show exactly what Dr. Daszak said. There's a mouse-adapted SARS, called MA15 in here, and then there's a chimeric virus, which is a WIV1 spike, on the mouse-adapted SARS backbone. And the results showed higher levels of pathogenicity with respect to the mouse-adapted SARS as a whole rather than the chimeric virus. That is what Dr. Daszak said.

Just sort of a threshold question. To the extent that you have a recollection or understanding sitting here, the mouse-adapted backbone, again, from my rudimentary understanding, that that -- because it's been already through serial passage in mice, it's adapted to mice, it's not wild-type SARS, is there a sense in which that comparison is not necessarily apples to apples, that you would expect it to perform well in mice because it's mouse adapted?

A So what do you mean by perform well?

Q The comparison that Dr. Daszak is drawing attention to is, on the one hand, MA15 had a very high level of pathogenicity as a full-length virus, and on the other hand, when we attach the WIV1 spike, it was lower than that, and so that shows that my experiments are likely to produce a lower level of pathogenicity, it was a loss of function.

And I guess I'm wondering, it wasn't in Dr. Daszak's explanation, he just used the

word "SARS." He didn't identify that it was mouse adapted. But the fact that it was mouse adapted, I'm just wondering, in a sense, is there any sense in which that creates sort of an artificially high ceiling in which it would not be surprising that you would have decreased pathogenicity from the mouse-adapted virus but a comparison to wild-type SARS, I think, or I thought, is the thing that's being considered here?

A I see. So the gain-of-function research funding pause, you'll recall, is specific to mammals, right, and making something more pathogenic in mammals. The reason that investigators created the mouse-adapted version of SARS-CoV-1 was because the wild type, or what we call the -- like a natural isolate, didn't cause much disease in mice. And so they performed, as you said, serial passaging to adapt it to get it to cause disease, right.

And so in terms of the gain-of-function research funding pause, when you look at a comparator strain, you look at sort of the wild-type backbone, right, or, in this case, because the wild type does not cause disease, you look at the mouse-adapted version as sort of the high benchmark.

And so anything you compare to that would be does it make it worse than this virus that has already been passaged in mice to cause disease?

Q But your analysis, I think, is, are we going to create something more or less pathogenic than wild-type SARS, right?

A Well, so the comparator here is the mouse adapted, right, so that was one piece of the puzzle, was that if you have a mouse-adapted SARS-1 and you've put in these other spike proteins on it, how you assess the pathogenicity, and you need an animal model for that, and so this is an animal model to do that -- animal surrogate.

Q The letter saying wild-type SARS from you all, that -- is it that that functionally may mean that it's not SARS?

A Right, because this -- a mouse-adapted model is a surrogate for the wild type, right, so you need to be able to assess these things in an animal model in a controlled experiment, and so that was the comparator.

Q Okay. It seems as if elsewhere in this paper comparisons were drawn between -- Urbani is synonymous with wild-type SARS. Is that right?

A Yes.

Q Okay. It seems as if, on the next page, comparisons were drawn directly between wild-type SARS and WIV1 in mice with human ACE2 genes.

I guess it's not immediately clear to me, but if you could explain to me why would the experiment involving the mouse-adapted SARS be more pertinent than the one involving the wild type?

A So I wouldn't say it's more pertinent.

Q Okay.

A You know, you consider the data as a whole, right. And so generally with some of these coronaviruses, you can't study them directly in animal models without doing some sort of manipulation, either altering the host to express the receptor or altering the virus to cause disease in the animal model.

Q Okay. And that's actually very helpful in the sense of, if you recall your process -- in other words, Dr. Daszak really only pointed to one discrete part of this paper. Do you recall what your sort of internal -- was it, hey, let me make sure I read both of these papers and evaluate them as a whole?

A Yes, definitely. Generally speaking, when we've reviewed anything under the gain-of-function research funding pause, we don't, you know, take at face value necessarily what an investigator says. That's one part of what we look at, and we look at the contemporaneous literature and also other -- you know, the state of the science at

the time.

Q So the other paper seemed not -- well, let me put it this way, before I ask about the other paper. The logic for Dr. Daszak, it seems, of pointing to the 2016 paper was the experiment that that paper performed using the WIV1 spike protein.

I think that the experiments that are in question here or that were in question at this time proposed nothing at all with respect to a WIV1 spike. It was Dr. Daszak saying, What I'd like to do is take a WIV1 backbone, and I've got these other novel coronaviruses, bat coronaviruses for which I've created chimeras with the spikes of those novel bat coronaviruses on the WIV1 backbone.

In that context, what is the relevance of -- I mean, in a literal sense, like, can you describe for me the connection between that situation and experiments evaluating the WIV1 spike?

A Right. So the experiments involving investigating the WIV1 spike, right, so, for context, these were completely novel viruses, right, that no one had studied before. And so we -- in order to characterize them, which is what they were funded to do, was to characterize novel viruses, you need a system in which to do that, right.

And so you start with a virus that you understand, WIV1, which had been previously described and pretty well understood how it causes disease, and then you can move discrete parts of that. So the spike, for example, you can put in a different spike and investigate that in models that you understand how that backbone virus grows or causes disease.

Q But performance of the WIV1 spike, what would that tell you, if anything, about the future hypothetical performance of the spike of some other novel bat coronavirus?

A So it would tell you -- so if it, you know, widely increased the viral growth or

the pathogenicity, for example, you know, that would be an indication that moving these parts of the coronaviruses that are related but a little bit distant phylogenetically, right, that they -- that you would need to pay close attention to what you were doing, right.

But the evidence that we had at the time was that when you make these small changes, you really aren't necessarily changing the whole -- the way the virus functions as a whole, right. It's just a small piece of the outside of the virus, and mainly it's involved in viral entry, right, and so that's one of the first things that you want to look at when you characterize a new virus.

Q Okay. Great. And so then with respect to the 2015 paper, it seemed as if the experiments in that paper were largely testing the spike protein of a different novel bat coronavirus, not WIV1, but, in this case, SHC014. And so in figure 1 of that paper, it looks like what they've done is they've got the same mouse-adapted SARS strain, and, separately, they've created chimeric virus with the spike of SHC014 on the mouse-adapted backbone. And in that case, it looks as if the mouse-adapted full-length strain was more pathogenic than the chimeric that they've created.

Just from a superficial point of view, SHC014 being one of the novel spikes that Dr. Daszak planned to experiment with -- he had already created those chimeras at this point, and there were two novel spikes, and this was one of them -- is it odd at all that in his argument to you he didn't mention this experiment?

A I don't think it strikes me as odd, no.

Q May I ask why?

A I mean, so odd in what way?

Q Well, this seems as if it's an experiment whose purpose is to test the pathogenicity or function, however -- whatever the right term is -- of the SHC014 spike, which is the spike that Dr. Daszak plans to test as well.

Would that not be more relevant than something involving a different spike?

A Well, but he cites this paper, though, right, in his response?

Q He does indeed, but he doesn't -- he mentions specifically experiments involving the WIV1 spike but not anything related to the SHC014 spike.

Does that seem curious?

A No, because not necessarily because he's cited it there. And so the best of my recollection is that we evaluated these papers in the context of what he had asserted as well.

Q Okay. Nothing unusual? In other words, as a reader, certainly, if you say, okay -- which it's great that you did and, of course, one would expect that you would go to the papers and read them in their entirety. But in terms of his framing of the argument to you, it seems as if experiments related to WIV1 spike are certainly less important to this analysis than those involving SHC14, doesn't it?

A Well, again, I'd say that, you know, the statement here that says, This is further supported by the group, right, and then -- so in scientific papers, right, that's how you cite it. You have a list of those other articles that articulate your point as well.

Q Yeah. The rest of that sentence is, took WIV1 spike, inserted onto a SARS-CoV backbone.

A Right. And so the other paper is in there. So this other 2015 Nature paper is considered in that body of evidence.

Q Okay. So towards -- it's worth noting that, later in that paper, it looks like they ran the same full-length comparison between Urbani and SHC014. And it seemed as if Urbani -- that's figure 2 of the paper. I don't have any questions about it. I think it's just worth noting that Urbani seemed as if it was more pathogenic than SHC014 in a full-length length-for-length comparison. But towards the end of the paper, if I could

point you to -- it's page 1512 in the bottom left.

So there is an excerpt in the paragraph that's in the bottom left-hand side of that page. In the middle of that paragraph -- I'll read it out loud, but it starts with the words, Although SHC014. So I'm just going to read a couple of sentences there.

"Although SHC014-MA15 is attenuated relative to its parental mouse-adapted SARS-CoV, similar studies examining the pathogenicity of CoVs with the wild-type Urbani spike within the MA15 backbone showed no weight loss in mice, had reduced viral replication. Thus, relative to the Urbani spike MA15 CoV, SHC014-MA15 shows a gain in pathogenesis. On the basis of these findings, scientific review panels may deem similar studies building chimeric viruses based on circulating strains too risky to pursue as increased pathogenicity in mammalian models cannot be excluded."

So if I correctly perceive what that excerpt is saying, it seems to be saying, hey, when we compare two chimeric viruses on the one hand, SHC014 as a spike on an MA15 backbone; on the other hand, wild-type Urbani spike on an MA15 backbone, the SHC0 spike actually seems more pathogenic.

Do you recall how, if at all, that factored in your analysis? In other words, that seems as if it could or would be a cause for concern in the context of making an analysis under the 2014 moratorium.

A Right. So the gain-of-function research funding pause, right, was specific to mammals, right. And so as we've discussed earlier, you look at sort of the most pathogenic version of that, right. So you have the MA15 virus. That causes a lot of disease.

And so when we evaluated these types of requests, we look at what is the most appropriate comparator. And what he is comparing in this sentence is the mouse-adapted version with the wild-type spike, right. And so that is not what, you

know, our internal committee uses -- would consider using as an appropriate comparator strain to determine the applicability of the gain-of-function research funding pause, because you have a baseline of the mouse-adapted virus that had already been created and causes a lot of disease. And so in order to have something that would meet the pause, we would have had to see something that showed evidence of increasing pathogenicity beyond that.

Q Beyond the mouse-adapted virus?

A Yes. Because the chimeric version is already artificial, right. You have passaged that virus 15 times in mice, right. So there's a lot of changes that are -- that accrue over 15 passages, and then you're putting a wild-type spike back on. And so it's already -- that's artificial. It's not a true representation of the pathogenicity of this virus in mice.

Q If I could ask, specifically with respect to the first part of that sentence, that there are a number of changes between Urbani and MA15, 15 rounds of serial passage. I assume there -- there are a substantial number of changes in those viruses that -- it sounds like that's what you said, right?

A Yes.

Q I guess I don't quite follow why is that new, different virus the comparator for purposes of the 2014 moratorium which just says SARS?

A Because the context is in mammals, right. And so they had already made, prior to the gain-of-function research funding pause, this mouse adaptation, right. So that is -- so you -- in order to assess pathogenicity, right, you need to have a system in which to do it, right. And so that was why they passaged this virus and created this pathogenic in -- this virus that's pathogenic in mice, right.

And so that is sort of the high level, right. So this is -- they set out with the intent

to increase pathogenicity in mice so that you could study this virus, right. And then these other viruses that they're studying did not rise above that threshold of pathogenicity in the animal models.

Q Is there a sense, though, just as a listener, in which those other viruses have not had the opportunity to adapt to mice that MA15 has already been given?

A So -- right. So the wild-type viruses, yes, they had not been further adapted.

Q Well, so it seems as if it would be unsurprising that they would not be as adapted to mice as the mouse-adapted virus.

A Right, but the gain-of-function research funding pause covered experiments anticipated to increase pathogenicity, right, and so increasing your -- beyond your baseline --

Q Okay.

A -- in the model is what we consider the mouse adapted --

Q So the mammal in this context is the mouse?

A Is the mouse.

Q Is there a sense in which that makes it challenging to ever -- not ever. Ever is too strong, but makes it less likely that any particular experiment is going to violate the pause because the comparison, if it's in its wild natural state and being compared against a mouse-adapted virus, it seems less likely than it might otherwise be that you would have a reasonably anticipated increase in pathogenicity? Doesn't seem like a fair fight between a wild virus and a mouse-adapted virus.

A Right, but I don't think of it in terms of as a fair fight, but in terms of implementing the policy that was in place at the time, right. The policy for the gain-of-function research funding pause was increased pathogenicity or transmissibility

via the respiratory route in mammals, right.

And so we have this SARS virus that causes this level of disease, right. And so that was what we determined would be the baseline. And so anything that went beyond that, we would consider as potentially being subject to the gain-of-function research funding pause because it's increasing the pathogenicity.

Q And it's just a clarification for me, but in the original query to EcoHealth Alliance, when we say, compared to wild-type SARS, in function, what that really -- in practice, what that should say is mouse-adapted SARS?

A Well, it was both, right. The second paper also had the human ACE2 expressing mice where they showed that the wild-type SARS killed more mice than the chimeric.

Q Yes, certainly. But which one was the analysis for this purpose?

A My recollection is that we considered the body of evidence, not just a single experiment or paper.

Q But which one is the comparator point for purpose of applying the 2014 policy? Because I assume there can only be one, because there were two different answers for the two different viruses.

A So we look at it, right, in terms of -- in this context, right, because the mouse is a mammal, we look at it, are we expecting these experiments or anticipating these experiments to cause more disease in mice, right? And so we look at both the transgenic mice, and we look at the data from the mouse-adapted versions, because those are the only tools -- even if they are imperfect, they're the only tools we have to assess pathogenicity.

Q Okay. And if the answer to either of those is yes, it implicates the policy?

A Yes.

Q Okay. In the example of just that excerpt, just to finish the thought -- and we're almost done with the science part of it -- if you have two chimeras, each of which are on a mouse-adapted backbone, and you've got one spike against the other spike, which feels as if that's a like-for-like spike competition within the mice, and, in this case, the SHC014 showed higher level of pathogenicity than the wild-type spike, if I'm understanding what you're saying correctly, it's even if that's true, even if the novel spike is more pathogenic sort of on its own than the wild-type spike, it doesn't really matter, because the question is, are we likely to increase pathogenicity in mammals, meaning in mice, in this case, meaning ultimately the comparator is mouse-adapted SARS?

Is that -- am I summarizing that right?

A I'm not sure I follow.

Q That excerpt at the end that I read out loud tells us that if you have SHC014 spike on a mouse-adapted backbone and you also have Urbani spike on a mouse-adapted backbone, that that first chimera with the SHC014 spike is more pathogenic, and that's one of the spikes that Dr. Daszak wants to use for his experiments, but it sounds like -- and so that would seem to indicate that, between those two spikes, the SHC014 has a higher degree of pathogenicity. Because everything else is equal, the backbone is mouse-adapted SARS in both cases.

But if I'm hearing correctly, it's even if that were the case, even if the SHC014 spike were more pathogenic than an Urbani spike, ultimately the thing we're trying to figure out is, are we likely to increase pathogenicity in mammals, meaning mice here, meaning, regardless of everything I just said, the comparator really is mouse-adapted SARS?

A Yes, for this model, right.

Q Okay.

A But -- and so the experiments that they performed didn't show anything that increased above the mouse-adapted version.

Q Right. The only thing that could have resulted in a triggering of the policy here is if something had gone above and beyond the mouse-adapted SARS?

A Yes.

Q Okay. Got it.

[redacted]. I think I'm going to pause there for a second. We can go off the record.

[Recess.]

Mr. Benzine. So I want to ask a few clarifying questions about the paper that we were just talking about. It's minority exhibit F, I believe. That one.

Dr. Stemmy. This, the Nature Medicine paper?

Mr. Cooke. Yeah.

BY MR. BENZINE:

Q And you were describing the baseline that you use internally is the MA15, the mouse-adapted SARS virus, correct?

A For the gain-of-function research funding pause, yes.

Q Yes. And then the experiment described in here that we were talking about on the bottom of 1512 took two different spikes, took the wild-type SARS spike and the SHC014 spike and made a chimera out of the mouse-adapted with each of them, right?

A Yes. So they made chimeras on the mouse-adapted backbone.

Q Okay. And then the sentence that looks like -- that says gain in pathogenesis is comparing those two chimeras, not the chimeras with the mouse adapted. Is that right?

A Let me look at that figure one more time. Figure 1, he says.

Right. So he's saying that relative to Urbani spike on the mouse-adapted backbone, SHC014 mouse adapted shows a gain in pathogenesis.

Q So it's not a gain in pathogenesis as compared to the mouse -- the full-length mouse adapted?

A It's not a gain in pathogenesis compared to the full-length mouse adapted, correct.

Q And that would be the standard, right? So, like, I'm going to gesture, but I'll try to explain the gesture. Mouse-adapted is like tier 1, and taking these two experiments, you would put the SHC014 chimera, tier 2, and the wild-type chimera, tier 3. But because SHC014 never surpassed the tier 1 virus, it didn't trigger in your brain that this might be a gain-of-function pause issue?

A Correct --

Q Okay.

A -- because you had that high -- the higher level for the mouse-adapted version.

Q Yeah. And my last one, just so we can all hopefully understand, the sentence where it says: "Gain of pathogenesis is just comparing the -- as I just used the analogy -- the tier 2 and tier 3 viruses", not those to tier 1?

A Correct.

Q Okay.

BY MR. STROM:

Q So but the Urbani SARS variant -- probably not using the term "variant" correctly -- all that is is an early outbreak SARS sample, isn't it?

A Which -- which one are you talking about?

Q The SARS Urbani strain --

A Yes.

Q -- that is an early -- it was collected early in the SARS outbreak, but it is still a iteration of SARS?

A SARS-CoV-1, yes.

Q Yes. SARS-CoV-1, yes.

A Yes.

Q So why was that not considered the measuring stick as opposed to later in the pandemic SARS? Because that -- the Urbani spike iteration of SARS still binds and transmits effectively amongst people, amongst mammals.

Why was the policy to use the, I guess, enhanced -- I assume late-outbreak SARS as the measuring stick?

A So it wasn't, right. So the -- the measuring stick, as the term you used, right, is the mouse-adapted version, and so they took that Urbani and passaged it, so -- right. So that was where that came from, and so that's why that was the comparator strain.

Q But why isn't the Urbani strain the comparator for whether it's gain of function?

A Because the Urbani strain did not cause disease in wild-type mice. That's why they had to passage it.

Q But wild-type SARS also doesn't cause disease in mice?

A In wild-type mice. It does in the transgenic --

Q Okay.

A -- mice.

Q Yeah. In the transgenic mice, yeah.

I guess what I'm trying to suss out here -- I'm probably doing a poor job -- is you guys picked MA15, mouse-adapted 15, as the surrogate for SARS in this experiment for how you measure. If it goes above MA15, it's an issue. But how did you, as a policy matter, choose between basically SARS and SARS Urbani as being the measuring stick?

A Because the mouse-adapted version was already much more pathogenic, right, so that SARS virus has already been made more pathogenic in mammals, in mice.

Q Okay.

A And so we interpreted the policy to say, okay, will the experiment -- do they have the potential to make something even more pathogenic than something that's very pathogenic in mice?

Mr. Strom. Okay. I'll let you -- I've got to think a little bit more about my question here, but I'll turn it over to you.

BY MR. BENZINE:

Q We're going to go a little bit out of order, but I want to bring you back to minority exhibit A, the pause document.

Since we're talking a little bit about how it was interpreted, you were asked in the last hour kind of like the letter of the law, how it's written. And I think Dr. Daszak said a similar thing in the letter, that it applies to SARS -- SARS-1, SARS-CoV, correct?

A Correct.

Q That's not how it reads. So it reads: "gain-of-function projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses."

Maybe it's just written in virology speak and not like kind of how a reasonable person would interpret that, but I would interpret that as any influenza, MERS, or SARS virus, not necessarily SARS-1.

A Well, so one thing I would say to that is in the context of 2014, when this

policy was released, right, so all influenza viruses are clearly covered, right, and we know -- and we understand that. But MERS and SARS viruses, right, we didn't have a lot of knowledge about these other MERS-like, SARS-like viruses, right.

And so that was one reason why we at NIAID expanded what we thought, right, when I said, you know, it met the spirit, right. So these are MERS-like and SARS-like viruses, so that's why we considered them to be -- to evaluate those projects to see whether they were subject to the research funding pause.

Q All right. So NIAID's interpretation of the pause included the SARS-like and SARS-related viruses?

A Yes.

Q Okay. You were also asked a little bit about -- and used pathogenicity a lot, so it kind of bounced back and forth about the claim that getting more evolutionary distant from SARS, if it was then safe to assume a lower pathogenicity, is I believe how the question was phrased.

And you said, not necessarily lower pathogenicity, just that it wasn't going to behave like SARS.

A Right. So with unknown viruses, right, you can't always predict what the outcome will be, and so that's why you try and characterize them in a system that you understand.

Q I'm just trying to understand --

BY MR. STROM:

Q Why assume that divergence from SARS means it's going to be less transmissible or pathogenic?

A Well, so, again, we were operating under the gain-of-function research funding pause, right, so the further you get from a MERS or a SARS-like virus, right, the

less likely it is that you will be -- that you will have a virus that's subject to it, right, because it's a different virus. The more different the virus is, the less likely -- the less similar it is to MERS or SARS, right, and so that was one aspect of it.

Q But, I mean, what we've seen with, like, SARS-CoV-2 is that it's about an 18 percent difference in the spike thereabouts, 18-23 percent, somewhere in there. And it's much more transmissible than SARS-CoV-1. So what was the sort of scientific basis for the assumption that any SARS-related virus that has a divergent -- that is 10 percent or more different than SARS-1 is going to be less transmissible, less pathogenic as opposed to more transmissible, more pathogenic?

A Well, so you also have to think about that -- just the spike protein, right. So transmission and pathogenicity are mediated by things beyond the spike protein where you have to consider the virus as a whole.

We do not actually have any good models of transmission in coronavirus.

Q So, then, how is it reasonably foreseeable?

A Well, so that's what we struggled with, right. That's what the crux of the issue is. You have to think about what the likely impact would be, right. If you have genes that you maybe can associate with pathogenicity, that's something you can consider.

But that was -- it's a problem, right. I mean, we know this from influenza viruses where we have sort of limited transmissibility models, but we don't have good transmissibility models in coronaviruses.

Mr. Strom. I can keep going or if you want to --

Mr. Benzine. We can revisit in a bit.

BY MR. BENZINE:

Q I want to just kind of establish a baseline. Are you generally aware of what

is or what is not gain of function in your role?

A I am aware of what is gain of function for the research funding pause.

Q Okay. Are you aware of what is now defined as ePPP, or what would flow through the P3CO?

A Yes.

Q All right. Are they different definitions? Can there be a research experiment that is gain of function but not applied to the P3CO?

A So the gain-of-function research funding pause was established to pause a big chunk of research, right, and then -- or allow the U.S. Government to undergo a deliberative process to really understand and refine what would be considered potentially risky experiments.

And so through that several-year deliberative process, through the NSABB, the National Academies, lots of commentary, they refine that definition to gain-of-function research of concern, which is what became the P3CO policy. So, by definition, ePPP is a subset of what would have been considered subject to the gain-of-function research funding pause.

Q Online, the NIH's definition of gain of function, at least prior to October of 2021, was a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent.

Do you generally agree with that definition?

A So I don't -- I'm not involved in writing that definition. I --

Q But do you agree with it? I mean, you have to determine what is and what isn't. Do you agree that if I take a biological agent and confer a new or enhanced activity to that agent, it's gain of function?

A So there's a difference between gain of function and gain-of-function

research funding pause, right. So there are things that you would not necessarily consider risky just to confer new attributes onto it.

For example, creating a mouse model of MERS-CoV, which is an example we had with something that was captured via the research funding pause. The MERS-CoV had emerged and was causing disease, and we had no way to evaluate medical countermeasures. And so because you are passaging it in mice, you are -- mouse, you are conveying new attributes to that virus.

Q So that is gain of function; it's just not an ePPP?

A It's a definition.

Q Okay. I think, in general, there's a lot of definitions that a lot of people conflate as the same, and so I'm trying to get a baseline of what gain of function is versus what gain of function of concern is versus what ePPP is.

So you are okay with the definition of gain of function as conferring a new attribute onto a biological agent?

A Yes, that is a definition.

Q Okay. Thank you.

Is the gain-of-function determination -- so during the pause, would you consider yourself as having expertise in order to make the gain-of-function determination?

A I would in terms of the gain-of-function research funding pause, yes.

Q Okay. I want to go -- try to get back in order here. This has not been introduced, but I want to introduce the original notice of award from May 27th, 2014, from NIAID to EcoHealth as, what, as majority exhibit 4?

[Stemmy Majority Exhibit No. 4
was marked for identification.]

BY MR. BENZINE:

Q Are you generally aware of this document?

A Let me just take a minute to look through.

Q Yep.

A Yes.

Q Can you explain just briefly how you become assigned to awards?

A So at NIH, awards are assigned based on subject matter, right. So there are different portfolios that focus on different aspects of, in NIAID's case, infectious diseases. I am in the respiratory diseases branch, and so we have different people that manage different research with different focuses, whether it's vaccines, coronaviruses, RSV, generally based on the type of research being done.

And so an award will be submitted -- or an application will be submitted -- excuse me -- to the CSR, and then it is referred out and assigned to a specific program staff based on its subject.

Q I want to ask about a line on the first page. It's the paragraph that's just one sentence: "Acceptance of this award including the terms and conditions is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system."

So I think that's kind of what -- or a little bit of what Alan touched on earlier that the moment a check goes out the door, you're assuming the grantee has accepted the terms and conditions?

A I wouldn't -- so I'm from the -- from the program perspective, I'm, you know, not involved in that aspect of the award. My understanding is this doesn't assume; it requires the grantee to comply.

Q Okay. To the best that you know, understanding it might be a separate side of the house, are some of those standard terms and conditions this line would apply

to submitting progress reports on time?

A My understanding would be that they are required to comply with all of the terms and conditions in the Grants Policy Statement.

Q That would include submitting timely progress reports?

A Yes.

Q What about disclosing their subgrantees?

A I'm not certain about that. That's more of the grants management aspect. I don't know if they are required to -- I don't know.

Q What about monitoring the subgrantees?

A Generally, NIH does not monitor the subawardees.

Q But by taking dollars, NIH requires the prime to monitor the subgrantees, correct?

A Yes.

Q Okay. So we talked a lot about the funding pause, so I'm going to skip over some of these questions, and my colleague, John, might have some.

You talked a little bit about the struggle of the language "reasonably anticipated." The pause came from the White House. Was anyone at NIAID or, to your recollection, was anyone at NIAID or NIH involved in crafting the pause?

A I don't recall. No, I don't think they were.

Q After the pause came out, did you have an internal policy that defined reasonably anticipated?

A I don't recall us having a formal policy, no.

Q Did you feel you had to -- you had to apply the pause. Did you feel the pause was confusingly worded?

A I think the wording of the pause is fairly straightforward.

Q Do you think it could be interpreted in multiple ways?

A In what way?

Q I mean, just even the phrase "reasonably anticipated," do you think that has more than one interpretation?

A Potentially.

Q We also talked about MERS and SARS viruses. That language could have more than one reasonable interpretation?

A It could.

Q Do you think the pause could have been drafted better?

A I'm -- I don't know. I mean, I think we implemented the gain-of-function research funding policy as it was written. You know, I don't think that's something that I have any reason to comment on.

Q No, I know, but you had to apply -- you had to describe it to your grantees. You had to work with your grantees to work on it. Did you get a lot of questions? Did you get a lot of confusion from institutions or grantees on what this applied to?

A I think, to the best of my recollection, early on, there was engagement with the investigators about what was covered and what might not be covered. But, you know, the -- as program staff, our role is to implement, right, not to craft the policy for -- even at the NIH level, but level of the U.S. Government policy, we implement the policies that are in place.

Q Okay.

BY MR. STROM:

Q Did you or NIAID or the branch have a functional definition of reasonably anticipated? Because, like, in law, we have, you know, preponderance of the evidence. We've got beyond a reasonable doubt. We've got sort of standards that have, like,

colloquial but fairly defined definition.

And so I don't know if NIAID or the committees that reviewed these had that same, okay, we're not getting guidance from up top. This is scientifically what reasonably anticipated is, you know, understood to mean.

A I don't recall us having a formal policy of what reasonably anticipated meant. My recollection is that, for all of the projects that we reviewed, we reviewed the body of scientific evidence in bulk and made our determination about what the group thought was reasonably anticipated outcome would be.

[12:12 p.m.]

BY MR. STROM:

Q I guess, what level of certainty would you attribute reasonably anticipated to mean?

A So there's always some level of uncertainty when we are talking about an anticipated outcome. That was -- that was part of the rationale behind us putting terms in some of the awards that establish sort of guardrails that would allow us to revisit in projects.

Q And then so, other than the EcoHealth Alliance grant, you mentioned you did some work with Professor Fouchier. Did you have any other grants that were impacted by the pause?

A I did.

Q Could you elaborate on those?

A Yes. So I was the program officer for the human coronavirus research portfolio. There were a number of projects, I don't recall offhand specific numbers, but as I mentioned earlier, the ones that stand out are the ones focused on MERS CoV. We were in a, you know, significant outbreak scenario where we had no medical countermeasures for a highly pathogenic coronavirus, and we desperately needed a mouse model to begin to evaluate countermeasures. And so I had about five or so projects, I think, that were focused on medical countermeasure development that were ultimately granted exceptions to the pause.

Q So you had five projects that were granted exemptions as opposed to like a determination that the pause didn't apply. So, you know. There -- because there's that release valve that if it's, to your point about MERS being, I guess, in 2014 a very live issue still, that those were ones that the Director specifically ruled on and said were

critical, and so they need to continue?

A Correct. These were -- you know, it was unquestionied that by serial passaging, for example, in a mouse that you are making it more pathogenic in the mouse, and it unequivocally met the --

Q Sure.

A -- definition of the gain-of-function research that we --

Q Do you recall if all those -- all those five were in the U.S.?

A I believe they were.

Q Okay. And then, so you identified five that got the sort of Director exemption. Were there another subset of projects where you guys did a similar assessment to what we've seen with EcoHealth and then determined they didn't fit the definition?

A Yes. So, when the gain-of-function research funding pause was put in place, we evaluated all projects that involved influenza, MERS, or SARS viruses. And so it was only a subset that we determined might have been subject to the pause.

Q Okay. Do you -- just an approximate number?

A I could not.

Q Sure.

A I'm sorry; it was like 2014.

Q That's okay. It was a long time ago.

A I don't think I could pull out any numbers.

Q So the process -- so this isn't a one-time thing with EcoHealth. This is something you're doing as part of like a programmatic review in response to the pause. So how did you initially flag, just as a process matter, that a grant may implicate the gain-of-function pause? Did some aspect of the research implicate it?

A So, in 2014, when the gain-of-function research funding pause was put in place, as I said, program staff that had grants in their portfolio or contracts that involved any of those three pathogens. We looked at in detail all of those projects, evaluated what they were proposing to do, and then looked in detail about whether they were manipulating the viruses in any way, and what a reasonable anticipated -- reasonably anticipated outcome would be. And so, you know, many of those were -- were not doing any sort of manipulation of any of those viruses and were -- we determined internally that they were not subject to the pause.

Q So, when you're -- just to break -- so you're going through, you're reviewing the grants. I assume that includes like the progress reports, the peer-reviewed articles that are coming out of these grants are included in that assessment?

A Yes.

Q As to whether there's -- as to whether they need -- we need to take a closer look. So, when you identified those grants, did you then consult with someone at NIAID to say, "Here's the universe of grants that I think are -- we need to look at further," or did you just on your own immediately start reaching out to the grantees?

A No. We had an internal committee in our division that covered the whole division that we brought these projects to to evaluate.

Q Okay. And then -- so how did that decision tree work within that committee of intake of a potential grant that's covered by this pause? What did the committee -- what sort of steps did the committee do next?

A So generally what happened is the program officer would -- we would convene the meeting. We would meet, and the program officer would basically present a short summary of what their research is, the investigator, what they were doing, what results they had. We would discuss whether or not we felt that the experiments they

were doing met the gain-of-function research funding pause. If we thought it might then a letter was drafted, such as the one that we discussed earlier, that said, "Your project X, aim Y, may be -- contain research that is subject to the research funding pause. Please provide additional information." And --

Q And sort of -- it sounds like it was a very collaborative process, which makes sense for, you know, these sort of peer-review things and whatnot. Did somebody have final decisionmaking rights on, okay, let's -- let's make this actionable, let's reach out to this grantee and get more information?

A I recall it more as a consensus of the group.

Q Okay. And that stayed at the division level to whether --

A Yes, at this point.

Q You didn't forward it up to Office of Director for like a decision memo or anything like that?

A I personally did not, no.

Q I think that's all I had for that.

BY MR. BENZINE:

Q Okay. At the time, so 2016-ish, who was the head of that committee?

A So we didn't really have a head of the committee. It was our -- our divisional leadership with our branch and division.

Q Do you remember who else was on the committee?

A So it was relevant program staff, right, so all of the program staff that worked in that area. It was our section chief. It was our branch chief. It was our division director, our deputy director, some other leadership individuals that had expertise in biosafety and biosecurity in our division, and I believe also a couple of the Office of Science policy people as well.

Q Okay. I think I'll ask a couple more specifics about that in a minute, but I want to skip over the May letter that was previously introduced and go straight to the June 1, minority exhibit C. It's from EcoHealth. It's got a -- June -- June 8th.

A Yes.

Q So this is their response to your request for more information. And we went through quite a bit of it already, but I want to talk about what they -- the special award condition that they suggested, the 1 log growth in cells expressing the human, bat, mouse, or other DPP4 receptor for MERS, and that they would -- they suggested the same thing for the SARS experiments too -- they would stop all experiments with the mutant, inform the NIAID program officer -- I assume it was you --

A Yes.

Q -- and then the IBC of wherever the experiment took place, so the Wuhan Institute of Virology, IBC. Was that kind of standard to have grantees suggesting award conditions?

A So standard in what way?

Q In your decade of experience, did you have other grantees that would say, "We want to continue doing this, but if X, Y, or Z happens, we'll let you know"?

A So, at the time, we -- so, in 2016, we had been working under the gain-of-function research funding pause for a year and a half or so, 2 years, so we had a number of projects that we had gone through this process with. And, prior to that, we had already established this kind of a guardrail of increased growth by 1 log and was a term that we had put on other awards as well.

Q Outside of the 1 log growth term, in your negotiating back and forth with grantees, is it common that they come to you with terms to add, or is that normally the prerogative of NIAID?

A No, I wouldn't say it's a negotiation. It was what NIAID determined would be appropriate term to put on the award.

Q How did EcoHealth know about the term?

A I -- I -- I don't know how they came up with that. I mean, they have collaborators that worked in the space. I can't speculate as to who they talked to, but --

Q You said for it -- the 1 log growth term had been common across NIAID through the year and a half of the funding pause.

A Yes.

Q Were there other EcoHealth grants that you put the 1 log growth language on? I'm trying to determine, like EcoHealth proposed the 1 log grant language. There would be no way that they would know unless they saw other grantees get it.

A Right. So they could've talked to some of the other grantees. I --

Q Okay.

A You know, I don't know who they talked to or didn't talk to. But, prior to their setting this -- sending this letter to us, it was a condition that we had already put on other awards.

Q Okay.

BY MR. STROM:

Q Did they provide any documentation beyond that letter, exhibit C?

A Documentation for what?

Q For how they're going to proceed with their experiments, like, you know, "Here is the proposal; this is how the experiment will run; this is my -- you know, step one, we do this, step two we do that," I mean, just any other documentation laying out how they plan to approach this issue or their rationale for thinking that it was exempt?

Mr. Rechter. If you can recall.

BY MR. STROM:

Q Yeah, if you can recall. It's not a trick question.

A So -- sorry, so --

Q So what we have in document production is that letter. Do you recall there being a packet of any other information that EcoHealth sent to you as you got -- to help with your sort of internal determinations and deliberations?

A I don't recall any other information. I recall this letter and reviewing the literature at the time.

Q Okay. Yeah, that's what I was getting at.

Mr. Slobodin. John, could I follow up?

Mr. Strom. Go ahead, Al.

BY MR. SLOBODIN:

Q So, just to clarify, so do you have any recollection of whether EcoHealth discussed the -- this research project in question with you before they sent the letters, before they -- before you had an exchange of -- before you saw it in the -- I guess it was in the year 4 RPPR? How did you become aware of this research project with the transgenic mice?

A So I believe the transgenic mice were always part of their project to characterize viruses from the original application.

Q Yeah, but the mention was in year 2 where they talked about our plan for year 3 is we're going to do some experiments with these endobiotic mice, transgenic mice. Well, originally they told you North Carolina, then they corrected to it to Wuhan Institute of Virology. But that triggered, you know, going back to whatever this exhibit C, the letter -- the May 2016 letter that you -- that you cosigned went to EcoHealth.

A So what's the question? I'm sorry.

Q So did you have any dis -- had EcoHealth discussed this experiment with you prior to talking about their plans in the year 4 progress report?

A So there's a difference between the transgenic mice work and the chimeric virus work. My recollection is that they had planned previously to look at the mice. Mice were separate. What triggered the gain of -- the review under gain-of-function research funding pause was their year 2 progress report where they indicated making chimeric viruses.

Q Okay. But, when you sent the letter in May of 2016, did you do that on your own, or did you have to run that through the internal review committee to say -- well, I think I understood you -- again, I'm just trying to get clarity here. I thought you were saying before for NIAID to make a request for more information about some proposed work to a grantee, that would be after the program officer consulted with this internal review group. So was there a -- was there an earlier consultation with the internal review group about whether we should ask for more information on this?

A So -- yeah, so the -- my recollection for that year was the progress report was due mid-April. Upon reviewing it, I saw that they were referencing chimeric viruses that hadn't previously been referenced. And so, at that point, I started the internal process that I previously described, where I came to our internal committee, described the experiment, and the group came to the consensus that we should request more information, and that was how that May 2016 letter was drafted.

Q So that was before you sent the May 2016 letter?

A Yes, our internal discussion.

Q So there were two -- actually, so there were two meetings then at the internal review, one was before you sent the -- you and Ms. Greer sent the May 2016 letter. There was some -- this gain-of-function review committee.

Mr. Strom. I've got that coming up, and we can circle back when we've got the exhibit, and he can refresh his recollection.

Mr. Slobodin. Right. But I -- you're saying there were two meetings?

Dr. Stemmy. So I'm saying that we had our initial. The letter was drafted and it was sent out. Their response came back in June. The committee met to consider the response and made a final determination, and that final determination letter was sent, I believe, in July.

BY MR. STROM:

Q So the excessive growth, the 1 log -- 1 log growth policy is a standard or regularly used standard NIAID policy. It was just in this instance proposed by EcoHealth?

A Yeah. I'd say, it was a standard policy that we developed for the gain-of-function research funding policy.

Q But it -- but it's not memorialized in any sort of formal like policy memo or guidance?

A Not to my knowledge, just the notices of award that went out previously that may have contained it.

Q So, if EcoHealth proposed this measure, presume -- I mean, presumably they would've conducted experiments that would have allowed them to accurately measure like 1 log viral growth, because if you propose this is the measuring stick we're going to use, wouldn't you design experiments that would capture that or at least data collection from experiments that would capture that?

A For example, it's sort of standard when you're -- especially growing a virus culture, for example, if you look at the titers, right, and that can be described as a log, you could do that on logarithmic scale.

Q Sure.

A And so it's a standard way to measure viral growth in the field of virology.

Q Uh-huh. So the expectation would be that they would do an experiment or they would analyze the data from their experiment in such a way that they could identify the -- whether they had come across this, whether they had tripped over the threshold?

A Yes, the idea being that these would've been their readouts anyway, and if something crossed that threshold of 1 log increased growth, it would have been apparent.

Q And then the requirement to immediately notify NIAID, how quickly, to your recollection, was EcoHealth supposed to notify you guys if they went over the greater than 1 log growth?

A I don't recall us setting a, you know, formal definition of what immediately meant.

Q Is sure.

A You know, my personal understanding would be sort of within a few days.

Q Okay. So, if it's within a few days of it happening, then was there an expectation that EcoHealth would monitor the virus growth throughout the experiment in terms of, if the point of this -- of putting this in there is to prevent accidentally violating the policy, because you don't have perfect foresight into like what's going to happen. If the point is to avoid -- is to, I guess, avoid violating the gain-of-function pause, if they only take the samples at the end of the experiment, they will only then find out that they violated the pause, but the experiment is done.

So what was -- what were the expectations from NIAID to EcoHealth as to how they would monitor for viral growth during the life of the experiment?

A Right. So what I'd say is that, when you do an experiment like this, so what

we call a time course where you have an infection and samples that you are collecting over several days or weeks, generally what investigators do is you collect samples over the course of the timeframe, and then you don't always -- depending on how long the experiment is, if it's a short experiment, you're not always doing the analysis in realtime. What you often do is you collect all of your samples, you know, have the animals finished, processed away, have all the tissues that you need, and then afterwards you subsequently do your analysis. You start with things you're most interested in, and then you, you know, analyze based on your research aims.

Q So are there, I guess, less formal ways or things that might raise a flag that there was viral growth? For example, and I'll just -- exhibit E here, the "SARS-like WIV1-CoV poised for human emergence" article on 3050, left-hand column, long paragraph says, "Based on pilot studies and previous studies with ACE2 transgenic animals, mice experiencing rapid weight loss were predicted to have lethal," and you can help me with that word.

A Sorry, which part of the paragraph is it?

Q Oh, about two-thirds -- it's about two-thirds of the way down that large paragraph. The sentence begins right after the reference to figure 3B: "Based on pilot studies and previous studies with ACE2 transgenic animals, mice experiencing rapid weight loss were predicted to have lethal encephalitis" --

A Encephalitis.

Q -- "and were humanely killed and harvested for lung and brain titer if weight loss approached 20 percent of body weight." So, in that instance, a red flag that there's maybe viral growth is dramatic, you know, 20 percent weight loss?

A Sure, because you can, you know -- the mice die.

Q They might get sick, yeah, exactly.

A Yeah, that's a good indication.

Q So, you know, death is a practical measuring point for whether you've got virus growth. Weight loss is another key sign. Did the policy get in -- did the NIAID policy, as part of how they were supposed to immediately notify you guys, get into that? Like, "Hey, if the mice die during the experiment, call us; if they have 20 percent body weight, call us"? Were those expectations sort of communicated to EcoHealth?

A My recollection is they were not. The sort of rationale behind that growth --

Q Well, and obviously there's some like professional, you know, virology understanding that 20 percent weight loss is like a red flag?

A It's a humane end point --

Q Yes.

A -- for an experiment, yes.

Q Better said than I can. But the policy itself, there was no order that, hey, if you have rapid weight loss, that's a -- a notification, one you've got to trigger notifying us?

A So my recollection is that the 1 log growth was actually framed in the context of viral growth in culture, right, because what you're often doing is you're -- you grow these viruses in culture first before you even put them in a mouse, right. And so our thought was, if you see increased growth in culture, we want to take a look at that.

We didn't specify that because we didn't want to exclude other end points as well, so we left it as 1 log in growth, but the assumption being that, before someone puts a virus in a mouse, for example, and gets an -- a death readout, that you would ideally have the in vitro culture data that could indicate or potentially would indicate increased growth.

Q So, just so that I understand the full width of the policy, is that it didn't

specify how they're supposed to -- how the PI is supposed to monitor viral growth?

A We did not specify that, no.

Q And there's no requirement -- there's no specification as to when they have to notify you other than just immediately? There's no -- we expect you on day 5 to do this kind of pathology work; we expect you to notify us if it's a 20 percent weight production or if you have a -- your mouse dies in these experiments?

A Correct. For the 1 log growth, it was just the immediate, you know, once they observed the increased growth.

Q And then it's -- what is the, like, specific scientific basis for that? Why is it 1 log not 2 log growth?

A So it's -- it is a bit of an arbitrary bar that we set. Some of these things, as we talked about earlier, because these are new viruses and you don't necessarily totally understand or understand how they grow, we set a little bit of a conservative benchmark to say, okay, if suddenly you have your -- you know, the viruses that you know grow at a lower level and then all of a sudden this new virus is, you know, several or, you know, 1 log or more higher, and then that's something that we would want to look at and reevaluate the data. Not necessarily that it would be subject to the gain-of-function research funding pause, but just something that, okay, if we see increased growth, we want to look at and reevaluate what might be reasonably anticipated.

Q Can we go off the record?

[Discussion off the record.]

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

So I'd like to show you what's -- we are going to introduce as majority exhibit 5.

[Stemmy Majority Exhibit No. 5
was marked for identification.]

Mr. Strom. It is an entry for a meeting held on June 15, 2016, and it's -- you previously referenced it. It's the conference to discuss -- or the committee meeting to discuss the EcoHealth research proposal. So I'll let you guys --

Mr. Rechter. Is this 5?

Mr. Strom. This is 5, yeah.

BY MR. STROM:

Q So you've mentioned this before. So you recall the meeting and that you attended it. One thing I'd like to ask before we go into the specifics of this one, and the two attachments are just the two iterations of the EcoHealth letter that I think are already a minority exhibit.

Is this a -- are these meetings, these DURC gain-of-function meetings like a regular standing meeting that your office would do?

A Yes.

Q What was the, like, approximate frequency?

A My recollection is early on in the gain-of-function research funding pause it was more in the terms of weekly or biweekly. Once we sort of did our heavy lift and had a good understanding of the projects, it switched to monthly.

Q Okay. Do you have approximate timeframes for when it sort of became a monthly meeting? By 2016, is it a monthly meeting?

A Yeah, by 2016, I recall it being a monthly meeting. I don't remember when we made the transition.

Q Okay. And then, to Alan's earlier question, when you were doing your sort of pre-grantee outreach discussions, would those also occur at this meeting?

A The out --

Q So you indicated that you were reviewing it to determine whether it's within

the am -- potentially within the ambit of the pause, you also had a meeting -- like a committee meeting to discuss whether you needed more information from the grantee, how close do we think it is to the pause, do we need more information. Do you recall that -- would those kind of situations, before you've reached out to the grantee, also be done at these meetings?

A They would not be done live at the meeting, no. They would be -- we would discuss the project, the particulars of the project, and discuss if additional information was needed and what that information would be, so what information would the committee need to make a determination.

Q Uh-huh. But, I guess, was it common for these -- and we'll just look to the memo here or the agenda, project for gain-of-function review. Would you do the review once or twice? I mean, I'm trying to understand, you've identified that the EcoHealth Alliance grant is a potential -- potentially subject to the pause.

You -- then you said you had an internal discussion with your colleagues on this committee or in your office onto whether or not you needed to reach out to the grantee to get more information. This particular agenda is from after you've -- you've obviously gotten EcoHealth's response, and I would assume -- and I'll let you answer this -- you would be discussing whether the pause applied to this --

A Yes.

Q -- grant in this instance?

A Yes.

Q So is there -- is there another meeting where this grant was discussed that predates June 15th?

A Yes. My recollection is that we met in May of that year at some point.

Q Okay. And that certainly fits with the timeline for the letters. So, at the

typical iteration of these meetings, what did you guys discuss?

A So, generally, it would be a program officer presenting the experiments in their project that they had. We would discuss the details of the experiments, what was reasonably anticipated -- the -- what the reasonably anticipated outcome would be, and then what the next steps would be, would it -- whether it was, you know, draft a letter for more information, whether it was considering the information that had been submitted, and if more information was needed or if it was a final determination.

Q And then was this the group that had sort of decisionmaking authority for NIAID to determine whether the pause applied?

A I don't know if it was institutewide. I would say, it had decisionmaking authority for our division.

Q Within your division, yeah.

A I don't -- yeah, I don't know if it would speak for the entirety of NIAID.

Q Was that -- were those decisions reviewed by the -- I assume they were reviewed by the Director because you mentioned earlier you had recommendations that the director overrule the pause because you had the MERS outbreak sort of currently ongoing.

A So, in the example for the MERS models, we certainly drafted letters to go to the NIH Director level outlining what the projects were, why they were subject to the pause, why they were urgently needed for public health, and, you know, requesting exception from the gain-of-function research funding pause.

Q You sent to the NIH Director not to the institute director?

A The exceptions to the gain-of-function research funding pause were from the NIH Director.

Q Okay. Can you look at the list of -- take a minute to look at the list of the

attendees and let me know, if other than those listed, if anybody else attended those meetings on a regular basis, to the extent you remember?

A To the extent I remember, that's the basic group. Occasionally there were other program staff that may have had a project that they needed to present, but that appears to be the core staff.

Q And then is -- who is Dr. Teresa Hauguel? Am I saying that correctly?

A Hauguel.

Q Hauguel.

A She was formerly a program officer in our Respiratory Diseases Branch, and she was sort of the organizer for the -- these meetings.

Q And is she -- is she sort of senior to you, a colleague of yours? Did she lead the group or more of a convening function?

A No, it was more of a convening function. We were -- we were colleagues.

Q Okay. So, for this June 17th meeting, the documentation that you presented for it, was it just these -- just the attached EcoHealth letters?

A To my recollection, yes, it was just the EcoHealth letters. But also, as I mentioned, you know, the -- my understanding of the current status of the research at the time.

Q Did you use any kind of PowerPoint or provide supporting written materials?

A I don't recall, no. Generally, for these meetings we would provide them ahead of time, and they would've been attached to the -- to the meeting invite.

Q And then, so -- and we're just going to call this the gain-of-function committee. Did you guys -- what was the process for -- did you explicitly evaluate the risk and potential benefits of this research? Did you look at alternate -- did you sort of make an assessment on the viability of the alternative approaches that were proposed?

How did those deliberations go?

Mr. Cooke. Are you asking in general or with respect to this particular grant?

BY MR. STROM:

Q I mean, just both if you can, just applying -- what were the general processes and then how did -- to the extent you recall, how did they play out in this instance?

A So you may be kind of conflating two things, right. So this meeting is not just related to the gain-of-function research funding pause but also the DURC policy, or dual-use research of concern, right. And so, when you start talking about things about risk mitigation plans and alternative experiments, those are things that are really considered in the terms of DURC.

The gain-of-function research funding pause didn't really include any, you know, alternative approaches or risk mitigation plans. That came later with P3CO. And so, at the time, related to the gain-of-function research funding pause, we didn't really do those sorts of considerations with the exception of being, you know, if an investigator said, "Oh, I no longer want to pursue this research; I would rather do this instead, then we would evaluate whether their alternative experiment was related or subject to the gain-of-function research funding pause or not."

Q But, I mean, if you look at the EcoHealth letter, it says in the second page towards the sort of last full paragraph of the second page, "If it is determined that this research concludes gain-of-function work subject to the pause," you know. "Here is detailed information on what research will remain viable and appropriate budget adjustments and sort of what our alternative options." That wasn't something -- you didn't discuss --

A Well, so I think that came from our original letter, right. So that was what I was saying, so the options were an investigator could provide this documentation, or they

could say, "Oh, I don't want to do this anymore; I would like to do a different experiment." And so that would be where --

Q But you guys -- you didn't do an independent risk assessment of, "Okay, this is close to the pause, we suggest you, grantee, take your second option, take this alternative"?

A No, I don't recall us taking that approach. We evaluated what they proposed to do, and it was up to the investigator to decide whether they wanted to continue with the -- their main approach or if they wanted to alter it to potentially have it not contain experiments that could be subject to the pause.

Q And so, in this instance, because you determined it didn't -- wasn't subject to the pause, they never had to take that second step of considering an alternative avenue?

A Correct. We determined that the experiments they were proposing were not subject to the research funding pause.

Q Okay. And so real quick, and I'll wrap up on time, maybe a minute long, but I want to go back to exhibits E and F from the minority, the two articles, and back to sort of this issue of reasonably anticipated. So these were sort of two, maybe not seminal papers, but two important papers at the time that they were published on this discussion about coronaviruses and this kind of research. Is that a fair layman's assessment?

A Yes.

Q So, turning to -- we'll start with exhibit E. The WIV-1 and obviously the difference between using the spike from the backbone are relevant here. But, as you're assessing whether it is reasonably anticipated that you would have a loss of function, which was the conclusion EcoHealth reached, did you guys consider the fact that in this experiment, on page -- and I'll find it -- on page 3051, it mentions that the WIV spike -- and this is on the sort of top right in the first paragraph of the discussion

section -- that while it's -- the virus WIV-1 is still attenuated to -- relative to SARS-CoV-1 that you have this augmented replication in the presence of human ACE2 in vivo. And the paper goes on to say, "which suggests that the virus has significant pathogenic potential not captured by the current small animal models."

How do you -- how do you deal with that sort of uncertainty, because I think, in both of these articles, the authors are very clear about -- and you've been very clear frankly about what you don't -- what you didn't know in 2014, 2016 about coronaviruses and how unpredictable parts of the -- just these experimental results can be?

So, when you have a flag, and by all accounts, most of the WIV-1 spike were -- appears to be attenuated relative to SARS. But you do have this sort of unresolved issue in that you have -- and it's on the previous page -- you have, I believe, 100 log growth when WIV-1 is exposed sort of to human ACE2 as compared to mice. So how do you reconcile that?

A Sorry, I'm just taking a --

Q Sure, yes.

A -- minute to read through that caption.

Q And, if you need the viral titers reference, it's about halfway down page 3050 on the left column, large paragraph where this sentence begins "whereas day 2 lung titers were still attenuated relative to SARS-CoV Urbani, titers for WIV1-CoV were hundredfold higher in the presence of human ACE2 compared to wild-type BALB/c, with no similar augmentation observed in epidemic SARS."

Mr. Rechter. And, while Dr. Stemmy is reading that, is this about the last --

Mr. Strom. Yeah. I mean, I have just a similar couple of questions.

Mr. Benzine. And, like to kill the line, I've got like three, so we might go 5 minutes over the hour.

Mr. Rechter. Okay.

BY MR. STROM:

Q So this issue of the experiment otherwise everything is trending towards attenuation, but you have this augmented replication of the presence of human ACE2 that suggests that there's this unknown factor at play.

A Right. So, you know, that's -- I would say that's one of the issues with these surrogate animal models, right. You -- that's one -- one of the difficulties with making -- with establishing these models is that you can't always control for all of the variables. And, when you do things like mouse adapt or if you're using, for example, this -- this transgenic model that expresses the human ACE2, you know, you have to look at the -- sort of the bulk of all the experiments together, right, and maybe not necessarily focus on any single, you know, data or time point.

Q Sure. So, going to exhibit F, that is, I think, a little more direct in its warnings, is right here in sort of the bold summary on the first page. It begins, "The results indicate that group 2b viruses encoding the SHC014 spike in a wild-type backbone can efficiently use multiple orthologs of the SARS receptor human ACE2 to replicate efficiently in primary human airway cells and achieve in vitro titers equivalent to the epidemic strains of SARS."

And so you have this -- EcoHealth proposed this experiment, we're using the WIV backbone, and the WIV spike -- WIV-1 spike is not that pathogenic or transgenic. It doesn't cause -- seem to cause a lot of illness. But they're not using that, they're using the WIV-1 backbone. And one of the viruses that they intend to use the spike from is SHC014, which does replicate efficiently in primary human airway cells in an equivalent matter to epidemic SARS.

And then, you know, obviously, at the end of this article, in addition to the

efficient replication, you also have an issue of these guys got an unexpected result. And this is the last big paragraph here on 512: "On the basis of previous models of emergence, the creation of chimeric viruses, such as SCH014-MA15," which is the mouse adapted one, "was not expected to increase pathogenicity." And then, again, while it's attenuated to the parental mouse-adapted SARS, it does show a gain in pathogenicity over the Urbani spike-MA15.

That leads to this sort of conclusory statement where they say, basically, reviewing panels need to take a hard look about whether building chimeric viruses based on circulating strains is too risky to pursue. And that's kind of a heck of a conclusion.

So I'm just wondering, if the spike of SHC014 shows so much potential, how did they conclude it was likely to result in loss of function, especially when the overall grant goals, you know, aim 3 and others -- and I'm to do this as an exhibit maybe for the next hour -- is you're constant -- they're constantly looking for the next human-adapted SARS virus or one that's poised for emergence. And so the idea that they would do a loss-of-function experiment, they're looking for something that doesn't bind as well, seems a little counterintuitive and inconsistent with aspects of both of these papers.

A So, when you say "they," who are you referring to?

Q EcoHealth.

A Okay.

Q The grant's objectives were to find virus strains that were on the, you know, ready to go, ready to emerge. Both of these experiments, while they show some attenuation, have -- I think the exhibit F for SHC014 has some very dire warnings about the risk of this kind of research and the uncertainty of outcomes. And so I'm just curious as to how collectively that became reasonable -- reasonably anticipated to result in loss of function.

A Right. So what I'd say, especially with regard to exhibit F, we talked earlier about how the authors of that paper were not exactly using the -- what we would've thought of as the correct comparator in terms of assessing gain-of-function research funding pause.

My reading of what they're saying there is that scientific review panels may determine that or may deem that these studies are -- have the potential to be risky, and so my reading is that he's saying that it may become more difficult to characterize these viruses that may have pandemic potential.

Q But he's still saying that it's -- it was a risky, unexpected event. And I understand -- I've read the supplemental materials, and they were in BSL3 plus; they seemed to have done everything in a very responsible fashion. But how do you get from something that warns about that with an unexpected result to taking that same spike, putting it into a different backbone and we're going to get loss of function? We reasonably anticipate loss of function in light of the goals of the grant and the unknowns or concerns that are expressed in these papers.

A Right. Well, so the goals of the award, right, not the exhibits --

Q Uh-huh.

A -- not the paper, right, the goals of the award were to understand sort of the constellation of viruses that were circulating in these bat populations, right, that humans were exposed to. And so they didn't -- a priori set out to do a loss-of-function experiment or, a, quote/unquote, gain-of-function experiment. They proposed to characterize these viruses using these techniques.

And so, when we evaluated this in the context of the gain-of-function research funding pause, we used the best tools that we had and the best models that we had available at the time and determined that the preponderance of the evidence here would

suggest that just moving out a single spike does not exactly necessarily correlate with an increase in pathogenicity.

Q And it's a preponderance of the evidence standard?

A I mean, at the time, yes. We considered -- the evidence that we considered we found, as the committee consensus, that we didn't expect that there would be increased pathogenicity based on what they proposed.

Q I really do appreciate y'all's indulgence to let me wrap up that question.

BY MR. BENZINE:

Q I just have one clarifying question and then we can take a longer break. The exception in the pause was if the head of the U.S. Government funding agency determines that the research is urgently necessary to protect the public health or national security. In your case, that was the head of the NIH, not the head of NIAID, correct?

A Correct.

Q Okay. Thank you. We can go off the record.

[Recess.]

[1:38 p.m.]

BY [redacted]:

Q All right. We can go back on the record.

Dr. Stemmy, I just had two quick clarifications about some of the things we talked about and then you ended up having to talk about again. We can go a third time, but it will be quick. And then just a few more questions about other related matters.

So the first quick clarification is, from minority exhibit B, as in boy, if you're able to shuffle your way to it. Yeah, it's the May 28th letter from yourself. On the second page of that document, towards the top, the first bullet is the request for information from Dr. Daszak about the SARS-like viruses and what might happen there.

I'm just going to read the -- sort of the second half of that sentence: "Whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild-type SARS-CoV," as we sort of discussed at length, you've explained to me the comparator point is mouse-adapted SARS-CoV. And so, just for my understanding and clarification, the term "wild-type SARS," I'm assuming, is a term of art that encompasses both Urbani and mouse adapted?

A Yes. So I would say that it -- like I said, it covers the body of data, right. And there are limited ways that we have to evaluate pathogenicity, right. And some of them we have to use a surrogate mouse adapted, and some of it we have to -- we can use a transgenic mouse model, right. So there are ways, so we -- that covers both of those.

Q The phrase there "wild type" covers both of those?

A Right.

Q Got it. Great.

The other thing I wanted to confirm was, we've touched on it several times, but just for the sake of total clarity, is it correct that the view of NIAID was that SARS-like

viruses, as a technical matter, were not implicated by the 2014 pause. Is that right?

A So my recollection was that we elected to treat SARS-like and MERS-like viruses as if they were covered by the gain-of-function research funding policy.

Q And that's a distinction I just want to make sure I've got it. It's -- it was that SARS-like were not subject to the pause, but to be extra cautious, let's sort of pretend that they are, but they are not. Is that what it was?

A Yes, my recollection is that's the approach we took.

Q Okay. Great. And so that there's no confusion, that was what essentially one of Dr. Daszak's arguments, said, you know, WIV-1 is 10 percent different; we don't think WIV-1 is covered by the pause. That was not one of the arguments that you cited in your letter back to him. If you recall, do you recall why that was?

A Right. My recollection is that, like I said, we considered the SARS-like and MERS-like viruses as if they were part of the gain-of-function research funding pause. And so that was not part of our determination as to whether or not the research that they proposed were -- was -- or was not covered by the research funding policy.

Q I got it. Great. And, in theory, I suppose, from a purely technical point of view, the -- you could have ended up with viral growth above and beyond any of these different versions of SARS, and as a technical matter, that would not have implicated the gain-of-function pause. You all decided to proceed as if it would because that was something that you chose to do to be extra cautious. But this could not -- you're not a lawyer, I know, but as a technical matter, this could not have violated the gain-of-function pause on the SARS-like side. I'm hearing that right, I think, right?

A So, I'm sorry; I didn't follow.

Q It didn't even -- really, you could have said back to Dr. Daszak, "You know what, none of this involves SARS, so it doesn't matter; it's not covered by the pause." All

these other arguments about chimeras and papers and this chart or that technically didn't matter, right?

Mr. Rechter. Based on your understanding.

Dr. Stemmy. Right. Yeah, based on my understanding, we could have, but we -- yeah, we did not.

[redacted]. Okay. Great. I wanted to ask a little bit, we -- you spoke with my colleagues about the 1 log rule and its origins, and it was used elsewhere, things of that nature. I just wanted to look at some of the EcoHealth annual reports that have been the subject of attention as it relates to that 1 log grant term.

And so I will introduce minority exhibit G.

[Stemmy Minority Exhibit G
was marked for identification.]

BY [redacted]:

Q And this is the year 4 EcoHealth annual report, and it's Bates-stamped, first page is NIH 2593. This is obviously a long document. It's over 30 pages. There is no need for you to refamiliarize yourself with all of that content. But if I could direct you to figure 35, which the page for that is Bates-numbered 2622, and I might just give you a moment, or you might not need it, to just sort of absorb that figure, and then if you'd like some of the text describing it, which would be on the preceding page.

A Yes.

Q So there has been some confusion or debate or discussion about whether or not these results that are reflected in figure 35 do or do not show viral growth in excess of 1 log such that they would trigger the special grant term. So I suppose, just maybe the question for you is, do you understand figure 35 to show growth in excess of 1 log such that it would trigger the special grant term?

A No. My reading of the data that's presented in the progress report, first of all, there's no statistical analysis that is included. And so that's one way where scientists can tell if there are actual differences between values that are graphed, because it's not always obvious. And then the second point is that there are -- you know, there's variability often when you do an experiment, and so when you look at these types of data you kind of consider the overall data set as a whole and not necessarily an individual time point. And so, while there may be a transient level of difference, that's not maintained throughout the entirety of the experiment.

Q Okay. And so I don't -- I'm certain that there cannot be any disagreement or nuance as to the view that, on day 2, for example, we do appear to see the chimera is growing in excess of 1 log as compared to the backbone. No doubt about that, right?

A Yes. At that time point, the first one appears to be lower.

Q And, as you say, I think this is what you're alluding to, by the time we reach the dead point or day 8, those differences had more or less evened out. It looked like the SHC014 chimera might still be a tad higher than the WIV-1 backbone, but it's not possible to tell, or if you had to pick, I would suggest that that is something less than 1 log that we're seeing there at the end.

You talked about the nature of transient results. Could you talk a little bit more about that, and maybe I'll preface it by saying that the grant term, just by its terms as a reader, does not make any reference to that concept or to particular points in time, you know, not day 2 but day 8. So could you just explain a little bit about that lens for you?

A Yes. So, like I said, the -- you consider the entirety of the experiment, right. So that's one of the reasons why scientists do multiple time points is because there can be individual variability. You know, for example, one virus may grow a little bit quickly initially and then level off, and it doesn't by the end have an increased growth. And so

that's one of the reasons why you have multiple time points and why you look across a series of different data points.

Q And that is different from how, I guess, maybe a layman would read it, it sounds like. Because it reads as if thou shalt not go over 1 log, but that's not really what it means. It's just at the end of the experiment?

A If a difference -- so, from my perspective, if a difference would've been maintained throughout the course of the experiment, then you would've been more able to say, "There's maybe a difference here; can you provide statistical information that's not included here?" But that was not the case.

Q If you recall, it sounds like probably that was also your view at the time that you reviewed the year 4 annual report?

A Yes.

Q Okay. If you recall, because I know this was a long time ago, to what extent, if any, did you have pause or concern that one of those chimeras did show excess growth as compared to the backbone?

A I don't recall having any concern with the data presented here. In some sense, the titer data becomes a little bit less important than the weight loss data, which is a more direct measurement of pathogenicity. And so you see such variability across all of the strains they're testing that we wouldn't say that there's really any meaningful difference between those experimental conditions.

And so, ultimately, with regard to these experiments, you -- you look at what's most accurate to whatever you're wanting to look at, right, in this case pathogenicity, and we wouldn't see any -- we wouldn't describe that 35a as having meaningful differences between those strains.

Q And, well, so 35b is what we were just sort of looking at. And I think -- let

me just make sure that I'm hearing you correctly, that that body weight or pathogenicity maybe is a little bit more important in this context?

A It depends on what you are evaluating. If you're evaluating pathogenicity, a body weight reduction in an animal is a more direct measurement of that, because if the animal is feeling sicker, they're not eating; they're losing weight, right. So the -- the viral titers, I believe this is in the lung tissues, right, so, you know, there can be some variability in earlier time points, but overall, I would not say that there are sustained differences in the strains measured here.

Q And, in figure 35a, which seems to measure percentage of starting body weight, am I reading that correctly that mice infected with the SHC014 chimera, which is represented in green, ultimately had -- I don't know how you want to measure it -- a materially lower percentage of starting body weight than mice infected by WIV-1 backbone, or full length, I should say, which is represented in pink?

A So it's hard to make that determination because when you look at these types of data, the error bars are the part that poke up and down from the single data point, and when they overlap with each other, that's where you need to use statistical analysis to determine if there are real differences in what you're observing.

Q It seems as if the gap between green and pink was not that wide at the beginning or in the first half and seemed to sort of open up as the days went on. Does that go to your point of, well, even if they appear to be a little bit wide at the end, the bars that extend from the lines are still sort of touching each other, and so it's still in a zone of uncertainty?

A Yes. So the bars then sort of overlap especially at that last time point. In my view, the green bar goes up past the sort of orange bar that is the WIV-1.

[1:51 p.m.]

BY [redacted]:

Q The green bar goes up past the orange bar.

A Right. So the green line, at that last time point, has a bar that goes up as well. And so it's right there, right around that center pink and orange dots in the middle. So they overlap there.

Q All these lines, am I sort of sensing correctly, have a center point, which is the horizontal line, and then there's a bar that extends, I guess, equal lengths above and below the horizontal line?

A So it's not necessarily equal up and down. So it describes the variability of the individual. So each time point usually has multiple mice that you're measuring from. And so when you have different numbers, it's sort of like an average. When you have -- the dot in the middle maybe describes the average, and then the bars that go above and below sort of represent the uncertainty of the measurement that you are taking.

Q I got it. And so the line that moves horizontally is -- those various dots are essentially representing average points?

A Yes.

Q If you recall, was there any concern that the average point of SHC014 seemed to be at a lower body weight percentage than the backbone?

A No, because, again, especially at that last time point, when these error bars overlap that much, you can't really describe a meaningful difference.

Q Was there any extent to which that 35A figure, in concert with 35B, which does seem to show the chimera -- the SHC014 chimera ending up slightly higher than WIV1 and having been noticeably higher than WIV1 on the way to the dead point -- when

those two figures, when put together, were a cause for concern, if you recall?

A No. Again, because the viro-titers -- the genome copies that they're measuring in 35B -- again, maybe transient differences early on, but by the end of the experiment, are equivalent -- appear to be equivalent.

Q On the first page of this document, which is an email, Dr. Daszak sort of -- this wasn't the official way of submitting the year 4 report, as I understand it, but it seems like separately from his official submission, he emailed you a copy of the year 4 report. A little color commentary there on the bottom of the first page. He talks about, hey, we've had fantastic results this past year, and I put those in the report summary.

If you recall, did he ever say anything to you about this year 4 report as it relates to figure 35 and/or the one log grant condition?

A I don't recall him mentioning that figure -- those figures in conjunction with the one log growth increase.

Q Okay. This requires a little speculation, but in the sense that those figures -- I understand the understanding that they did not show excess growth in excess of one log. I get that.

But given the results that they did seem to show, which is the chimera being in a very similar place to the backbone, would you ordinarily expect the grantee to mention it, or it's not even something that would be worth mentioning other than just submitting the report?

A No. I mean, I think that submitting the report was what I would have expected.

Q Got it. And you did not, at the time, understand this to be Dr. Daszak submitting his immediate notification that he had gotten over one log?

A Correct, yes, because I didn't interpret the data as having that statistically different increase.

Q Okay. If we could look at the year 5 report. I will introduce that as minority exhibit H.

[Stemmy Minority Exhibit No. H was marked for identification.]

[redacted]. I'm sorry. This is a different email. It's the one you're supposed to have, but it is a different email. We're not quite at the year 5 report yet.

Mr. Rechter. This is H?

[redacted]. It is H. That part is correct.

BY [redacted]:

Q This document is Bates No. EHA70, and I'll give you a second to look it over. Our understanding of it is that this is when you all had reached out to EcoHealth -- essentially, it looks like the gain-of-function pause had been replaced by P3CO, and so the grant term and condition had been tweaked to reflect that change.

I don't know if that -- I mean, you're cc'd. You didn't send it. But is this document generally familiar to you?

A Yes.

Q Okay. And on the page towards the back Bates labeled EHA73, at the very bottom of that page, we can see the newly rephrased grant term and condition. I'll just read it out loud: "The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild-type strains, you must notify your NIAID program officer and grants management specialist immediately and that further research involving the resulting viruses may require review by the DHHS in accordance with DHHS P3CO

framework."

And then, very briefly, two pages prior to that, Dr. Daszak says: "We will comply with the details and inform you immediately if any of our work results in the conditions laid out in the letter."

That all seems, I think, consistent with what you're describing, which is, at this point, which is after the submission of the year 4 report, neither the NIAID side of things nor it sounds like Dr. Daszak understood the one log rule to have been previously implicated. In other words, you all sort of were on the same page that year 4 report did not show growth greater than one log. Is that right?

A Yes. That's my best recollection, yes.

Q Okay. And I guess just one clarification on the revised term. It says that: "Further research involving the viruses may require review in accordance with P3CO."

I mean, that's pretty clear. It speaks for itself. But just to confirm, do I read correctly that, to the extent that from this point forward EcoHealth hypothetically went over that one log threshold, it may have meant that they would have been subjected to the P3CO regulatory framework?

A I don't think you can say that it would have. It would have indicated that we will take a look and see whatever the details of the results that you are submitting, and then we would determine internally whether or not it met the P3CO policy and would need to go for further review.

Q It would have required a closer look?

A It may have, yes.

Q Now, the promised year 5 annual report. I believe this is the last exhibit. Minority exhibit I.

[Stemmy Minority Exhibit No. I

was marked for identification.]

BY [redacted]:

Q And, again, this is a long document. And, again, I'm only going to ask you about a very small piece of it.

So the document is Bates labeled NIH1. If you want, you can just flip to page 16, and that's -- figure 13 is shown on that page.

So the same sort of set of questions but now for figure 13B. At this point, am I right as a reader to think that we have sort of a conclusive showing of chimera viruses exceeding one log growth as compared to their backbones?

A It's hard to make a definitive statement, again, without statistical analysis indicating here.

Q Well, if we look at the bars at the dead point, and the first bar is with one, and if we look at really almost any of the other bars but I guess particularly the third and fourth, we can see on the left that each segment there is five logs. You don't view it as conclusive that that shows more than one log?

A I think it's hard to say without statistics.

Q I don't mean to be flip, but in the absence of statistics, just sort of measuring the space, why is that not conclusive?

A Well, because that's why we do statistical analysis. Because looks can be deceiving. So that's why you need statistical power to determine whether something you're observing is an actual difference or not.

Q Okay. Let me ask you some questions about this report.

The report, as we understand it, shows work that would have been conducted in year 5, and so running from 2018 to 2019, and would have been due in September of 2019. Is that right?

A That's correct.

Q And the report was not ultimately submitted within that timeframe. It was submitted a couple of years later as part of a back-and-forth between NIH -- not yourself, but between NIH and EcoHealth. Is that also your understanding?

A Yes, that's my understanding.

Q Do you have an understanding of why the report was not submitted within that 2019 timeframe?

A So I can't speak to why the grantees might not have made the submission. I do know that the normal enforcement process for NIH, when things like progress reports are delinquent, were interrupted and stopped in effect by the termination and suspension and reinstatement and suspension of the award.

Q Okay. There is a broader point of contention, which I understand to be a question of whether the experiment results that we're looking at here in the year 5 report are from the same or from a different experiment as compared to the one we looked at in the year 4 report. I know EcoHealth Alliance has said it's all part of one single experiment. I think we've heard elsewhere that maybe at least NIH might be a little bit unsure about that and would like a little bit more information.

I think I would love to know whether you have a view on that question.

A So I don't have a firm determination of whether it's one experiment or two. I think it's plausible that it is one experiment and just different tissues. They are presenting, for example, brain tissue here versus lung tissue in the previous report.

So it's certainly feasible that your first analysis could be targeted at lung because you're looking at respiratory viruses, and it's possible they did subsequent analysis with other tissues later on, but I can't speak to whether definitively it's one experiment or two.

Q A question about -- on the preceding page, there's, you know, that text or

paragraph that describes what the reader is about to see in figure 13, and that paragraph begins with: "In year 5, we continued with in vivo infection experiments of diverse bat SARS-related-CoVs on transgenic mice expressing human ACE2."

Again, as a layman, "but we continued with experiments" seems as if they continued with experiments. In other words, this is a new experiment.

Do you read it similarly or no?

A So I think you'd have to speak to the authors about what their intent for that language was there. Like I said, I can speak to the data that's presented. Whether or not the language they use reflects that or not -- I can speak to the plausibility of one experiment versus two, but, again, I can't say definitively.

Q This is just a big picture question, and it was touched on in a prior round a little bit, but the question of biosafety and the regulatory framework around biosafety and the way that biosafety is monitored, whether it's for a grantee or subgrantees.

Just from a big picture, do you think that additional investments or reforms from Congress could help strengthen biosafety oversight as a whole?

A Can you focus that a little bit more? I mean, that's sort of a broad statement. Like, in what way?

Q Well, I mean it broadly. Do you think that there is a role for Congress -- to the extent that we are able to either provide additional investment or substantive reforms, but you're a subject matter expert -- could improve biosafety as a broad topic or any facet within that?

A So from my personal perspective, I mean, I think that the biosafety guidelines established with the BMBL and other policies such as Select Agent and P3CO -- those are the ones that we implement. We directly don't create those policies, right. We maybe provide some context or comment, but we are not the ones that set

that policy. So I think that would be a question for those that set that policy.

[redacted]. Thank you. We can go off the record for a moment.

[Discussion off the record.]

[redacted]. We'll go back on the record. Thanks.

BY [redacted]:

Q Dr. Stemmy, my name's [redacted]. I'm from the Energy and Commerce Committee minority staff. Thanks for being here today.

Just a few questions for you. I'd like to sort of zoom out a little bit on, you know, the work that you do, your portfolio, its relevance more broadly.

I think, could you speak to -- you know, we can focus in a little bit, I think, if it helps in the, say, 2018, 2019 time period. Could you just talk through the kinds of work that was being done across your portfolio and its relevance to pandemic preparedness?

A Sure. So during that timeframe, I was largely responsible for the human coronavirus research portfolio at NIAID, and I was sort of tangentially involved in the Centers of Excellence for Influenza Research and Surveillance network that we had funded at the time. So those are my two primary roles.

Broadly, I think the -- so when you ask your question, what do you mean in terms of the pandemic preparedness?

Q Yeah. So what kind of research was being done that either did or was intended to, you know, in some way better prepare us to identify, prepare for, respond to potential pandemics?

A So a number of things. There were significant efforts that we had invested in universal influenza vaccine development. We had a strategic plan that NIAID put forward in that as a part of pandemic preparedness for influenza.

Broadly speaking, in terms of coronaviruses, there were efforts underway to

create vaccines that were -- and also potential therapeutics as well, mainly focused on MERS-CoV, but also with the, you know, understanding that there is the potential for emergence of other pathogens as well.

Broadly speaking for both influenza and coronaviruses, we do a lot of work to understand the viruses that are circulating in animal populations and how humans that interact with those animal populations may be impacted by those viruses.

Q To the best of your knowledge, is there any research that was conducted, you know, within your portfolio prior to the COVID-19 outbreak that, you know, in any way assisted with addressing it, whether it sped the development of countermeasures, whether, you know, things were actually themselves developed through ongoing research? Can you speak to that?

A Certainly. It sort of laid the foundation for the speed at which we were able to develop vaccines for COVID-19. Some of the foundational work in understanding how the immunogenic -- the spike protein is, for example, right. We had investigators that were parts of the same teams that developed the mRNA vaccine at the Vaccine Research Center, right.

So some of those were part of my grantee portfolio as well that were doing some of the structural studies of the spike protein, for example, to understand, like I said, how immunogenic those proteins are.

Q So it's fair to say the research that was being funded by NIH prior to the pandemic helped speed our ability to respond to the pandemic when it did occur?

A Yes, absolutely.

Q Okay. Talking for a moment about the work that was done under the EcoHealth grant, we talked about making changes to viruses in a lab and examining how they react to things.

The purpose of changing viruses in a lab is to anticipate what might occur in nature, correct?

A Partially. It's not necessarily to anticipate what nature is going to do, right. In the case of this award, you have viruses that are sort of in place that we have, you know, historical evidence of coronaviruses emerging from this geographic region in similar ways, and you want to understand what viruses are circulating. And one of the first steps is to understand what receptors they can use or how they get into cells.

And so that's -- really, when we're talking here specifically about this project, is what they were doing, was to try to understand how -- what potentially of these viruses that already exist in nature do -- could potentially use human receptors.

Q And what would that information help us learn and do?

A So it would allow us to understand what viruses we need to pay particular attention to through some of our surveillance efforts, right. So if we are -- because these viruses also recombine in nature all the time, right. And so to recover, you know, a virus that has a spike that we know from some of this work can use human receptors, then you can target populations of humans, for example, that are close geographically and look for evidence of spillover there.

Q Okay. Thank you.

I just want to talk about your, you know, number of grants that you were actually overseeing at different time periods, because I imagine it fluctuated quite a bit. So could you just give a sense of, I don't know, let's say beginning of 2018 through the end of 2019, was it a relatively stable number of grants that you were managing?

A Yes, for the most part. I don't, you know, recall it exactly, but it was probably 20 -- around the neighborhood of 20 in my portfolio at that time.

Q Okay. And did that number change in any way as a result of the pandemic?

A Yes, substantially.

Q Okay. When did you see the numbers -- I assume it went up. Is that correct?

A Correct. Yes, it did.

Q Okay. So when did you start seeing increase in the number of grants that, I assume, first were being applied for and then were being funded and managed in your portfolio?

A So early on in the pandemic, NIAID released an emergency funding mechanism, two funding opportunity announcements that solicited applications to come in outside of the standard three-time-a-year peer-review process, which tends to be a slow process for investigators to apply and receive funding.

And so once that came in, the -- once those funding opportunity announcements were available, the numbers of applications sort of went up by orders of magnitude that were coming in.

Q Do you remember when those funding opportunity announcements went out?

A I don't remember the exact dates. I would like to say towards the end of 2020. Summertime 2020, I think. Somewhere around there.

Q Okay. So after -- I mean, obviously, you know, substantially after we knew that this was a pandemic that was affecting humans?

A Yes. It was in response to the pandemic.

Q Okay. Okay. Got it. And then there were a couple of things that you said I just want to make sure I understood correctly.

So you said that you saw the provision about notifying NIH about anything in excess of one log growth as a conservative benchmark. Is that right? I think that's the

language you used.

A Yes.

Q Can you just explain for the uninitiated why, you know, one log -- you think of that as conservative versus presumably some higher number, but still, you know, more appropriately conservative than some lower number?

A Sure. So we think about it in sort of in a sense of what would be still kind of a meaningful difference, right. And so in the absence of established models to really evaluate this, one of the first readouts that you always get is, if you're putting a virus in a cell culture, you can pretty quickly evaluate the titers of how well the virus is growing.

And so our thought -- to the best of my recollection, our thoughts were that, if, you know, we suddenly see a virus that's growing substantially more or faster consistently than what we'd seen previously, then that would be a suggestion for us that we should reevaluate the data and the viruses and potentially have further evaluation or another determination.

Q But there's nothing, like, that's sort of special in the scientific community about one log growth? That's just the number that was arrived on?

A No.

Q Okay. And you describe it as conservative. I mean, is that because anything that over the course of an experiment breached that limit, that would give you notice to pay closer attention versus notice only when it was too late and something was out of control? Was that the thinking?

A Right. So I think it would be in the sense of, you know, it's a comparatively modest increase, right, one log, when you look at some of the scales at which some of the viruses grow, right. So it would be -- ideally, it would have been an early indication for us to take a closer look, but not necessarily correlating with -- one log growth doesn't

necessarily correlate with pathogenicity or transmissibility, to be clear.

Q Okay. Got it. And then you said that, you know, if I'm understanding the conversation that you had earlier with [redacted], you didn't view the one log growth as like an immediate trigger? If at any point during the experiment it exceeded that, that that needed to be -- that that would be cause for notification, but rather that there was some room for judgment over the course of an experiment to determine if the one log growth trigger was breached?

A Right. So typically, investigators, you know, would do their analysis right at the end, right. You wouldn't necessarily -- I mean, investigators are all different, right. But for the most part, most people would do sort of bulk analysis, right. So you finish the experiment, and then you start to run your viral titers.

And so, you know, I would not have expected anyone to do, say, day two, and then say, oh, hey, this happened. I would more commonly expect the experiment to be completed and then receive a full dataset, because the -- you know, from my perspective, if that would have happened, then the follow-up question would be, okay, well, this is day two. What does day three look like? What does day four look like? What does day six look like? So you need to evaluate it in the context of the entire experiment.

Q Okay. Going back to something I asked earlier, after the funding opportunity announcements went out, how many grants ended up being under your management? You know, how did it increase?

A So it went from around 20 to -- I think close to 70. And then at that point, we started subdividing and having other program staff take over.

Q When did it get up to that number? Was that in 2020 or 2021?

A I would say probably that transition period from 2021 on.

Q Okay. Got it. Thank you.

I think just one last question from me. You said in terms of the gain-of-function pause that you could have just decided to say that the work that EcoHealth had proposed was completely outside of its consideration because it was not, you know, literally the SARS virus.

So can you just talk through the thinking of, okay, you know, we could have a nice, clean, easy answer here. They're not actually working with SARS-CoV-1 or SARS at the time. Why did you then do any additional, you know, evaluation at all?

A So my recollection of the time was, you know, we had just gone through that process with the papers that were published by Dr. Fouchier and Dr. Kawaoka, which sort of led into that gain-of-function research funding pause space.

And so because the intention of the gain-of-function research funding pause was to pause and evaluate what sorts of experiments might be risky, we thought over an abundance of caution that things -- that a project that described the work as SARS-like or MERS-like -- right, looking at those viruses -- it was at least worth taking a look at and saying, okay, well, how SARS-like is it? How MERS-like is it? And would we reasonably anticipate either of these outcomes?

Q Okay. So the one log growth was essentially out of an abundance of caution in terms of putting in a guardrail, right?

A Yes.

Q And same thing with taking an extra look at the experiments that were proposed, even though they didn't literally involve the SARS virus?

A Correct.

[redacted]. Okay. That was it for me for questions.

I don't know if -- back to you?

Okay. We can go off the record.

[Discussion off the record.]

Mr. Benzine. We can go on the record.

BY MR. BENZINE:

Q Some of these hopefully will be quick questions.

I want to introduce majority exhibit 6. This is the year 3 notice of award to EcoHealth and the WIV.

[Stemmy Majority Exhibit No. 6
was marked for identification.]

BY MR. BENZINE:

Q So in this one, flipping to page 5 is where it starts discussing the special terms and conditions. And the fourth kind of paragraph or set of text down is, "Per the letter dated July 7th, 2016, to Mr. Aleksei Chmura at EcoHealth," and then talks through the one log growth.

[Stemmy Majority Exhibit No. 7
was marked for identification.]

BY MR. BENZINE:

Q I want you to keep this one out while I introduce exhibit 7, which is the year 4 NOA. And you can take a minute and flip through this one. But on my read, and please correct me if I'm wrong, there's no one log growth special award condition in the year 4?

A Yeah, I don't see one.

Q All right. Do you know why?

A So I can't speak to why. I do know that, as a program officer, I complete my program officer's checklist, and I put in the term that should have gone on that award for that year. And I can't speak to the reason why it didn't because grants management

processes is the notices of award. But from my perspective, the term should have been on those -- that award.

Q So in your checklist for this, you had the one log growth?

A Correct.

Q And then when the NOA came out, somewhere along the line, it got taken out?

A Correct.

Q Would that have been Dr. Carine Normil?

A I don't know, and I can't speak to how or who officially puts the notices of award together. I can't speak to that process. I don't know.

Q Okay.

BY MR. STROM:

Q So one of the, I guess, other irregularities on this grant is that there are two copies of the year 4 progress report. And so we were wondering if you could explain the errors in the year 4 progress report that justify the regeneration of a new -- of a secondary year 4 progress report.

A I can't speak to those. I don't have access to or really an understanding of how that eRA system works or what would trigger that to happen. I do recall that progress report was submitted on time for that year.

Q And so were you aware that EcoHealth contacted the NIH or NIAID Helpdesk to update enrollment information on the year 4 progress report in September of 2020?

A I don't know if I -- I don't recall that specifically.

Q I believe NIH has publicly said that when they went in to update -- when EcoHealth went in to update the enrollment information, that that's what generated the second report. Do you know -- have you heard that claim before?

A I think I heard it sort of in the context of the media. I don't recall ever being involved in any of that discussion.

Q And then how do you keep records of grant documents outside of those stored in the eRA Commons system?

A So the eRA Commons is the -- or the eRA system for us is the official grant record. So anything that comes in, you know, in terms of letters -- we've discussed things like that -- get documented and then placed into the file by the grants management staff.

Q And so EcoHealth -- just to make sure I understand, EcoHealth didn't contact you, didn't email you, to your recollection, in September of 2020 saying they needed access to their grant again so they could update enrollment information?

A I don't recall. It's possible, but I don't recall that happening.

Q Okay.

Mr. Benzine. All right. I'm sure the answer is the same, but I'm going to introduce it as -- exhibit 8 is the year 5 NOA.

[Stemmy Majority Exhibit No. 8
was marked for identification.]

BY MR. BENZINE:

Q And, again, at the bottom of page 5 is where the special terms and conditions start, and then flowing on to the top of 6 is where the one log growth comes in again.

So you wouldn't have knowledge as to the discrepancy between 3, 4, and 5?

A No. I mean, it appears that the text that I placed into my program checklist made it into this year, and I can't speak to why it was not on the previous year.

Q All right. Were there any -- in your kind of oversight and management,

were there any problems that arose from not having the log growth language in year 4?

A Not that I recall.

Q Okay. So I want to talk a little -- we talked a lot about the gain-of-function pause. I want to talk a little bit about the establishment of the P3CO framework and how -- if that changed anything.

Generally, you're familiar with this framework? I imagine you're --

A Yes.

Q -- very familiar with this framework.

How did the P3 guidance differ from the gain-of-function pause?

A The gain-of-function research funding pause was specific to three viruses -- influenza, MERS, and SARS -- and involved experiments reasonably anticipated to increase pathogenicity or transmissibility via the respiratory route in mammals.

The P3CO oversight covers what are called enhanced potential pandemic pathogens, or ePPPs. And so a potential pandemic pathogen is something that is highly transmissible in people and highly pathogenic in people. And so the P3CO policy covers work that is anticipated to either generate or use an ePPP.

Q Is the P3 more narrow or more broad than the gain-of-function pause?

A It's both, in my opinion. The gain-of-function research funding pause was three specific pathogens. The P3CO does not limit it to a particular pathogen. So any pathogen could potentially, with pandemic potential, be subject to it. But it a little bit more narrowly defines experiments that may potentially be of concern and the consequences that they might have in humans.

Q Dr. Tabak instructed the NSABB to review and update the framework in -- I think it was January of 2022. Were you involved in that at all?

A Not in that decision, no.

Q Have you been involved in the update at all with the NSABB?

A No. I've listened in to some of the public deliberations and things, but I've not -- to my recollection, I've not directly interfaced with them.

[Stemmy Majority Exhibit No. 9
was marked for identification.]

BY MR. BENZINE:

Q Okay. I want to introduce majority exhibit 9. This is a letter from July 5th, 2018, signed by you and Adam Graham. And in the letter it says that NIAID has reviewed the grant post P3 coming out and determined that the P3CO framework did not apply.

Can you walk us through how that review takes place?

A Yes. It's very similar to the review that we did for the gain-of-function research funding pause. In practice, what we did was, as a starting point, we started with projects that we had previously determined might have been subject to the gain-of-function research funding pause, and we evaluated all of those projects in the context of the new policy to see which, if any, of them would potentially be subject to that policy.

And it was essentially the same process where program staff would discuss or present the experiments, we would consider them in the context of the new policy, and the group would come to a consensus.

Q Is it an iterative group based on grant or is it kind of a standing meeting?

A It's a standing meeting. The previous one was the DURC and gain-of-function funding pause, but this pause -- the group now is the DURC and P3CO, and so it covers both policies.

Q What does the review consist of? Is it the same kind of thing? Like, you

can go out to the prime and request information to help inform your review? Is it that level?

A Yes, exactly. We, like I said, follow essentially the same process where we present the potential experiments, and if needed, we interface with the investigators.

Q Within that process, you obviously, in the EcoHealth example, made the determination that P3 did not apply. Who makes that determination?

A So the group who reviewed it and came to a consensus.

Q Is there anyone overseeing your group?

A There's not like a leader, per se, no. It's the representatives of the same divisional and branch leadership as well.

Q Do you report your decisions up to anybody in your chain of command?

A So my chain of command -- all of my immediate chain of command is part of the group as well. But I can't speak to beyond that, if our director --

Q Who would that be? Who's in your immediate chain of command?

A My section chief and branch chief.

Q Who are?

A Dr. Diane Post and Dr. Michael Ison as the branch chief.

Q Does Dr. Erbelding go to these meetings?

A Yes, usually.

Q Has Dr. Auchincloss, Tabak, or Fauci gone to these meetings?

A I don't recall them ever attending the meetings, no.

Q If there is -- and this is -- again, I don't know the context of the meetings, but if there is kind of a dissenting voice, how is that dealt with?

A What do you mean by dissenting?

Q So if there's nine people in the group and five say this doesn't need to go to

the P3, four say, oh, I don't know, it probably should, how do you reconcile that?

A I don't recall that ever having happened. I think that it's usually pretty unanimous when we discuss projects whether they fall in or outside of the P3C0 policy.

Q Does anyone from ASPR ever come to these meetings?

A I don't recall anyone from ASPR attending.

Q Okay.

Mr. Strom. Are any of the policies and, like, processes that govern this level of P3C0 review written down anywhere?

Dr. Stemmy. The U.S. Government framework is the one that we follow.

Mr. Strom. But there's no like subguidance below that that more specifically says, you know, here are the definitional terms, here's what you're going to discuss in these meetings, you know, here's how you get the decision up to the division head to ratify it? There is no formalized guidance process below the government policy here?

Mr. Rechter. To your knowledge.

Dr. Stemmy. So, to my knowledge, we have sort of a flow framework of, you know, program staff and then guidance to the program staff to how they should review their projects, and if they need to come to the committee, then they are brought to the committee.

BY MR. STROM:

Q And you guys referred three experiments to P3C0?

A I believe that's correct.

Q And you had five that were gain-of-function under the pause that were referred to the director for his, you know, approval that it go forward?

A You mean for the exception?

Q Yes.

A There were five coronavirus projects.

Q Talking about the exception now, did you ever have an experiment that you determined was subject to the pause but you didn't recommend the director make an exemption for?

A Yes, I do recall. And I think the justification -- I don't remember all of the details offhand, but because of that stipulation that an exception must be urgently necessary to protect public health and national security, I believe there was one other project that requested an exception. But we as the committee did not feel it met the urgent need.

Q Thank you.

BY MR. BENZINE:

Q Building off of that a little bit -- and I'm just trying to wrap my head around the numbers -- between 2014 and 2017, there were five coronavirus grants that were granted a gain-of-function exception, right?

A Yes, I believe that's correct.

Q So the baseline assumption there is that it met the gain-of-function pause, but the director determined that it was necessary to proceed?

A Correct.

Q Since the P3 was established 2017, only three grants have been referred to NIAID up to the P3, none of which have been coronaviruses. What happened to the five?

A What do you mean what happened?

Q Are they no longer gain of function? Did they meet the gain-of-function definition but not the P3 definition? Like, how did those five become, this is absolutely gain of function, we need an exemption, to, we're not going to refer it to the P3?

A Yeah. So they were absolutely gain of function because they were proposing to adapt the MERS coronavirus into a mouse model. So, by definition, they were proposing to make that virus more pathogenic in a mammal. So that, you know, unequivocally met that definition.

It did not meet the P3CO definition because it didn't -- it wasn't reasonably anticipated that -- well, also, at that point, those projects had ended, I believe. So they didn't need to be considered further. But that exception was necessary for testing of medical countermeasures.

BY MR. STROM:

Q In line with some of the questions Will was asking, what is the volume of experiments that you're reviewing in this committee regarding the grant proposals?

A So we have a standing monthly meeting. Occasionally, though, they get canceled because there's nothing to be considered. It's a little bit more kind of around the NIH review cycles, right. So if you have grants that are being considered for funding, then you usually have a few more.

I don't think I can give you specific numbers, but, you know, probably two to three projects a meeting, barring the -- you know, closely clustered around the review cycles, notwithstanding the, you know, DURC questions or things that, you know, the committee also considers.

Q What's that volume like?

A I wouldn't say it's substantially more. You know, we typically will discuss, like I said, maybe two to three projects per meeting.

Q Okay.

BY MR. BENZINE:

Q We're going to talk more specifics about some of the progress reports and

things, but I wanted to ask a general question.

So from really 2016 until like April 2020, the letters were coming from you and the management side of the house, right?

A Yes.

Q And then in April 2020, Dr. Lauer took over the sending of the oversight and enforcement letters to EcoHealth?

A Correct.

Q Over the course of April 2020 through reinstatement, did Dr. Daszak ever ask you about how to respond to any of Dr. Lauer's letters?

A I don't recall him asking me how to respond, you know, in any capacity in terms of what he should write.

Shortly after the awards were -- the award was terminated and then reinstated and suspended, I was instructed not to have contact with the institution until NIH resolved their oversight issues. So I was not really involved in that process beyond that.

Q Who gave you that instruction?

A I think it was from the NIH level. I don't recall exactly which individual it was, but it was, I think, from the NIH level that was -- the guidance was not to interact with them and to direct them to grants management with any contact.

Q During that time, did you have any interaction with EcoHealth?

A Peter, the PI, would, from time to time, copy me. I was not always copied on the communications going out from NIH. The PI would copy me, from time to time, on his responses back. I don't know if I was copied on all of them or how many or what percentage.

Q Okay. But he didn't reach out to be like, hey, I just got this letter from Dr. Lauer. Like, what should I do?

A I don't recall that conversation, no. I think -- my recollection is that his responses were all directly to Dr. Lauer as the -- you know, the authority figure for that oversight.

Q Some quick ones that we can run through.

HHS suspended the WIV on July 17th, 2023. Were you involved at all in that decision?

A No, I was not.

Q And then HHS debarred the WIV on September 19th, 2023. Were you involved at all in that decision?

A No.

Q I want to introduce majority exhibit 10, and talk a little bit more about the year 5 progress report.

[Stemmy Majority Exhibit No. 10
was marked for identification.]

BY MR. BENZINE:

Q So this is a July 23rd, 2021, letter from Dr. Lauer to EcoHealth. I don't know if you're -- you are cc'd. Do you recall this letter going -- being sent?

A Just give me 1 minute to flip through.

Yes, I think so.

Q Were you involved in drafting this letter at all?

A I don't recall being involved in drafting this letter, no.

Q Primarily in this letter, in addition to a couple other requests, but Dr. Lauer informs EcoHealth that at this point they were 22 months late on their year 5 progress report.

When did you first learn that the year 5 report was late?

A I don't remember the exact date when I learned this. It may have been with this letter. But because the award was terminated, I wasn't doing the normal sort of oversight work that a program officer would have done, right. Or notifications weren't coming out as well, so --

Q So the year 5 report was due September 2019?

A Correct.

Q And terminated -- the grant was terminated April 2020?

A Correct.

Q So it was already significantly late.

Were there no checks between September and April?

A Well, no, those checks were interrupted by the suspension.

Q It was suspended in April of 2020 as well.

A Right. So the way NIH enforces delinquent submissions such as progress reports, an award is made, and then you have a full year to work on that before the next segment of funding is provided. When you start to get close to the anniversary date for the next award, that's when automated messages start going out saying this report that should have been filed at this time hasn't been. You must submit it or you won't get any more funding.

And so that process, I don't know exactly when it would have started, but it would have started around or before that time -- or around that time that the award was terminated.

Q So you give a 10-month grace period on reporting?

A It's -- yes. It can be. So that's managed by the NIH grants management office and the policy statement. But the enforcement mechanism -- because the awards are made and the funding has gone out, the enforcement mechanism is that you will not

receive additional funds until you comply or provide the delinquent material.

Q Okay. What kinds of things are reported in an annual report?

A There are various budgetary things, policy-related things. They talk about the original aims of the award, what they plan to do for the next year, what they've accomplished, personnel on the project, whether there are any changes to any of the major areas, such as human or animal subjects, biohazards, things like that.

Q And I think you said, but I don't want to mischaracterize you, that around the time of this letter would have been the time that you noticed that the progress report was late?

A Probably, yes.

Q Like, can you explain how an award being suspended inhibits your ability to oversee it? Like, it doesn't make sense to me that just because the award is suspended, they get off scot-free, right? Like, can you explain how that works?

A So I don't know if I can explain how the award was treated once it was terminated and then reinstated but suspended. I can't speak to that process.

But the enforcement process is generally an automated one. So when you hit that trigger of a certain number of days out from the annual turnover, then emails start to go out saying this hasn't been turned in, this hasn't been turned in. And for whatever reason, the termination suspension interrupted that automated process as well.

Q Has that been changed?

A I believe it has, but I'm not --

Q Is there a manual check to that automation? Like, we all live in an automated world, but, I mean, 22 months -- like, someone would have thought to -- hey, I haven't gotten this yet. This award's been in the news a lot. This award's been in press conferences a lot. Maybe we should check the file and see if we've gotten any

reports.

Is there not a human level to checking?

A So the other part to that is that no work was being done on the award while it was suspended, so there was nothing to check on. So it was terminated, and it was suspended.

Q But the year 5 was work that had already been completed?

A Correct.

Q So you could have checked on what they did during year 5. I mean, presumably, they would have turned it in already.

A Well, presumably, but they -- because it was suspended, there were no actions to be done. There wasn't anything that I could have checked on.

Mr. Strom. Prior to April, it wasn't suspended?

Dr. Stemmy. Correct.

Mr. Strom. So, for example -- this will be majority exhibit 11. It is an email obtained by FOIA January 23rd, 2020.

[Stemmy Majority Exhibit No. 11
was marked for identification.]

BY MR. STROM:

Q And I'll distribute it and let everyone read it.

I guess this is what we're, like, struggling with from, like, just a practical -- how does something go missing for 22 months?

So this is an email. You can see at the end of page 2 where, basically, NIAID staff is going -- is requesting information on the EcoHealth grant to prepare Dr. Fauci to brief the Senate on the coronavirus response, including the exact nature of NIAID's support for the WIV. And then you're cc'd on this.

So presumably, you were involved in NIAID's effort to get background information on the grant. You're the last guy on the cc line at the top of the first page.

A Oh, right. Yes, I see that.

Q So given that the search is in January of 2020 when the grant is still alive, how did you not go into the e-report file or go into the grant file and how did you not see that the year 5 is missing?

A I don't recall that being the question. The question was, what are the -- what are projects that are -- that involve WIV? And that level of detail is not usually in the progress report beyond, you know, this is a Site for it, right.

So as I think I mentioned, the scientific updates aren't separated in such a way saying this person does this, this person does this, this person does that. It's just a summary of all the work that they've accomplished.

Q I mean, the year 4 renewal had a series of sort of job assignments for the subgrantees, for the different principal investigator, the other investigators. The application for back in 2014 had that same information. So, I mean, there is valuable information about the grant in the progress report that I would think be relevant to tell Dr. Fauci.

I'm just curious, like, do you recall what you looked for to get them this information?

A Right. So recall also that the renewal funding had also, I think, gone through before this, right. So the year '06 was awarded. And so that was the most recent update to the work that they were planning to do. And so that was where I recall going to --

[2:47 p.m.]

BY MR. STROM:

Q Well, but the year 5 would have been in the fall of 2019. I believe the year -- the renewal was written in November 2018.

A Right. But it was reviewed and awarded, right? And so that was the work that they were currently doing. The year 5 progress report would have been the previous reporting period.

Q But it would have been the earlier-in-time representation of what they were up to?

A But the new award was different than -- the renewal award was different from the original award.

Q So you looked into the grant file, and you saw the renewal, but you didn't notice that the year 5 was missing from the earlier iteration of the grant?

Mr. Cooke. If you remember.

Mr. Strom. Yeah.

Dr. Stemmy. So no. It's not readily apparent, right? So, when you go into the grant file, I would have gone in and pulled up the 06, right, so this is -- the renewal year is 06, right? So, from that, I pulled the application and looked to see what they proposed to do at the specific site, because that's different potentially from what they would have proposed in the original or in that progress report.

BY MR. STROM:

Q But the progress report -- if this is early 2020, the progress report represents stuff that they were doing into like mid- to late 2019 as opposed to the 2020 reporting year, year 6, had just started.

A You're correct, but, again, the awards are distinct, right? So you have the

years of 01 to 05, which are --

Q So, then, the canceling of -- the canceling of the first award, in April -- termination, suspension, whatever -- didn't affect you looking at the year 6 at all?

A Well, so, at this point, it was not canceled or terminated.

Q Okay. So you didn't look at the first five? Just to wrap this up -- I'm not trying to, like, belabor the point here, but, like, you didn't look at the years 1 through 5 in response to this? You looked at only year 6?

A Correct, because years 1 through 5 proposed slightly different work. It was a term.

Q Sure, but there is, like, a 2- to 3-year lag between, like, collecting a coronavirus, sequencing it, characterizing it, and then reporting on it. So we see this pattern that virus is collected in 2016, 2017, only published about in, like, 2022, 2023.

A Well, and that's what the 06 award proposed to do, was they talked about what they were going to do with the samples they had previously collected and what they were going to be doing moving forward.

Q Okay. So just the old 1 through -- years 1 through 5 were totally, like, irrelevant to the search and just how you went about it?

A In a sense, yes, because, again, the '06 application proposed slightly different work with slightly different people, and so that was why, in response to this question, that was the new award that I focused on to provide that information.

Mr. Slobodin. John, could I ask --

Mr. Strom. Sure. That would give me a second to pull the next one.

BY MR. SLOBODIN:

Q So Dr. Fauci was briefing Senators in response to a news article, The Daily Mail. There were issues about what exactly is our support, what are we doing with

these entities in Wuhan?

So there was no year 5 progress report submitted at that point. It was missing from the file. You're the program officer. That was due in September. The deadline was September 2019. So, you know, as a program officer who is reviewing the progress, you're looking over, you're kind of the steward of what did they accomplish under this grant, you know, what did the taxpayer get in return for investment?

And I'm just having a hard time understanding why that wouldn't have been relevant to preparing Dr. Fauci for this briefing, how you did not have even looked at -- how could you not have even looked at the previous -- of what actually was done?

The year 6, that's what they're proposing. That's what they're planning to do, but they haven't done it. That was the renewal application at that point.

So wouldn't have looking at the year 5 report make sense in helping prepare Dr. Fauci for this briefing to see what was done?

A So what I'd say is that years 1 through 5 were what they did previously, right? So the question is: What are we funding, right? And, at that point in time, what we are funding was different than in the previous iteration of the award.

Q Well, I'm not sure it's -- you know, we're talking, you know, angels dancing on the head of a pin here. Do you really want Dr. Fauci going into a briefing with Senators with less information, or more information? I would think you'd want him going in with more information.

Mr. Strom. I can give something that's maybe, in this next exhibit, emblematic of this issue.

So we are on, I guess, exhibit 12 for the majority.

Mr. Rechter. We were on 11.

Mr. Strom. We were on 11, yeah, so this is 12.

[Stemmy Majority Exhibit No. 12
was marked for identification.]

BY MR. STROM:

Q This is another FOIA that's an email exchange between you and Lillian Abbey at NIAID.

And so, again, this is April 21, 2020. Let's start at the earliest email in this exchange, and so that actually begins on page 2, runs through to page 3.

So who is Abbey Lillian, or Lillian Abbey? Excuse me.

A Lillian Abbey is a staff member in the office of our director of our division.

Q Okay. And then Chase Crawford?

A Chase Crawford is with NIAID's legislative group.

Q And I assume, just NIAID BUGS, NIAID DEA DART, NIAID Leg Affairs -- what is NIAID BUGS and NIAID DEA DART?

A So NIAID BUGS is our coordination group within the office of our division director. The OCGR Leg is our Office of Congressional and Government Resources, I think, our legislative office at NIAID. And NIAID DEA is our Division of Extramural Affairs, I believe, if I have the acronym correct.

Q So this April 21st email, again, it looks like you guys are trying to collect information on sort of the full scope of your all's engagement with the WIV. This email from Lillian says, "Chase, Erik notes that the vast majority of the sites on Mark's list were part of the prior award and are no longer active. Grant was renewed last May. The current award just lists the China sites and Singapore. Therefore, we've provided information on what's active in the 2019 renewal now."

Erik -- and then there is some discussion about the changes in funding level,

but -- so, first of all, who is Mark Helfman, who I believe is the Mark referred to in the letter, or in the email?

A That, I don't know.

Q Because he got -- somehow, he got the list of both -- we'll call it the first grant, subgrantees from the prior award, as well as the current China ones. And then, when you noted that these are not part of the renewal, how did you know that they weren't -- I mean, did you go and check the original grant to make sure that it was a one for one here?

A Yeah. So my recollection of this was a little bit later, right? And so, at that point, I believe I had gone back and compared the sites that were active versus inactive.

Q And you did that with the year -- with the renewal, like the year 6 stuff, and you didn't compare it to the year 5 progress -- you didn't look to the year 5 progress report for the sites? Where did you get the sites from the first grant?

A The sites from the first grant are -- I mean, they say -- you don't need the progress report to know that -- what those sites are.

Q I mean, can you -- like, you can rattle them off now? You just knew them?

A No. There is a foreign site tracking system called FACTS that all of the awards have records in, and so that's the record of file, right, like, I guess, equivalent to the --

Q And I guess just because I'm not familiar with FACTS myself, but where did you know to get, or where did Mark, I guess confirmed by you, get the description of what each of these people were doing, which each of these components were doing?

So it says, "The sites below are part of the prior award. All had the same role. Samples were collected from animals from each of these sites," urban, yada, yada, yada,

and were sent to the WIV and analyzed to determine what coronaviruses are present.

So does the FACTS include that information? Does it have a description of what each group does?

A Yes.

Q Okay.

Mr. Benzine. Is the FACTS outside of the grant file? You could access FACTS without accessing the grant file?

BY MR. STROM:

Q Yeah. You could access the FACTS from the first grant without going to the first grant's grant file?

A Yes. Yes.

Q Okay.

Mr. Strom. My last exhibit on this thread is another FOIA email.

[Stemmy Majority Exhibit No. 13
was marked for identification.]

BY MR. STROM:

Q This is a May 22nd, 2020, email chain that ends with -- so, if we'll go to the back page here -- I guess it really begins with -- sorry. There is no ending email. An exchange between Ashley Sanders and David Miller of the FBI that you're cc'd on.

The subject matter heading lists both the R01 grant and the R02 grant numbers.

While it's heavily redacted, it appears that you provided responses to the FBI about both the first grant and the second grant. Is that correct?

A I believe so, yes.

Q So, just generally, what information was the FBI looking for?

A I don't recall each question. My recollection is that it was generally about

the work at WIV and what they were doing there.

Q Sure. And then, I mean, the FBI has never talked to me in a professional capacity, thankfully, so was this an unusual occurrence for you?

A Yes, it was. I believe it was the first time.

Q Yeah. So --

Mr. Benzine. Hold it.

Mr. Strom. Yeah.

BY MR. BENZINE:

Q Was it the last time?

A There was one other time as well.

Q About when?

A I don't remember the exact date. I believe it was last year.

Q Okay.

BY MR. STROM:

Q So, in an effort to provide accurate information to the FBI on both the first grant and the second grant, how did you not see that the year 5 was missing at that point?

A I don't recall the questions that he asked to require looking at the progress report. He was -- they were bigger-picture questions, if I'm not mistaken, that didn't need the individual missing progress report to answer.

Q So you were comfortable talking to the FBI without sort of looking at the grant file?

A Yes. I didn't -- I don't recall needing or noticing that there was a missing progress report to prepare for that meeting.

Q I mean, I guess what we're struck with is, like, have you had a situation

where other grants had been submitted -- had a progress report submitted, like, over 2 years late?

A I don't recall any other progress reports from my portfolio being submitted over 2 years late. I also don't recall any other grants having been terminated and suspended in the same way.

Q Sure.

A So I don't expect it would have gone past that 1 year.

Q And so what is your confidence level that what is portrayed in the late year 5 progress report accurately represents the research being done at the WIV in mid-2019 rather than having been revised at some point prior to submission?

A I don't have any -- so, based on what was submitted in year 4 through year 5, it's sort of a logical progression, and so I don't have any reason to suspect that it was not submitted accurately.

Q Okay.

Mr. Slobodin. Can I just follow up for just a second?

BY MR. SLOBODIN:

Q So the FBI -- I'm just looking at the subject. So it does include the R01, and this was in May of 2020, so this would have been after the termination. But this looks like it's several pages. So were you impeded from being able to respond to the FBI, do you recall, to this inquiry?

A Impeded in what way?

Q Well, they're asking for information on the R01. I don't know what it is, because it's all blacked out, or most of it is blacked out.

A I don't recall being impeded, no. I -- like I said, I don't recall any information that they requested being relevant to the inquiry.

BY MR. STROM:

Q To Alan's point out, it is almost 2.5 pages, 3 pages -- no -- 3.5 pages of redacted material, and you're saying you were able to just pull that all from memory?

A So, from memory or broad summaries that I have, I believe they also asked about the gain-of-function funding pause review and P3C0 review and definitions of it, so it wasn't all strictly related to the grants, if I remember correctly. It was broader questions about some of these policies as well.

Mr. Benzine. I have one followup question, but I want to point out for that record that that document has not been produced in committees.

Mr. Rechter. Happy to follow up with our own documents.

Mr. Benzine. If a grant is suspended or terminated, does the prime awardee still have to complete the requirements under the grant -- administrative requirements?

Mr. Cooke. If you know.

Dr. Stemmy. So my understanding is that this was a unique situation. I do recall that, when they came up for their first annual progress report, I believe the 07, they reached out to grants management to ask what they should submit. So I believe they still have to submit something, but, in essence, it was a paper that said, "This grant is terminated," and no action has been undertaken.

BY MR. BENZINE:

Q No. I'm saying -- so the grant that was suspended was the renewal, the type 2, right? But they hadn't completed all the requirements on the type 1 prior to having the funding for the type 2.

A Correct.

Q If the type 2 is suspended, does it just waive their requirements to complete the type 1?

A No.

Q Okay. Thank you.

Has EcoHealth been late on progress reports before?

Mr. Rechter. To the extent you know.

Dr. Stemmy. To the extent I recall, I don't ever remember them being excessively late. Maybe a week or so. I don't really remember anything that stands out as being very late.

BY MR. BENZINE:

Q All right. Some general questions, just if you know through your work doing this.

Do principal investigators routinely publish every virus they sequence or collect?

A I can't speak to whether or not everyone publishes every virus.

Q In your experience, is it common to publish everything that you sequence?

A Sort of. So the way publications work is that, you know, generally you're not just publishing a laundry list of what you are collecting, right? There are other ways to do that through public databases, like GenBank. You can submit sequences, things like that, and not all of those make it into publications.

Q Would it be possible that there is a viral sequence in a database that is not public?

A I don't know. I can't speak to that.

Q All right. Do researchers routinely publish every experiment that they conduct?

A It's not my experience, no, that every single experiment that is conducted is published.

Q I want to go --

Mr. Strom. Can I ask a quick question here?

Mr. Benzine. Yeah.

BY MR. STROM:

Q So this is minority exhibit G. It is the year 4 progress report along with the sort of cover email from Dr. Daszak to you in April 25th, 2018.

So we have this email attaching the year 4 report where he's going outside of the eRA Commons system to sort of personally hand you a copy of what he's up to. They had the big success with SADS and some other notable events.

Did he do this for year 5?

A I believe he sent me an email in -- contemporaneous with when he submitted the progress report in 2021, I believe that August, right? Is that when that one came in? So I believe he copied me on a message then, but not around the time that it would have been due.

Q So he went to the trouble of copying -- after you -- grant's been suspended. You're no longer talking to him at Dr. Lauer's direction or at NIH's direction. He still sends you, like, a sort of personal copy of the progress report, but he didn't do it -- he did not send you an email in 2019 with the progress report attached?

A He did not, no.

Q Okay.

BY MR. BENZINE:

Q We've talked about it a little bit, so we can move pretty quickly through this, but the experiment that tripped the 1 log policy in the year 5 report, as I'm sure you're aware -- I think you got questioned on it a little bit -- EcoHealth claims that the year 4 report and the year 5 report are the same experiment. You said you can't really tell. It's plausible that they are, but you can't really tell.

I think you touched on this a little bit earlier. In your estimation as the one that has to actually enforce the policy, what qualifies as immediate notification of a 1 log growth?

A I would say personally within one or two business days.

Q Was that communicated to EcoHealth?

A I don't recall ever defining what "immediate notification" meant.

Q Why not?

Mr. Rechter. Why doesn't he recall it?

Mr. Benzine. No.

BY MR. BENZINE:

Q Why not define it?

A I don't recall us ever establishing what "immediate notification" meant within our group. I don't --

Q All right. So you just don't remember if you did or didn't?

A No. I don't recall communicating that --

Q Do you remember what period --

A -- because I don't recall us ever establishing what "immediate" means.

Q Okay. I understand.

So the underlying kind of gain-of-function committee didn't establish "immediate notification," so, therefore, it was not -- what "immediate notification" meant, so, therefore, it was not communicated to EcoHealth?

A That's my recollection.

Q Is that correct? Okay.

Had Dr. Daszak or anyone at EcoHealth -- have they communicated with you at all regarding the year 4 and 5 experiments? Have they insinuated at all that they're

different experiments to you?

A No. I don't recall them insinuating different experiments.

Q You mentioned this a little bit and just to have clarity on the record, did the year 4 experiment in their progress report show greater than 1 log of viral growth?

A They -- the year 4 progress report showed a transient difference in viral growth, but equivalent by the end.

Mr. Strom. Does the -- sorry.

Mr. Benzine. No, go ahead.

BY MR. STROM:

Q Does the viral growth policy state when virus growth is supposed to be measured? So the determining --

A The term --

Q Sorry. I didn't mean to cut you off.

A The term does not.

Q So the transient viral growth is a potential policy violation?

A So, again, you have to look at the experiment, right? So what you would evaluate is the viral growth over the course of the experiment. And, in my opinion, you would evaluate what -- is there consistent differences across the experiment, because there can be individual variations and variability at different time points that may or may not be meaningful.

Q Because you said you didn't recall having any concern at the time you were reviewing the year 4 about the experiments.

A Correct.

Q But that you indicated that the weight loss may be a better way to gauge virus level pathogenicity?

A Pathogenicity, yes.

Q Yeah. So the average 20 percent weight loss for all of the -- the average weight loss for the mice who were injected with or inoculated with SHC014, that wasn't a concern for you?

A Again, not because -- because it overlaps with the back -- the wild-type backbone, so it's hard to -- it's hard to tell if there are any statistical differences there.

Q Because it's the same rate of weight loss as the SCH0 experiments in the Menachery paper when they sacrificed them -- I think he said humanely sacrificed them after 20 percent weight loss. And you did say that you would need statistical analysis, that you would need more data to know if it was a statistically relevant outcome. Is that correct?

A Yes.

Q And you didn't ask for more information after you read it?

A No.

Q You also mentioned that the figure 35b wasn't a concern because, again, the viral titers are the same by the end, but you wouldn't measure the viral titers until the end of the experiment, so how would you stop it from going -- violating the policy if you waited until the end of the experiment?

A Well, you wouldn't know if -- until the end of the experiment.

Q So, when they began to lose -- and I believe it's like day four, they begin to lose 10 percent of the body weight; day six, 20 percent of their body weight.

Would those have been signs that you should have -- that EcoHealth should have ended the experiment and reported it to you?

A Not a priori, no. Anything usually up to about 20 percent is what the guidelines are for humane euthanasia in animal and mouse experiments in particular.

Q Just to make sure I understand, anything up to 20 percent, so not 25 --

A Yes.

Q -- and 26 and 27?

A Correct.

Q Okay.

A Correct. There is a little bit of variability between institutions, but generally 20 percent is the humane cutoff.

Mr. Slobodin. Can I ask a followup there, John --

Mr. Strom. Sure.

Mr. Slobodin. -- on figure 35?

BY MR. SLOBODIN:

Q So the figure 35a only goes up to 6 days post infection.

Mr. Rechter. Which exhibit are we in?

Mr. Slobodin. I'm sorry. Was it minority exhibit F --

Mr. Cooke. It's G.

Mr. Slobodin. -- with figure 35?

Mr. Strom. G.

BY MR. SLOBODIN:

Q So, on the left-hand side, on the X axis, this bar graph only goes to six days post infection, but the graph on the right side goes past day six to dead point. Why would that be? Why would you have -- if it's the same experiment, why wouldn't we have the graph on the left going the same length of time as the graph on the right?

Mr. Cooke. If you know the answer.

Dr. Stemmy. So I can't speak to why they graphed what they did or how they did it. What I'll say is that progress reports like these are intended as snapshots of progress.

It's not what you would expect for a peer-reviewed publication, for example. These are, for lack of a better phrase, sort of rough snapshots of what investigators are doing at that time. And so they report -- they report the data that they have.

BY MR. SLOBODIN:

Q Okay. So, if you take, again, a look at figure 35a, you'll see here there are five different columns. There is a line for control in addition to WIV1 parental backbone. There is no control in the 35b.

So, first of all, why would they have a control if it was all about having a comparator in the experiment? What's the point of having a control?

A Well, in this case, control on the left is an uninfected mouse, and, for 35b, it's measuring copies of a virus. And, if you've not infected a mouse with a virus, you have no virus to measure.

Mr. Rechter. Can I get a time check real quick?

Mr. Osterhues. Just under 5 minutes.

BY MR. BENZINE:

Q You had said that, in the year 4 report, you needed more statistical analysis to determine if there was a violation of the policy. Is that fair?

A I said that you can't make a meaningful distinction without additional statistical analysis.

Q Why didn't you ask for more?

A Because the -- as I said, toward the end of the experiment, the viruses appear to have equivalent levels of virus.

Q Okay. Would the lab notebooks contain the kind of analysis that you need to differentiate between year 4 and year 5?

A I don't know.

Q All right. I want to talk about the reinstatement a little bit.

Mr. Benzine. Well, let's go off the record.

[Discussion off the record.]

BY MR. BENZINE:

Q So I want to talk about the reinstatement a little bit.

First, were you involved at all in the decision to reinstate?

A So in what way?

Q Were you -- obviously there was discussion about whether or not to reinstate the grant, what was enough compliance to get back into NIH's good graces and get the grant back. Were you involved in any of those discussions?

A I was not involved in any of the discussions from the NIH level. My understanding is that there were sort of two separate things. One is NIH level addressing compliance issues with EcoHealth directly. Once they satisfactorily addressed those concerns that the NIH level had, NIAID was then free to pursue renegotiation.

BY MR. STROM:

Q And, just to make sure I'm tracking, that process that you just described at NIH would originate with Dr. Lauer's office? Is that your understanding of --

A Yes. That's where that --

Q Okay.

A Yes.

BY MR. BENZINE:

Q So NIH would make the determination whether or not they were in good enough compliance to get a grant. You would then be involved in the renegotiation of the grant, so the new award conditions and terms?

A Correct.

Q All right. So were you involved in the discussions of what special conditions to put on the grant?

A No. My recollection is that those special terms and conditions were set at the NIH level and provided to us.

Q Okay. Were there any additional ones that NIAID placed on the grant?

A I don't recall if there were specific terms and conditions. I -- my recollection is that they were almost all related to the special terms and conditions from the NIH. I don't recall if there were additional ones.

Q All right.

BY MR. STROM:

Q So what was your role in the reinstatement?

A My role was to evaluate their scientific proposal to see if what they proposed could still address the original aims that they had proposed.

Mr. Benzine. I want to introduce exhibit 14.

[Stemmy Majority Exhibit No. 14
was marked for identification.]

BY MR. BENZINE:

Q So this goes to -- this is a letter from August 19th, 2022, from Dr. Lauer to EcoHealth running through some of the termination conditions, renegotiation conditions, and the specific award conditions placed on the new grant.

I want to flip to -- it's page marked 3980. It's a large chart. We discussed this a little bit about reviewing subaward agreements.

Do you review who the subawardees are going to be? Does the prime award tell you who they're going to subaward to?

A Yes. The applications will have proposed subawards, yes.

Q And is the capacity of the subawardee reviewed at the peer-review level, or is it a determination of peer review?

A What do you mean by "capacity"?

Q If the subgrantee is capable of performing the work requested.

A Yes. That's usually addressed by peer review.

Q Okay. And you don't review the subaward agreements prior to them being executed?

A No.

Q Okay. I want to run through the chart. This is just a chart from Dr. Lauer of the written subaward agreement requirements and EcoHealth's status.

There are one, two, three, four, five, six, seven, eight, nine, all of which they are noncompliant with. Do you think it would help you in your job if you were able to review subaward agreements prior to them being executed?

A Generally, I don't know how that would improve my role. My role is really to monitor the scientific progress, and so the specific contractual details of the subaward agreements aren't always relevant to my expertise or evaluation of progress.

Q Some of the agreements are sharing data, sharing notebooks, sharing scientific progress. If EcoHealth left that off, which they did -- left that off a subaward agreement, that would hinder your ability to manage the science.

A Well, I can't recall of any instance where I needed to review a lab notebook or anything -- raw data, for example, for any other awardee.

Q Okay. Just this awardee?

A Just this one.

Q All right.

BY MR. STROM:

Q So your point of about the scientific, I guess, redetermination, we had a briefing from Drs. Lauer and Erbelding a couple of months ago about the reinstatement and the rationale for it. And one of the reasons given for reinstating the grant is that there were thousands of bat samples collected from China with funding from this grant that still needed to be tested for the presence of viruses.

Is that accurate?

A I believe so, yes. They needed -- they had samples archived, yes.

Q Do you know how many are archived?

A Offhand, I don't recall.

Q And these were all samples collected from China?

A I believe they were.

Q Which subgrantee collected the samples?

A I believe the -- let's see. It was -- I believe it was the -- so, for the first award, so the first section was, I believe, the Institute of Pathogen Biology was the entity responsible for the field work.

Q And, when you say they're archived, are they archived in EcoHealth's possession?

A I don't know where they're archived. I don't expect them to be physically at EcoHealth. I imagine they are with their partners or former collaborators.

Q So one of the justifications is that the collaborators in China still have thousands of bat samples at EcoHealth, feels it can get access to such that this is a high-priority grant to continue funding?

A Yes.

BY MR. BENZINE:

Q And EcoHealth has told you that they have access to these samples?

A Yes.

BY MR. STROM:

Q So, again, having reviewed the progress reports, all of the bat sampling and field work were done in China by the WIV, other Chinese institutions. You've mentioned one.

So we're surprised that they're still accessible to EcoHealth given that EcoHealth didn't have access to the WIV's notebooks, they haven't had access to a lot of the underlying data that's resident in China.

So are there additional terms or conditions or even, you know, a gentleman's agreement that gives some confirmation that we'll have access to these samples?

Mr. Cooke. If you know the answer.

Mr. Strom. Yeah. I mean, if you know. Exactly.

Dr. Stemmy. Right. So my understanding is that the samples will be shipped from wherever they are to, I believe, Singapore is where they, under the renegotiated agreements, will be analyzing these samples.

BY MR. STROM:

Q Okay. And you don't know where the samples are because EcoHealth hasn't said, or you just don't recall?

A I don't recall them saying specifically where they are. I believe they are also going to be using samples that were collected not just from China, but, in the first section of their award, they had other areas -- other countries in southeast Asia where they were collecting samples as well.

Q Not under this award, though?

A They can analyze them under this award, but my understanding is they were

collected previously on the first part of the award.

Q Sorry. I should have been clear.

According to all the progress reports, none of this grant, whether it's the first iteration or second iteration, was used to fund sample collection outside of China? All of their tables in their progress reports list all the sampling was done in China. So are they now saying, "We have samples in China, and then we have samples elsewhere that we're also going to sort of roll into this testing and collection"?

A I believe also their archived samples go back to prior funding as well from other institutes or agencies. So they have a longstanding sample collection history in the area.

Q Sure. So, prior to Duke-NUS. stepping in, the WIV was the place where these samples were archived? It's where they were sequenced, characterized, you know, uploaded to GenBank or whatever.

So how is it that the WIV doesn't have the samples?

A I can't speak to where they're archived. WIV was doing the characterization of them, and I don't know that all of the samples were shipped there for storage or if they remained with the original collector.

Q Okay. And then there has been some allegations, and they're not important enough for an exhibit here, central enough for an exhibit here, that EcoHealth had potentially double billed USAID and HHS for field work. And so, given these allegations, how do you know that NIAID isn't simply paying to double bill work that they're doing for DOD or USAID?

A I don't know if I can speak to the particulars of that without really knowing what overlap you're talking about. I recall for the -- when the first award was made, there was some discussion from peer review about overlap, and, at the time, it was

addressed and clarified.

Q So I guess we were -- I was surprised to learn that there are all these samples, presumably in China, that EcoHealth still has access to. And now, in addition to the samples in China, there are samples, I guess, going back to somebody's archive from other countries.

How do we know that another U.S. Government program isn't already paying for that work?

A I don't know. I can only speak to what they report as their other support, and I've not seen evidence of overlap in the other support that's been provided.

Mr. Strom. Okay. Thank you.

BY MR. BENZINE:

Q Do you independently validate how many samples they say they have?

A No. I -- in terms of counting them? No.

Q Yeah. So you wouldn't be able to validate that they're actually taking all of the samples that the U.S. paid for?

A No. And, you know, not all the samples may not have viable virus in them, so it's not exact -- it's not exact numbers that came in.

Q I want to ask you a couple questions about the DEFUSE proposal if you know about it.

Mr. Rechter. I'll just jump in here real quick. As an accommodation with majority staff here, with the understanding that majority staff will move efficiently through these questions, we'll make an accommodation to the scope of the authorization memo for these questions.

Mr. Benzine. We'll rip them through.

BY MR. BENZINE:

Q Are you generally aware of the DEFUSE proposal submitted by EcoHealth to the WIV and UNC to DARPA?

A I'm aware of the reporting, I guess.

Q To your knowledge, has NIH funded any research like what is proposed by EcoHealth in that proposal?

A Not to my knowledge.

Q In your experience, is it common for an organization to begin some of the work prior to submission of a proposal?

A What do you mean?

Q So, if I propose -- in DEFUSE, they propose inserting furin cleavage sites into novel coronaviruses.

Is it common prior to me crafting a proposal that I prove to myself I'm capable of doing what I'm proposing?

A Proposals generally require preliminary data, but generally you don't expect an investigator to have performed everything that they are proposing to do.

Q Okay. And then, in your experience, if a grant application is denied by the Federal Government, are there other avenues to receive funding?

A So I don't know what you meant by denied by the Federal Government.

Q DARPA denied the proposal. If they didn't fund the proposal, could the grantee go to the Bill Gates Foundation and get money to do it?

A Investigators can apply to whoever they'd like for funding.

Q All right. And then the U.S. Government wouldn't be able to oversee what they were doing, correct?

A To my knowledge, no.

Q We touched on this a little bit, which I'm sure the date range kind of lines up

with this. I'm sure you're aware of the intelligence community investigating the origins of COVID-19. Are you aware of those efforts?

A Yes.

Q Were you contacted at all by the intelligence community during the course of those efforts?

A I don't know if it was in the course of those specific efforts, but I have been contacted twice by the FBI.

Q So the first instance was the exhibit that my colleague showed, correct, requesting information about the grant, and the second --

A Correct.

Q -- instance was separate from that?

A Yes. It was about a year ago. I think it was last year.

Q What did that interaction consist of?

A Two agents came to my building in Bethesda, and I met with them for approximately an hour.

Q What did they ask you.

Mr. Cooke. So, to the extent that this relates to, you know, an FBI investigation, I don't think we're going to be able to get into that in this context.

Mr. Benzine. I don't think it does.

Mr. Cooke. I mean, we're talking -- you're asking him --

Mr. Benzine. Depending on what they asked him -- I have no idea what they asked him. Do you know what they asked him?

Mr. Cooke. You're asking about specific information that the DOJ and FBI asked him about. I mean, we're not going to be able to get into that in this setting.

Mr. Benzine. Why?

Mr. Strom. Are you saying there is an active investigation?

Mr. Cooke. I'm saying I don't know.

BY MR. OSTERHUES:

Q Dr. Stemmy, when you met with the FBI agents, did they, at the conclusion of the interview, tell you not to discuss what they had discussed with you?

A I don't recall them, no, saying that.

Mr. Rechter. Either way, we're going to ask these questions at a higher level here.

Mr. Cooke. Yeah.

BY MR. BENZINE:

Q What general topics did the FBI ask you about?

Mr. Cooke. That's fine.

Dr. Stemmy. Generally about the award itself, generally about gain-of-function research funding pause, generally about P3CO. I don't remember the specifics. It's been some time.

BY MR. BENZINE:

Q Did they ask about what the EcoHealth and the Wuhan Institute were working on, what kind of research they do, what kind of science they do?

A I recall broadly talking about the research goals and objectives of the project.

Q Thank you.

So I have two final questions. For better or worse, your name has been attached to this grant for a long time, publicly for a little while as well. Has HHS or any other agency briefed you on any threats against you?

A No.

Q Okay. Final one: It's been publicly suggested that Dr. Daszak or

EcoHealth has a relationship with the Central Intelligence Agency.

Do you have any knowledge of that?

A I have no knowledge of that.

Mr. Benzine. All right. Thank you.

Mr. Rechter. Is that it?

Mr. Strom. I have a quick run through to make sure that I'm understanding one issue related to the P3CO process and the viral growth pause policy. It will take, like, 5 minutes hopefully.

BY MR. STROM:

Q So you said earlier that the P3CO process is substantially similar to how you guys handled -- is procedurally substantially similar to how you guys handled the analysis of whether the gain-of-function pause applied to a certain experiment?

A Correct.

Q Okay. So these are asked to both the P3CO process and to the gain-of-function pause process to make sure I'm understanding the process correctly.

So there is no written guidance on the implementation of either the pause or the P3CO sent to NIAID to have for grantees other than the publicly available framework?

Mr. Rechter. To your knowledge.

Dr. Stemmy. So, to my knowledge, we have our internal sort of workflow that we follow. It's a small flowchart, but I don't -- I'm not aware of public --

BY MR. STROM:

Q And, just by way of example, what we're talking about here is this was exhibit -- majority exhibit 14. It is the August 2022 letter from Dr. Lauer. And, I mean, the chart that Mitch went over here, you know, it mentions specific CFR sections. It mentions specific guidance and requirements that have to be followed and that

presumably have a written form, whether it was subregulatory guidance or something that went through notice of comment. There is nothing like that beyond, again, the workflow chart and the framework?

A Not to my knowledge, no.

Q And then these policies contained no guidance on when during an experiment the PI is supposed to test for growth?

A The P3CO policy itself?

Q Just your -- when you're sending out this continuing -- this 1 log standard that you carried over from the pause to P3CO, there is no guidance on when they're supposed to test to see if it went over 1 log?

A To my knowledge, no.

Mr. Rechter. The doctor has definitely answered this question.

Mr. Strom. I'm just trying to --

BY MR. STROM:

Q And then there is no direction on how to design the experiment or how to do data collection to ensure that that 1 log growth is measured or that it's measured for?

A So, generally, NIAID staff doesn't directly direct investigators on how they conduct their research objectives and research strategy.

Q So no guidance on how to measure the viral growth; hence, EcoHealth going with the logs -- the genome copies as opposed to using the 1 log -- the viral titer standard?

A Correct.

Q And then, as part of this process, you guys don't do -- your group, your committee, doesn't do the risk-reward assessment as to whether or not the potential scientific benefits of the experiments outweigh the risk of it, that final chapter or final

section in the Menachery article?

A So, if a project is referred to HHS for review, that's when risk/benefit is addressed.

Q Okay. And then last question on this: Reasonably anticipated is the standard for when this review is triggered or when the gain-of-function pause was triggered, has no formal written definition in NIAID guidance, but that you understood it or were effectively using a preponderance of the evidence standard?

A Yes.

Mr. Strom. Okay. That's it. Appreciate it.

Mr. Rechter. Okay.

Mr. Benzine. We can go off the record.

[Whereupon, at 3:37 p.m., the interview was concluded.]

Certificate of Deponent/Interviewee

I have read the foregoing ____ pages, which contain the correct transcript of the answers made by me to the questions therein recorded.

_____

Witness Name

_____

Date