May 1, 2024



AN EVALUATION OF THE EVIDENCE SURROUNDING ECOHEALTH ALLIANCE, INC.'s RESEARCH ACTIVITIES

Interim Staff Report of the

Select Subcommittee on the Coronavirus Pandemic Committee on Oversight and Accountability

U.S. House of Representatives

Dear Colleague:

Since I was entrusted with the Chairmanship of the Select Subcommittee on the Coronavirus Pandemic, we have been dutifully living up to our charter and bringing accountability and transparency to the American people. This interim staff report, the second in our series, seeks to provide evidence and information regarding the government's funding and lack of oversight of gain-of-function research, EcoHealth Alliance, Inc., and the Wuhan Institute of Virology.

The Select Subcommittee has conducted the most thorough investigation into this topic to date. Without the support of the American people, these efforts would not have been possible.

The below report provides extensive evidence, including firsthand testimony and primary source documents. It is clear that EcoHealth and its President, Dr. Peter Daszak, acted with contempt for the American people. Further, EcoHealth's actions were often enabled by the incompetency of the National Institutes of Health and National Institute of Allergy and Infectious Diseases. It is this contempt and incompetence that necessitates both Congressional and Administrative action.

In addition to other specific actions, the Select Subcommittee is making two primary recommendations, one to the Congress and one to the Administration:

- 1) To the Congress: Reign in the unelected bureaucracy, especially within government funded public health. NIH and NIAID are no longer the trusted preeminent scientific institutions they once were. It is imperative upon us to establish more stringent guardrails, higher standards of oversight, and limit adversarial interference in our grant making processes.
- 2) To the Administration: Recognize EcoHealth and its President, Dr. Daszak, as bad actors. This investigation establishes neither can be trusted with taxpayer funds. It is imperative upon the Administration to immediately begin suspension and debarment proceedings and ensure neither EcoHealth nor Dr. Daszak are awarded another cent, especially for dangerous and poorly monitored research.

Pursuant to H. Res. 5, please use this report as a resource while developing continuing legislative solutions to ensure safe and effective research, good stewardship of taxpayer dollars, and a more accountable bureaucracy.

Sincerely,

Brad Wenstrup, D.P.M.

Chairman

Select Subcommittee on the Coronavirus Pandemic

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TABLE OF KEY TERMS AND INDIVIDUALS

Select Subcommittee on the Coronavirus PandemicSelect Subcommittee
White House Office of Science and Technology PolicyOSTP
Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases
EcoHealth Alliance, Inc
Wuhan Institute of VirologyWIV
Dr. Francis Collins
Dr. Anthony Fauci Director (former) National Institute of Allergy and Infectious Diseases
Dr. Lawrence Tabak
Dr. Michael Lauer
Dr. Emily Erbelding
Dr. Erik Stemmy
Dr. Peter Daszak President EcoHealth Alliance, Inc.

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	Dr. Zhengli Shi
	Di. Zilengii Siii
	Senior Scientist
	Wuhan Institute of Virology
	wullan institute of virology
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EXECUTIVE SUMMARY

Since April 2020, House Republicans have been investigating the origins of SARS-CoV-2, the virus that caused the COVID-19 pandemic. This includes investigating the U.S. government's funding and approving gain-of-function research, as well as the NIH and NIAID grant oversight process. This report examines these processes by analyzing NIAID grant, R01AI110964 – "Understanding the Risk of Bat Coronavirus Emergence," awarded to EcoHealth and the corresponding compliance actions taken against it by NIH.

During this investigation, the Select Subcommittee has reviewed more than one million pages of documents and interviewed more than a dozen fact witnesses. This work established the evidence to support five interim findings.

- EcoHealth submitted its Year 5 Report nearly two years late. Further, EcoHealth's claim that it was locked out of an NIH system and blocked from submitting the report on time is not supported by the evidence.
- EcoHealth violated its grant terms and conditions by failing to report a potentially dangerous experiment conducted by the WIV.
- EcoHealth used taxpayer dollars to facilitate gain-of-function research on coronaviruses in Wuhan at the WIV, contrary to previous public statements, including those by Dr. Anthony Fauci.
- Finding 4: NIH may not have known about EcoHealth's actions without proper intervention by former-President Donald Trump and former-White House Chief of Staff Mark Meadows. Further, despite suggestions of political persecution against EcoHealth, career NIH leadership supported every compliance action taken.
- While negotiating the reinstatement of the grant, Dr. Daszak omitted the material fact that unanalyzed samples and sequences—that the U.S. paid for—are in the custody and control of the WIV. This omission was taken as fact by NIAID and NIAID took no steps to verify the actual location of the sequences and samples. If Dr. Daszak had not made this omission it would have provoked questions from NIAID regarding EcoHealth's ability to fulfill the aims of the reinstated grant. Finally, as a result of Dr. Daszak affirmations, NIH is currently violating the terms of the debarment of the WIV.

Again, based on the evidence collected by the Select Subcommittee, there are serious and systemic weaknesses in the federal government's—particularly NIH's—grant making processes. The weaknesses identified by the Committees not only place United States taxpayer dollars at risk of waste, fraud, and abuse but also risk the national security of the United States. These weaknesses can only be remedied through both executive and legislative action.

The facts contained in this report necessitate action. It is because of this investigation that the Select Subcommittee believes EcoHealth is not a good steward of U.S. taxpayer dollars. For

this reason, the Select Subcommittee is recommending NIH recommend and HHS immediately commence suspension and debarment proceedings against both EcoHealth and Dr. Daszak.

The Select Subcommittee will continue to evaluate the federal government's funding of gain-of-function research, the associated guardrails, and if sufficient care and oversight exists. This continued effort includes the evidence surrounding NIAID's deliberations regarding EcoHealth's research and the application of various policies and procedures.

Finally, the Select Subcommittee continues to be obstructed by pertinent custodians, including HHS and EcoHealth. The actions of these entities are unjustified and will not be tolerated.

ANNUAL REPORTING

During the life cycle of a grant, the principal investigator must provide annual reports, known as Research Performance Progress Reports (RPPR), to its funding agency. These reports provide the funding agency with updates on the progress of the work funded by the grant and any anticipated changes in the research approach or direction going into the next funding year. In the case of EcoHealth, these reports, especially its Year Five RPPR, have come under scrutiny from the NIH Office of Extramural Research and the Committees' investigation.

EcoHealth's Year 5 RPPR [hereinafter "Year 5 Report'] was due September 30, 2019. However, the report was not submitted until August 3, 2021—nearly two years late.² This failure was first reported to Congress via an October 20, 2021 letter from Dr. Tabak to then Ranking Member of the Committee on Oversight and Reform James Comer.³

EcoHealth submitted its Year 5 Report nearly two years late. Further, EcoHealth's claim that it was locked out of an NIH system and blocked from submitting the report on time is not supported by the evidence.

I. <u>EcoHealth Submitted Its Year 5 Report Nearly Two Years Late.</u>

Each year, regardless of whether a grant is being evaluated for a competitive renewal, the principal investigator must submit an annual progress report. As stated above, EcoHealth's Year 5 Report—the report that included the results of research and experiments for June 2018 through May 2019, the time period immediately preceding the outbreak of the COVID-19 pandemic—was due September 30, 2019. However, EcoHealth submitted this report nearly two years later on August 3, 2021.

For project years one through four, Dr. Daszak, in addition to submitting the annual report via the NIH online reporting system, would routinely also send it via e-mail to his program officer, Dr. Stemmy. The Committees are in possession of these e-mails for reporting years one, two, and four:

1) On May 1, 2015, Dr. Daszak emailed Dr. Stemmy the Year 1 RPPR stating, "[w]e just uploaded our Y1 Report for our Understanding the Risk of Bat Coronavirus Emergence award (1R01AI110964-01). I wanted to send you a copy of the report as well."⁴

¹ Research Performance Progress Report (RPPR), Nat'l Insts. of Health (last updated Nov. 2, 2022) (last accessed Apr. 24, 2024).

² Understanding the Risk of Bat Coronavirus Emergence, RPPR (Aug. 3, 2021).

³ Letter from Lawrence Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (Oct. 20, 2021).

⁴ E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Erik Stemmy, et. al., Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health (May 1, 2015) (On file with Select Subcomm. Staff).

- 2) On May 13, 2016, Dr. Daszak emailed Dr. Stemmy the Year 2 RPPR stating, "I just wanted to let you know that we submitted our Year 2 Report yesterday (attached as pdf)."⁵
- 3) On April 25, 2018, Dr. Daszak emailed Dr. Stemmy the Year 4 RPPR stating, "I just wanted to send you a pdf of our Year 4 Report which I submitted last week." 6

When asked why he did not continue this pattern for the Year 5 Report, Dr. Daszak testified:

Dr. Peter Daszak (Nov. 13, 2023)

- Q. Okay. And I think we had seen in, I think at least 1 year prior, maybe year 4, a practice of submitting the annual report through the Commons system –
- A. Yeah.
- Q. -- of course the way that it's submitted?
- A. Yeah.
- Q. And then separately from that, emailing it over to your grants office?
- A. Yeah. I remember doing that a couple of times, yeah.
- Q. Did that happen here?
- A. No, unfortunately. I wish I'd done that. I didn't do it. You know, it's unfortunate.⁷

Dr. Stemmy was the NIAID official responsible for tracking and ensuring EcoHealth's progress reports were submitted on time. According to Dr. Stemmy, Dr. Daszak did not send an e-mail with the Year 5 Report until Dr. Daszak officially submitted it August 3, 2021. Dr. Stemmy testified:

Dr. Erik Stemmy (Nov. 13, 2023)

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⁵ E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Erik Stemmy, et. al., Ph.D., Program Officer, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health (May 13, 2016) (On file with Select Subcomm. Staff).

⁶ E-Mail from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Erik Stemmy, et. al., Ph.D., Program Officer, Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health (Apr. 25, 2018) (On file with Select Subcomm. Staff).

⁷ Transcribed Interview of Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., at 51-52 (Nov. 14, 2023) (hereinafter "Daszak TI").

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.

Dr. Daszak also testified that "the information from the Year 5 Report was in the resubmitted - - [year 6 competitive] renewal submission, in the first part of that renewal submission." Specifically, he testified:

Dr. Peter Daszak (Nov. 14, 2023)

- Q. Could I ask –
- A. But -- yeah, go ahead, go ahead.
- Q. Could I ask why not, in other words, it seems as if there was a knowledge that you can always just attach the PDF to the email and send it over to Erik Stemmy.
- A. Yeah.
- Q. We're struggling, I think, a little bit to understand why that would not have occurred here.
- A. Well, you know, one, it's me second-guessing my decisions 4 years ago, but one reason why there's less concern is, the information from the year 5 report was in the resubmitted -- the renewal submission, in the first part of that renewal submission. We had information of relevance to the work we were doing in China in that submission. So Erik Stemmy, the program officer, had seen that, without a doubt. That was part of his job to read that proposal. ¹⁰

⁸ Transcribed Interview of Erik Stemmy, Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 142 (Nov. 13, 2023) (hereinafter "Stemmy TI").

⁹Daszak TI, *supra* note 7, at 52.

¹⁰ *Id*.

This sentiment was reiterated by multiple witnesses throughout the inquiry. However, after a review of the Year 6 competitive renewal, the Select Subcommittee does not believe the experiment in question in the Year 5 Report was in the renewal application. Regardless, simply because there is a renewal application, does not exempt EcoHealth from following the terms of its grant and submitting its Year 5 Report on time. As multiple NIH witnesses testified, the Year 5 Report is still due on time regardless of the competitive renewal application. For Example, Dr. Stemmy testified:

Dr. Erik Stemmy (Nov. 13, 2023)

Q. If a grant is suspended or terminated, does the prime awardee still have to complete the requirements under the grant -- administrative requirements?

HHS. If you know.

- A. 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.
- 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. 11

II. <u>EcoHealth's Claim That It Was Blocked By The NIH From Submitting The Year</u> 5 Report On Time Is Not Supported By The Evidence.

As an excuse for why EcoHealth's Year 5 Report was late, Dr. Daszak testified that he attempted to submit it but was "locked out" by the NIH system. This testimony does not stand up to further scrutiny. Dr. Lauer and NIH ran a forensic audit across their systems to attempt to confirm Dr. Daszak's claim, however, NIH could not verify the claim.

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¹¹ Stemmy TI, *supra* note 8, at 140-141.

The Select Subcommittee does not find EcoHealth's explanation for the delayed submission to be credible or consistent with testimony and documents produced during this investigation. EcoHealth asserted that it attempted to submit the Year 5 Report before the deadline of September 30, 2019 but the NIH's eReporter system, which is an online portal used by investigators to submit required grants documentation to NIH, would not allow them to upload the report because funding for year six of the grant, the first year of its renewal period, had already been released.

Dr. Daszak also testified to the Select Subcommittee that EcoHealth contacted NIH technical support and their grant management officer in an effort to resolve the problem, but that—to his recollection—there was no email communication between NIH, NIAID, or EcoHealth regarding the inability to submit the Year 5 Report. Dr. Daszak further testified that he did not attempt to contact the relevant grant officer, Dr. Stemmy. After attempts to contact NIH and NIAID by phone failed, Dr. Daszak informed the Select Subcommittee that he assumed the report was unnecessary as NIH continued to disburse funding.

Dr. Lauer testified:

Dr. Michael Lauer (Nov. 2, 2023)

- Q. Okay. Oh, I meant to -- I had one other question on this late year-five report. You said earlier to somebody's questioning today that you were not convinced that EcoHealth -- EcoHealth sent a product. They had a submission. They were trying to submit it in July 2019, and they experienced a lockout. They were locked out of the eRA Commons system, and they weren't able to do it. Now, you said you were not convinced. So could you explain why you were of that view?
- Yeah. So our office did an electronic forensic investigation of A. EcoHealth's encounters with our grant system, and that included both looking at activity logs. Every time that anyone interacts with our system, there is an activity log that describes when they came in, who came in, what actually happened. And it also involved our help desk ticket. So we have a help desk. And so whenever somebody calls in and says, "I am having problems with the system," that encounter that they have with our staff is recorded. We never found any evidence that they had been locked out of our system. We did see that on one day somebody from EcoHealth had attempted to log in through one -- you can log into our system in multiple different ways. And they had attempted to log in in one way and had entered the wrong password, I think, three times. And so that particular channel did get blocked. But then, on the very same day, later they were interacting with our system having logged in through a different route. And then we looked at the help desk tickets, we also looked at emails with NIAID staff, and we never

- saw any evidence that they claimed that they were unable to submit their progress report because the eRA system had locked them out.
- Q. Okay. And if it had locked them out, weren't there other ways they could have gotten the report into NIH if they had called somebody?
- A. If they were unable to submit any document because they had been locked out of the system, then what they would do is they could call up our help desk, and then our help desk would work with them to figure out what was going on.¹²

In response to Dr. Lauer's testimony, Dr. Daszak deflected by stating that both the facts that Dr. Lauer's forensic investigation failed to find evidence supporting Dr. Daszak's claim, and his underlying claim can both be true. Dr. Daszak testified:

Dr. Peter Daszak (Nov. 14, 2023)

- Q. So I'm going to show you what's going to be majority exhibit No. 5. This is an excerpt of a transcribed interview with Dr. Lauer that the committees took earlier this month. So we asked Dr. Lauer what, as part of his compliance review of the grant, what steps he did to look into this lockout issue...So we plan to ask for that, the results of that forensic audit. But, again, wanted to get your impression as to how correct that is.
- A. It's absolutely possible. What Dr. Lauer says there is true and what I'm saying to you is true. It can be true that there is, as he states, there's no evidence of us contacting the help desk and getting a help desk ticket because we maybe didn't do that. We contacted the grants officer. It can also be true that Dr. Lauer doesn't have any evidence that we'd been locked out of the system and that we were locked out of the system. Just because he can't find evidence of that doesn't mean it's not true. We were locked out of the system. Not only were we locked out of the system then, when Dr. Lauer wrote to us demanding that we immediately send the year 5 report and upload it into the system, NIH couldn't get the system to work for 11 days. We have it on record. And that's how we did keep email. So look, Dr. Lauer is a very senior manager at NIH. I'm sure that it's logical to him that someone would go to the help desk. But we had a direct point of contact in charge of grants management who never responded to us by phone. All we can do is try. And if NIH was unable to, even when they demanded the report 2 years later, they were unable to unlock the system for a number of days, it was clearly locked.

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¹² Transcribed Interview of Michael Lauer, M.D., Dep. Dir., Extramural Research, Nat'l Insts. of Health, at 102-103 (Nov. 2, 2023) (hereinafter "Lauer TI").

- Q. Sure. I'm just giving you the opportunity to comment on his [sic]. And we don't have the forensic audit so we don't have a firm idea of the scope.
- A. Well, if the forensic audit tests whether we got a help desk ticket or assesses whether we tried to log into a system or assesses whether we sent an email, then maybe the forensic audit won't find that. But we tried to upload that report. We even tried when NIH told us 2 years later immediately send it and we weren't able to. The system locked us out. It's a fact.
- Q. You said that you had emailed your point of contact at NIAID or NIH to try to rectify the situation, right?
- A. My admin staff called the point of contact.
- Q. Called?
- A. I believe so, yeah. I think they emailed her, received no response, called.
- Q. Because Dr. Lauer also testified that during the course of this audit they looked at emails with NIAID staff and still never saw any evidence that EcoHealth claimed you were unable to submit a progress report because the eRA system had locked them out?
- A. Well, again, like I said, they may find no email evidence, but we did try to submit the report. It did lock us out. I mean, you can't get much more clearer than when NIH specifically instructed us to upload it immediately, 2-1/2 years later, in a matter of urgency, where they knew all about it and were waiting for it, they still couldn't get the system to unlock. Clearly that system needs to be fixed. 13

Unfortunately, Dr. Daszak cannot prove these claims and NIH investigated and was unable to verify them. Evidence suggests that Dr. Daszak simply failed to upload the Year 5 Report on time. Dr. Daszak's excuse as to why lacks credibility because:

- 1. When resolving grant management issues, EcoHealth and NIAID appear to normally do so primarily by email. It strains credulity that EcoHealth would communicate with NIAID and NIH exclusively via telephone given their past practices.
- 2. Emails produced by EcoHealth during this investigation show that EcoHealth continued to work on the Year 5 Report after the date at which Dr. Daszak claims he attempted to submit the report. These emails make no mention of being locked out.

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¹³ Daszak TI, *supra* note 7, at 139-141.

3.	Moreover, Dr. Lauer testified to the Select Subcommittee that NIH conducted an internal
	review of their eReporter system and found no evidence that EcoHealth attempted to
	submit the Year 5 Report prior to August 2021.

4. The Select Subcommittee has repeatedly sought drafts of the Year 5 Report and other documents that would corroborate EcoHealth's version of events. EcoHealth has failed to produce much of the requested material, including the drafts.

AVOIDING TRANSPARENCY

Since EcoHealth was flagged by NIAID for experiments that may be dangerous, it was required to immediately report to NIAID if any experiments exhibited excessive growth. This term was memorialized into EcoHealth's grant terms and conditions and therefore mandatory.

After EcoHealth submitted its Year 5 Report, NIH believed that it facilitated an experiment at the WIV that violated this condition and thus should have been reported but was not subsequently reported.

EcoHealth violated its grant terms and conditions by failing to report a potentially dangerous experiment conducted by the WIV.

I. <u>EcoHealth Was Required To Report Experiments That Showed Excessive</u> Growth And Failed To Do So.

EcoHealth is required to "monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with Federal statutes, regulations, and the terms and conditions of the subaward . . ."¹⁴ As stated in the Notice of Award, "[a]cceptance 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."¹⁵ Even grantees that function as pass-through entities must monitor the activities of subrecipients, including foreign subrecipients, to ensure that subawards are used for authorized purposes in compliance with relevant laws and the terms and conditions of the subaward. ¹⁶

This was particularly true when NIAID identified possible gain-of-function research concerns in an experiment proposed by EcoHealth and conducted by the WIV. In a July 7, 2016 letter to EcoHealth, as a grantee undertaking potentially dangerous gain-of-function experiments, NIAID officials advised:

NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grant Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.¹⁷

This advisement was memorialized in EcoHealth's Notice of Award.

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¹⁴ 45 C.F.R. § 75.352(d).

¹⁵ NIAID, Notice of Award, EcoHealth Alliance, Grant Number 1R01A1110964-01, *Understanding the Risk of Bat Coronavirus Emergence* (May 27, 2014).

¹⁶ 45 CFR § 75.352.

¹⁷ Letter from Erik J. Stemmy, Ph.D., Program Officer, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health to Mr. Aleksei Chmura, EcoHealth Alliance (July 7, 2016).

SECTION IV - Al Special Terms and Conditions - 5R01Al110964-03 REVISED

REVISED AWARD: This Notice of Award is revised to provide approval for collaboration with the **Wuhan University School of Public Health (CHINA)** in accordance with the request submitted by Aleksei Chmura, Ecohealth Alliance, Inc. on October 6, 2016.

Supersedes previous Notice of Award dated 7/26/2016.

No funds are provided and no funds can be used to support gain-of-function research covered under the October 17, 2014 White House Announcement (NIH Guide Notice NOT-OD-15-011).

Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.

In Dr. Tabak's October 20, 2021 letter to Mr. Comer, he noted that an experiment published in EcoHealth's Year 5 Report exhibited greater than one log growth and should have been reported to NIAID but was not. Dr. Tabak wrote:

However, out of an abundance of caution and as an additional layer of oversight, language was included in the terms and conditions of the grant award to EcoHealth that outlined criteria for a secondary review, such as a requirement that the grantee report immediately a one long increase in growth. These measures would prompt a secondary review to determine whether the research aims should be re-evaluated or new biosafety measures should be enacted. EcoHealth failed to report this finding right away, as was required by the terms of the grant. ¹⁸

NIH concluded that EcoHealth conducted an experiment that was published in its Year 5 Report that violated this policy and was not reported. EcoHealth has argued that if an experiment did violate the one log notification requirement, it was reported in its Year 4 Report. This argument is contested by NIH. Regardless, the term required "immediate notification" and witness testimony confirms that notification should occur within one or two business days and that simply adding the experiment to an annual report does not satisfy that requirement. ¹⁹

¹⁸ Letter from Lawrence A. Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (October 20, 2021).

¹⁹ Stemmy TI, *supra* note 12, at 73-743; Transcribed Interview of Emily Erbelding, M.S., M.D., M.P.H., Dir., Div. of Microbiology & Infectious Diseases, Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 102-103 (Nov. 28, 2023) (hereinafter "Erbelding TI").

As stated, whether the experiment in question occurred during Year 4 or Year 5 is contested by both EcoHealth and NIH. After reviewing the experiment, NIH determined it believes there are two separate experiments. According to witness testimony:

Dr. Erik Stemmy (Nov. 13, 2023)

- Q. ... 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?
- Yes. That's my best recollection, yes.²⁰ A.

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. It says in the fourth paragraph, the first sentence, "The limited experiment described in the final progress report provided by EcoHealth Alliance...." Is it your understanding or recollection that the experiment in year 5 was different from the experiment in year 4?
- That was our conclusion.
- Q. Okay.
- That was our conclusion. Yes.²¹

Further, Dr. Baric testified that he believes this to be two separate experiments and should have been reported to NIAID:

Dr. Ralph Baric (Jan. 22, 2024)

- Q. Dr. Baric, you've read the year 5 paragraph now, the in vivo infection where five of the seven mice infected with just the WIV1 backbone survived, but only two of the eight mice infected with the WIV1 SHC014.
- You should be able to do the statistics on that, and it should show A. that there's a statistical difference, which means there was an

²⁰ Stemmy TI, *supra* note 8, at 106.

²¹ Transcribed Interview of Lawrence A. Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health, at 81 (Jan. 5, 2024) (hereinafter "Tabak TI").

increase in virulence and the entire review process would have been triggered.

- Q. So that's --
- A. I think, if you did the statistics on those numbers.
- Q. That's my question, is that this wouldn't have triggered P3 because it's not a human virus.
- A. It doesn't matter whether it triggered P3 or not. It triggered the regulation that they agreed to in the document to follow.²²

To support Dr. Daszak's claim that the Year 4 and 5 experiments were the same, he called Dr. Shi who assured him. Unfortunately, Dr. Daszak has no record to verify this call or the experiment. Dr. Daszak testified:

Dr. Peter Daszak (Nov. 14, 2023)

- Q. This is 2021. We've had a year of all this controversy. We've had the grant canceled. We've had President Trump making his statements, Senator Cotton making his statements. And you just have this -- you have like a standing -- maybe not a standing call, but a call with the WIV, and you ask them, "One experiment or two?" "One." "I thought so. It seems like that was the case." And there was no further follow-up?
- A. Correct.²³

Without verifiable evidence—such as what may be in the NIH requested laboratory notebooks that Dr. Daszak has failed to provide—Dr. Daszak's claim lacks credibility.

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²² Transcribed Interview of Dr. Ralph Baric, Ph.D., Professor, University of N. Carolina, at 181-182 (Jan. 22, 2024) (hereinafter "Baric TI").

²³ Daszak TI, *supra* note 7, at 146.

GAIN OF-FUNCTION RESEARCH

EcoHealth's Year 5 Report contained the results of an experiment conducted in Wuhan at the WIV. As established above, the results of this experiment were meant to be reported in real time, however, EcoHealth failed to do so. Additionally, the results of this experiment were meant to be reported in annual reports, however, EcoHealth submitted its Year 5 Report nearly two years late. The Select Subcommittee investigated whether the experiment conducted at the WIV constituted gain-of-function research.

Finding 3:

EcoHealth used taxpayer dollars to facilitate gain-of-function research on coronaviruses in Wuhan at the WIV, contrary to previous public statements, including those by Dr. Anthony Fauci.

I. What Is Gain-Of-Function Research?

The term gain-of-function research encompasses a wide swath of life sciences research, a subset of which involves creating potential pandemic pathogens. The meaning to the public versus the scientific community is different and ever shifting, especially as federal government oversight policies and procedures have shifted. However, the term gain-of-function is not tied to any specific policy or oversight framework and, instead, has a long-established definition.

Throughout this investigation, the Select Subcommittee has found that the term "gain-of-function" could mean something completely different to one person in that field than to another person simply using the term. In fact, different experts also have different understandings of the term. Consequently, a nuanced understanding of the term is essential to facilitate effective oversight and understanding of this type of research.

According to the NIH website, as of October 19, 2021, gain-of-function is understood to mean "a type of research that modifies a biological agent so that it confers a new or enhanced activity to that agent."²⁴

Gain-of-Function Research

The term gain-of-function (GOF) research describes a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent. Some scientists use the term broadly to refer to any such modification. However, not all research described as GOF entails the same level of risk. For example, research that involves the modification of bacteria to allow production of human insulin, or the altering of the genetic program of immune cells in CAR-T cell therapy to treat cancer generally would be considered low risk. The subset of GOF research that is anticipated to enhance the transmissibility and/or virulence of potential pandemic pathogens, which are likely to make them more dangerous to humans, has been the subject of substantial scrutiny and deliberation. Such GOF approaches can sometimes be justified in laboratories with appropriate biosafety and biosecurity controls to help us understand the fundamental nature of human-pathogen interactions, assess the pandemic potential of emerging infectious agents, and inform public health and preparedness efforts, including surveillance and the development of vaccines and medical countermeasures. This research poses biosafety and biosecurity risks, and these risks must be carefully managed. When supported with NIH funds, this subset of GOF research may only be conducted in laboratories with stringent oversight and appropriate biosafety and biosecurity controls to help protect researchers from infection and prevent the release of microorganisms into the environment.

²⁴ Gain-of-Function Research Involving Potential Pandemic Pathogens, NAT'L INSTS. OF HEALTH (last updated July 12, 2021) (last accessed Oct. 19, 2021) (archived version on file with Select Subcomm. Staff).

This definition was confirmed by multiple witnesses interviewed by the Committees:

Dr. Hugh Auchincloss (Dec. 20, 2023)

Q. So, this is the NIH website for gain-of-function research involving potential pandemic pathogens, and this version was last updated July 12, 2021. There has since been a new version, and under the header "Gain-of-Function Research" is that definition that I just read to you. It does have the qualifier, not all research described as gain-of-function entails the same level of risk, and I guess one of the kind of semantics here is that what a layperson thinks of as gain-of-function, I think falls under this definition: Any research that attributes a new attribute to a biological agent, whether it's taking avian influenza virus that can't infect humans or making it able to infect humans or taking a bat Coronavirus that can't infect mice and making it infect mice, either of which would qualify as gain-of-function under that definition.

Do you agree?

A. I do, and I think that this is making the same points that I've been making earlier. There's gain-of-function which is common in virology and that's not the same as the gain-of-function research of concern.²⁵

Dr. Lawrence Tabak (Jan. 5, 2024)

Q. ...My, kind of, understanding is that there's -- it's a complicated definition. There's a lot of different pieces to it. There are pieces that NIH regulates; there's pieces that HHS regulates. There are pieces that have dual-use problems. So, I'm going to run through each definition, and you just tell me if I'm kind of on the right page. The high-level gain-of-function, as was defined by NIH: a type of research that modifies a biological agent so that it confers new or enhanced activity to that agent.

Is that right?

A. It -- as an agent, yes. 26

In addition to the above definition, the federal government requires that certain types of gain-of-function research receive further oversight and review. In 2014 OSTP determined that a

²⁵ Transcribed Interview of Hugh Auchincloss, M.D., Dep. Dir., Nat'l Inst. Of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 100-101 (Dec. 20, 2023) (On file with Select Subcomm. Staff) (hereinafter "Auchincloss TI"). ²⁶ Tabak TI, *supra* note 21, at 27.

subset of gain-of-function research needed further regulation and paused all new federal funding for that type of research [hereinafter "2014 OSTP Pause"]. OSTP determined: 27

New USG 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.

This definition is clear – it is not a pause on all gain-of-function research, but on a specific subset. Therefore, it is possible for research to qualify as gain-of-function without qualifying for the 2014 OSTP Pause.

In 2017, as a result of and replacing the 2014 OSTP Pause, HHS released the "Framework for Guiding Funding Decisions About Proposed Research involving Enhanced Potential Pandemic Pathogens (P3CO)" [hereinafter "P3CO Framework"]. 28 Similar to the 2014 OSTP Pause, the P3CO Framework did not apply to all gain-of-function research but only a specific subset.

The P3CO Framework applies to "[p]roposed intramural and extramural life sciences research that is being considered for funding and that has been determined by the funding agency as reasonably anticipated to create, transfer, or used enhanced PPPs [potential pandemic pathogens]..."²⁹ A PPP is defined as a pathogen that:

- (1) "is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations" and
- (2) "is likely highly virulent and likely to cause significant morbidity and/or mortality in humans."30

An enhanced PPP—the type of pathogen the P3CO Framework is designed to oversee—is defined as a potential pandemic pathogen "resulting from the enhancement of the transmissibility and/or virulence of a pathogen."³¹ This applies to only a very narrow subset of research. In fact, out of all the grants issued since the P3CO Framework went into effect, HHS has only reviewed

²⁷ U.S. GOVERNMENT GAIN-OF-FUNCTION DELIBERATIVE PROCESS AND RESEARCH FUNDING PAUSE ON SELECTED GAIN-OF-FUNCTION RESEARCH INVOLVING INFLUENZA, MERS, AND SARS VIRUSES, OFFICE OF SCIENCE AND TECH. POLICY, WHITE HOUSE (October 17, 2014).

²⁸ FRAMEWORK FOR GUIDIUNG FUNDING DECISIONS ABOUT PROPOSED RESEARCH INVOLVING ENHANCED POTENTIAL PANDEMIC PATHOGENS, U.S. DEP'T OF HEALTH & HUMAN SERVS. (2017). ²⁹ Id.

³⁰ Id.

³¹ Id.

three potential studies that fall under this definition. ³² Again, the framework is clear – it only applies to a small subset of gain-of-function research. Therefore, it is possible for research to qualify as gain-of-function without qualifying for the P3CO Framework. This was confirmed via witness testimony:

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. Can there be a subset of research that would qualify under that definition of modifying -- of providing a new function to a biological agent --
- A. Uh-huh.
- Q. -- without falling under the categories of being regulated by the P3CO?
- A. Absolutely. 33

II. <u>Applying The Definition Of Gain-Of-Function To EcoHealth's Reported Experiments.</u>

The Committees endeavored to determine if research facilitated by EcoHealth—paid for with U.S. taxpayer dollars—and conducted in Wuhan by the WIV qualified as gain-of-function research. The research in question was published by EcoHealth in its Year 5 Report.³⁴

Specific Aim 3: Testing Predictions of CoV Inter-Species Transmission

3.1 In vivo infection of Human ACE2 (hACE2) expressing mice with SARSr-CoV S protein variants

In Year 5, we continued with in vivo infection experiments of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were refected with 4 strains of SARSr-CoVs with different S protein, including the full-length recombinant virus of SARSr-CoV WIV1 and three chimeric viruses with the backbone of WIV1 and S proteins of SHC014, WIV16 and Rs4231, respectively. Pathogenicity of the 4 SARSr-CoVs was evaluated by recording the survival rate of challenged mice in a 2-week course. All of the 4 SARSr-CoVs caused lethal infection in hACE2 transgenic mice, but the mortality rate vary among 4 groups of infected mice (Fig. 13a). 14 days post infection, 5 out of 7 mice infected with WIV1 remained alive (71.4%), while only 2 of 8 mice infected with rWIXT-SHC014 S survived (25%). The survival rate of mice infected with rWIV1-WIV16S and rWIV1-4231S were 50%. Viral replication was confirmed by quantitative PCR in spleen, lang, intestine and brain of infected mice. In brain, rWIV1, rWIV1-WIV16S and rWIV1-4231S cannot be detected 2 days or 4 days post infection. However, rWIV1-SHC014 was detected avail time points and showed an increasing viral titer after infection. The viral load reached more than 10° genome copies/g at the dead point (Fig. 13b). We also conducted histopathological section examination in infected mice. Tissue lesion and lymphocytes infiltration can be observed in lung, which is more significant in mice infected with rWIV1-SHC014 \$ (Fig. 13d) than those infected with rWIV1 (Fig. 13c). These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARSr-CoVs in transgenic mice that express hACE2.

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³² Research Involving Enhanced Potential Pandemic Pathogens, NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS. (last updated June 5, 2023) (last accessed Apr. 23, 2024).

³³ Tabak TI, supra note 21, at 29.

³⁴ Interim Research Performance Progress Report, EcoHealth Alliance, Inc., at 15 (Aug. 3, 2021).

The Year 5 Report describes an experiment in which the WIV infected transgenic mice with four different coronaviruses, three of which were chimera or recombinant viruses with different spike proteins. The WIV then measured the pathogenicity of the novel laboratory created viruses as compared to the control, which was a full-length backbone of WIV1. The pathogenicity of the three chimeras was then compared to that of WIV1.

In the experiment, the survival rate of mice infected with WIV1 was 71.4 percent while the survival rate of the mice infected with one of the chimeric viruses (WIV1-SHC014) was just 25 percent. Therefore, the laboratory generated chimera was more pathogenic than the control virus and the mice infected with that chimera became sicker.

In the October 20, 2021 letter to Mr. Comer, Dr. Tabak described this experiment and its result as "unexpected." Regardless of whether the results were expected or not, it appears this experiment would constitute gain-of-function research. This appearance was confirmed by witness testimony:

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. NIH has said a lot that the experiment in the EcoHealth grant was not gain-of-function research, that it didn't qualify. Did NIH mean it wasn't ePPP research?
- It is certainly an example of generic gain-of-function, if that's what A. you mean.
- Q. Yes. So, I'm trying to get at, like, words matter. And using a term that has an established definition, "gain-of-function" -- it's on the NIH's website -
- Right. A.

Q. -- has an established definition, that when people say that what EcoHealth did was not gain-of-function research, that's not true. It's not gain-of-function research of concern or that HHS would regulate. Is that fair?

- A. That is fair. And I have always, when asked, tried to make that distinction.
- Q. All right.

Because, as you point out, there's lots of gain-of-function research, A. and, as is written here, however, not all such research entails the same level of risk.

³⁵ Letter from Lawrence Tabak, D.D.S., Ph.D., Principal Dep. Dir., Nat'l Insts. of Health to Hon. James Comer, Ranking Member, H. Comm. on Oversight & Reform (October 20, 2021).

- Q. And I agree with that. I'm just –
- A. Yeah.
- Q. When there's such a -- like, I don't remember the infection count or the death toll in 2021. And origins has been such a hot-button issue. But, like, when I write things for my bosses that are going to go out and speak or if I was prepping someone for congressional testimony, I'd want to make sure that they're using the right phrases. And whenever we've talked to NIH -- I think I was briefed by you once; it might've been on this letter -- maybe outside of that, we've heard "NIH did not fund gain-of-function research in Wuhan," period. That's, at best, misleading.
- A. I have always tried to make sure that whoever is asking the question is speaking about gain-of-function research of concern. I can only speak for how I'm trying to answer questions of this type. Because you're right, words matter.
- Q. And I won't harp too long, but just -- you would agree, what's described in this letter, what's described in the EcoHealth year progress report, would fit the definition -- the broad definition of gain-of-function research?
- A. The generic, broad description of what gain-of-function is, yes.³⁶

Dr. Ralph Baric (Jan. 22, 2024)

- Q. Dr. Baric, you've read the year 5 paragraph now, the in vivo infection where five of the seven mice infected with just the WIV1 backbone survived, but only two of the eight mice infected with the WIV1 SHC014.
- A. You should be able to do the statistics on that, and it should show that there's a statistical difference, which means there was an increase in virulence and the entire review process would have been triggered.

Q. So, my question is, and we've gotten different answers on everything, and it depends on if you're using the P3 definition or whatever definition. This reads like gain-of-function to me.

³⁶ Tabak TI, *supra* note 21, at 95-97.

- A. Okay. So what year was this? I just want to make sure I'm in the right gain-of-function regulation.
- Q. 2019.
- A. So, it's the NSABB regulation...So based on those regulations, yes, this is -- as my interpretation, is that, yes, these would be exempt. But is it a gain-of-function phenotype? Absolutely. You can't argue with that.³⁷

Dr. Baric has previously stated and testified that the WIV should not have been conducting this type of research at Biosafety Level 2 (BSL-2). This is a divergence from the beliefs of Dr. Daszak. This divergence was exemplified by the following email exchange:

From: Ralph Baric

Sent: Monday, May 10, 2021 12:21 PM

To: Peter Daszak

Subject:

BSL2 noted in methods

J Virol. 2016 Jul 15; 90(14): 6573-6582.

Published online 2016 Jun 24. Prepublished online 2016 May 11. doi: 10.1128/JVI.03079-15

PMCID: PMC4936131; PMID: 27170748

Bat Severe Acute Respiratory Syndrome-Like Coronavirus WIV1 Encodes an Extra Accessory Protein, ORFX, Involved in Modulation of the Host Immune Response Lei-Ping Zeng, a Yu-Tao Gao, a Xing-Yi Ge, a Qian Zhang, a Cheng Peng, a Xing-Lou Yang, a Bing Tan, a Jing Chen, a Aleksei A. Chmura, b Peter Daszak, b and Zheng-Li Shicorresponding author

J Virol. 2020 Oct; 94(20): e00902-20.

Published online 2020 Sep 29. Prepublished online 2020 Jul 22. doi: 10.1128/JVI.00902-20

PMCID: PMC7527062 PMID: 32699095

Evolutionary Arms Race between Virus and Host Drives Genetic Diversity in Bat Severe Acute Respiratory Syndrome-Related Coronavirus Spike Genes Hua Guo,#a,b Bing-Jie Hu,#a Xing-Lou Yang,a Lei-Ping Zeng,a Bei Li,a Songying Ouyang,c and Zheng-Li Shicorresponding author

I think there are at least one more such paper. i'll forward letter to the editor shortly, but thought you should be informed this methodology continued into 2020.

³⁷ Baric TI, *supra* note 22, at 181-184.

From: Ralph Baric Sent: Monday, May 10, 2021 4:44 PM To: Peter Daszak Subject: Re: Hi Peter, it is true that this isn't definitive proof and I agree there is no evidence of a SARS2 like virus in their collection that is closer than RaTG13, which is still pretty distant. I also still agree that a natural origin from nature is the most likely scenario. Take care, Ralph On Mon, May 10, 2021 at 1:57 PM Peter Daszak wrote: Thanks Ralph – I'd seen those and I understand your rationale for signing the letter. I've already seen a copy—reporters are already lining up questions for me, to which I'm saying — you should contact WHO. The real issue that everyone seems to forget is whether they had a virus similar to SARS-CoV-2 in their collection. Given that we published "650 novel RdRps (alpha and beta covs) in spring 2020, and that they were piling in every single positive they had, if just seems like a very implausible scenario. Yes, they cultured bata-CoVs as a safety level you don't, but there's no evidence anywhere that they had 5ARS2 or a progenitor. Journalists will write whatever they want I guess Peter Daszak President EcoHealth Alliance 520 Eighth Avenue, Suite 1200	net: Monday, May 10, 2021 4:44 PM Peter Daszak piect: Re: Peter, it is true that this isn't definitive proof and I agree there is no evidence of a SARS2 like virus in their flection that is closer than RaTG13, which is still pretty distant. I also still agree that a natural origin from ture is the most likely scenario. Take care, Ralph a Mon, May 10, 2021 at 1:57 PM Peter Daszak hanks Ralph – I'd seen those and I understand your rationale for signing the letter. I've already seen a copy— protters are already lining up questions for me, to which I'm saying — you should contact WHO. The real issue that everyone seems to forget is whether they had a virus similar to SARS-CoV-2 in their collection. Invent that we published ~650 novel RdRps (alpha and beta covs) in spring 2020, and that they were piling in every ngle positive they had, it just seems like a very implausible scenario. Yes, they cultured bar-CoVs at a safety level you on't, but there's no evidence anywhere that they had SARS2 or a progenitor. Journalists will write whatever they and I guess SSCP00406 eter Daszak	Sent: Monday, May	
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520 Eighth Avenue, Suite 1200	coHealth Alliance	Peter Daszak	
	20 Eighth Avenue, Suite 1200	Peter Daszak President	•
New York, NY 10018-6507	MATTINI PALIFA DEPOSIT PROSTO	Peter Daszak President EcoHealth Alliance	

From: Sent:	Ralph Baric 5/27/2021 7:00:34 AM
го:	Peter Daszak
Subject:	Re: ESL levels for viral culture in China, US, other countries
mentioned earlier pap rules and d appropriat	er. Your being told a bunch of BS. Bsl2 w negative pressure, give me a break. There last paper d bsl2 w appropriate PPE. This last part was the first and only time this was ever mentioned, never in pers, and in the latest paper never defined either. I have no doubt that they followed state determined did the work under bsl2. Yes china has the right to set their own policy. You believe this was the containment if you want but don't expect me to believe it. Moreover, don't insult my intelligence to feed me this load of BS.
On Thu, N	May 27, 2021, 1:08 AM Peter Daszak -
Hi Ralph,	
Hope all's	well, given this ridiculous week for politics around covid origins in the news!
Hope you	last spoke, I've checked on a bunch of rules governing culture of viruses in the US, China and other countries. don't take this the wrong way – I'm sending you this so you're aware, and in case you get questions from and other scientists, or the govt agencies etc., not to disagree with your opinion, which I respect.
checked w	the rules allow for organizations to conduct culture of animal viruses at BSL-2, including chimeras. We with Zhengli, who let us know that she used "BSL-2 with negative pressure and appropriate PPE". I also know are stricter now on SADS-CoV (it's BSL-31 believe) ever since you showed it was able to infect human airway cells, so that's evidence they do take these things more seriously than it would seem on the surface.
BSL-2 (e.g me know recombin	cked the rules on a bunch of viruses for the US and was surprised to find lethal human pathogens cultured at g. Rabies, some vector borne viruses) as well as many wildlife viruses. I also spoke with Chris Broder who let that the bat paramyxovirus Cedar virus (close to Nipah/Hendra) is cultured at BSL-2, including the lants he has made with Nipah and Hendra elements. Reference here: www.ncbi.nlm.nih.gov/pmc/articles/PMC5869790/
there are that I did sure it will hypothesi reasons for	hed a list of some of the findings with refs. Hope it's useful in case there are questions about this. I'm sure reasons for all of the above classifications, and justifications that can be debated, but I just want you to know the due diligence on this, and checked that they were following the rules, and that similar rules exist here. I'm II be criticized, and maybe there will be tightening of biosafety levels given the hype around the lab leak is at the moment. However, I'm still very confident that nothing untoward happened there, and have good or that based on the protocols they used, and the results they were sharing as we wrote a paper for Nat. ications in the lead up to the outbreak.
Cheers,	

III. <u>Dr. Anthony Fauci, In Testimony To The U.S. Senate, Misled The Public</u> Regarding NIH And NIAID Funded Experiments.

Throughout the COVID-19 pandemic, many scientists and government officials categorically denied that taxpayer funds were used for gain-of-function research in Wuhan at the WIV. These assertions rested on semantics and the misapplication of understood definitions.

On May 11, 2021, Dr. Fauci testified before the U.S. Senate Committee on Health, Education, Labor, and Pensions (HELP). At this hearing, Senator Rand Paul (R–Ky.) asked Dr. Fauci if gain-of-function research was occurring with NIH funding at the WIV. Dr. Fauci categorically denied it three times. The exchanges were as follows:

May 11, 2021 Hearing Before Senate HELP

Senator Paul. Dr. Fauci, do you still support funding of the – NIH funding

of the lab in Wuhan?

Dr. Fauci. Senator Paul, with all due respect, you are entirely and

completely incorrect that the NIH has not ever and does not now fund gain-of-function research in the Wuhan Institute of

Virology.

Senator Paul. Will you, in front of this group, categorically say that the

COVID-19 could not have occurred through serial passage

in the laboratory?

Dr. Fauci. I do not have an accounting of what the Chinese may have

done, and I am fully in favor of any further investigation of what went on in China. However, I will repeat again, the NIH and NIAID categorically has not funded gain-of-function research to be conducted in the Wuhan Institute of

Virology.

The Chair. I will allow you to respond to that, and then we will move

on.

Dr. Fauci. Yes. I mean, I just wanted to say, we – I do not know how

many times I can say it, Madam Chair. We did not fund

³⁸ An Update From Federal Officials on Efforts to Combat COVID-19: Hearing Before Sen. Committee on Health, Education, Labor, and Pensions, 117th Cong. (May 11, 2021).

gain-of function research to be conducted in the Wuhan Institute of Virology.³⁹

Dr. Fauci's testimony was, at a minimum, misleading. As established above, at the time of Dr. Fauci's testimony senior NIH officials and the NIH website defined gain-of-function research as "a type of research that modifies a biological agent so that it confers a new or enhanced activity to that agent." Further, witness testimony and a plain reading of EcoHealth's research conducted at the WIV using U.S. taxpayer dollars confirm it facilitated an experiment that conveyed new or enhanced activity to a pathogen—thus, satisfying the definition of gain-of-function research.

Dr. Fauci, during his transcribed interview before the Committees, testified:

Dr. Anthony Fauci (Jan. 8, 2024)

- Q. When you talk about this issue, this broader issue of gain-offunction and Wuhan Institute of Virology, publicly -- for example, the high-profile exchange with Senator Rand Paul --
- A. Right.
- Q. -- and if you say that NIH, quote, "has not ever and does not now fund gain-of-function research in the Wuhan Institute of Virology," is this layman's definition the definition that you are talking about in those occasions?
- A. No.
- Q. Great. What would you be talking about in those situations?
- A. What I was referring to when Senator Paul asked me and I repeated multiple times that we were not doing gain-of-function research, no -- I said that the NIH sub-award to the Wuhan Institute was not to do gain-of-function research. I was referring specifically to the operative definition of "gain-of-function" at the time, which is the P3CO framework. And the P3CO framework is a policy and a framework that came out of a policy guidance from 3 years of discussions led by OSTP, the National Academies of Sciences, and multiple scientific working groups that came out with a very precise definition. And the precise definition was: any experiment that is reasonably anticipated to result in the enhancement of a -- and by "enhancement," it is meant an increase in the transmissibility and/or the pathogenesis of a PPP. And what a PPP is is a potential pandemic pathogen. So if you enhance it, it's referred to as "ePPP." So then

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³⁹ *Id*.

you ask the question, what is a PPP? And by the regulatory definition, it is the following: It is a pathogen that is likely to be highly transmissible and spread widely in a population and a pathogen that likely will cause a high degree of morbidity and mortality in humans. So, when I was asked the question, did the grant that was a sub-award to Wuhan fund experiments that were enhanced PPP, that is what I was referring to when I said we do not fund gain-of-function -- gain-of-function according to the strict definition, which I refer to as the operative definition of "gain-of-function." So, when someone asks me, as a scientist, are you doing gain-of-function, is that gain-of-function, I always apply it to the operative definition of "gain-of-function."

- Q. That is very helpful. Thank you for drawing that distinction. And at the time of that exchange, it was the P3CO framework. There was also a time, I think from 2014 to 2017, when the gain-of-function moratorium was the operative policy.
- A. Right.
- Q. So a similar analysis, I assume, would've been the case for that –
- A. Right.
- Q. -- period of time.
- A. Yes. 40

Dr. Anthony Fauci (Jan. 8, 2024)

Q. I want to introduce the year 5 progress report as majority exhibit 18. And in the nature of time, it's a long report, so I'd ask you not to read the whole report, but I'm going to draw your attention to a discrete paragraph. It's on page 15 under aim 3.1.

Q. And I believe, and Dr. Tabak has confirmed that in his letter he is referring to the experiment outlined in this paragraph. And I'm going to -- you have it in front of you, but I'm going to read it in kind of layman's terms so it's comprehendible. But, in essence, it says that mice were infected with four strains of SARS-related coronaviruses with different spike proteins, including full-length recombinant virus of 4 SARS-related WIV 1 and 3 chimeric viruses, with the

⁴⁰ Transcribed Interview of Anthony Fauci, M.D., former Dir., Nat'l Inst. of Allergy & Infectious Diseases, Nat'l Insts. of Health, at 47-48 (Jan. 8, 2024) (On file with Select Subcomm. Staff) (hereinafter "Fauci TI").

backbone of WIV 1 and the spike proteins from three other bat coronaviruses. So that's what we were just discussing. All four of the viruses caused lethal infection in human ACE2 transgenic mice, but the mortality rate varied among the four groups. Fourteen days post-infection, five out of the seven mice infected with just the WIV 1 backbone remained alive, while only two out of eight mice infected with the SHC014 chimera survived. And the paragraph ends with, "These results suggest that the pathogenicity of SHC014 is higher than other tested bat SARS-related coronaviruses in transgenic mice that express human ACE2." I'll give you a minute to read the full version in the progress report. I know I kind of summarized it.

- A. [Reviewing.] Yeah.
- Q. So to me, it sounds like seven mice infected with the full-length WIV 1; five survived. Eight mice infected with a chimera of WIV 1 and SHC014 and two survived. Is that your understanding as well?
- A. That's what it says, yeah.
- Q. This to me sounds like the experiment that EcoHealth conducted by creating a chimera increased the pathogenicity of the underlying virus. Is that fair?
- A. The underlying virus is WIV.
- Q. Correct.
- A. And the spike that they put on indicated that the virus was more pathogenic than the WIV.
- Q. Correct. Is that right? So by replacing the WIV 1 spike with the SHC spike –
- A. Yes, yes. But, again, you got to put it into context because, again, these viruses, when you -- if you -- are you hearkening back to the definition of whether –
- Q. I'm getting there.
- A. Yeah, but then let's go there, okay? The fact is that what was built into the scope of the conditions was that if you do get an increase in viral load or pathogenesis, you've got to report it or reevaluate it, but it still doesn't change the underlying premise that this is not a PPP. That's the point. That's the conclusion -- that's the confusion people

get. By the operative definition of gain-of-function of concern, even with this, this is merely an added going the extra mile that if something like this happens you stop and you look at it and discuss whether or not to go forward, et cetera. And, to my understanding, that even if you do that, this still doesn't change that you're not dealing with a virus that's very likely to lead to widespread transmission, et cetera, et cetera. So it doesn't change the definition or the operative guideline for this experiment, but it tells you, you should report this, because that was part of the fail-safe.

- Q. And I don't disagree with you that it's not an ePPP –
- A. Yeah, right.
- Q. -- and it doesn't fall under the P3CO framework. What I think we're trying to understand is this was submitted, I mean, well, late, but the work was conducted during 2018 for the fiscal year 2018 to 2019 and the year 5 progress report. At that time, this definition of gain-of-function was still live on the website of enhancing a biological agent. And I guess what I'm trying to understand, and the minority talked about it too, is you said what your intent was with Senator Paul, that when you said NIH does not now and has not ever funded gain-of-function research in Wuhan was that you meant to say or you intended ePPP research.
- A. I said that before and I'll repeat it again. When I talk about gain-of-function, I talk about -- a gain-of-function of concern -- I am talking about the operative definition of gain-of-function of concern, which for me is the P3CO that we've discussed multiple times.
- Q. And I agree, again, agree that this experiment did not meet the P3 definition. Would you agree that it meets that broad definition of gain-of-function that was on NIH's website when this research was conducted?
- A. Again, I don't use the terminology "gain-of-function" because it can be very confusing, which was the reason why we went through 3 years of discussion to avoid the kind of confusion that we're going to get into now if we start going back and forth about this. That was the whole reason for 3 years of deliberation to establish a regulatory guideline based on a guiding policy that led to a framework. So, regardless of how you slice it, when I spoke to -- when I responded to Doctor -- to Senator Paul, I was referring to the gain-of-function research of concern as defined by the P3CO framework.

- Q. My last question. That hearing was May 11th, 2021. When you testified, like -- again, I apologize, but if I was a general C-SPAN watcher or watching the news afterwards it obviously became a big deal, and I went and I googled NIH gain-of-function research, this is what would come up. Do you think you could have -- like, you knew that you meant ePPP.
- A. Yes.
- Q. Do you think you could have been more specific in your answer?
- A. Well –

A. I think -- I think in terms of 3PCO, and that's embedded in my mind, he didn't appreciate what gain-of-function according to the regulatory guidelines are. I was speaking in that term. So he was thinking of a different thing. When I spoke to him, I'll stand by my statement that when I said we do not do gain-of-function I was referring to gain-of-function of concern according to the 3PCO guideline, done, full stop.

- Q. The last thing I'll say is we interviewed Dr. Tabak on Friday -- it's been a long weekend -- and we asked him a similar question. "What's described in the EcoHealth year 5 progress report would fit the definition -- the broad definition of gain-of-function research?" And he answered, "The generic, broad description of what gain-of-function is, yes." Would you agree with Dr. Tabak?
- A. You know, again, we're going in circles, because it's going to get the same confusion that the chairman was just talking about.
- Q. I'm –
- A. Because then, if I say yes, then, "Ah, yes, he says it was gain-of-function." It is not gain-of-function of concern that is associated with the regulatory operative definition of gain-of-function.
- Q. No. And I'm entirely willing to stipulate that and stipulate that it didn't need to go through the P3CO and it didn't meet the definition of ePPP. And I'll end on this, and if it's the same answer it's the same answer. But we've asked Dr. Auchincloss this question. We've asked Dr. Tabak this question. Both have said that it meets the definition,

the broad definition of gain-of-function research. I'm not trying to catch you in a trap. I'm not trying to catch you —

A. But the thing is I have been living a life over the last few years of getting total distortion of things that I've said and done, and you know that. So if you want me to –

- Q. You don't need to answer again. I'll take that what you meant is what
- A. Right.
- Q. And I agree that that is what you meant. I'm not trying to go against that. I'm just -- when people read things in black and white and words are said, it's hard to distinguish sometimes.
- A. Yes.
- Q. Our hour is up, and we can go off the record. Our day is up too.⁴¹

[Whereupon, at 6:57 p.m., the interview was recessed, to reconvene at 10:00 a.m., Tuesday, January 9, 2024.]

Dr. Fauci testified that when he testified before the Senate, he was using the "operative" definition of gain of function. Dr. Fauci is an expert. He knew the terms and applicable definitions and should have used them appropriately. However, that was not the definition of that term used by the NIH at that time. Unfortunately, the website containing that definition was unceremoniously removed and that definition deleted the same day the EcoHealth experiment was reported to Congress. Dr. Fauci's testimony to Senator Paul misled the public regarding NIH funding of gain-of-function research at the WIV.

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⁴¹ Fauci TI, *supra* note 40, at 219-226.

TERMINATION AND SUSPENSION

In response to allegations regarding EcoHealth's actions—including concerns that the research conducted at the WIV was funded by NIAID and may have started the COVID-19 pandemic—the NIH began compliance actions regarding the grant. These actions centered around both administrative and scientific failures on the part of EcoHealth and resulted in the eventual suspension of EcoHealth's grant and the debarment of the WIV.

NIH may not have known about EcoHealth's actions without proper intervention by former-President Donald Trump and former-White House Chief of Staff Mark Meadows. Further, despite suggestions of political persecution against EcoHealth, career NIH leadership supported every compliance action taken.

I. The Trump Administration Identified EcoHealth's Actions And Instructed NIH To Remedy It.

A. Grant Termination

On April 17, 2020, during a press conference, former-President Trump identified the grant to EcoHealth, and any other grants going to China, as potentially problematic. He said:

Coronavirus Task Force Briefing (Apr. 17, 2020)

Coronavirus rusk rorec Briefing (riph. 17, 2020)				
Q.	Thank you, Mr. President. U.S. intelligence is saying this week that the coronavirus likely came from a level 4 lab in Wuhan. There's also another report that the NIH, under the Obama administration, in 2015 gave that lab \$3.7 million in a grant. Why would the U.S. give a grant like that to China?			
THE PRESIDENT:	The Obama administration gave them a grant of \$3.7 million? I've been hearing about that. And we've instructed that if any grants are going to that area — we're looking at it, literally, about an hour ago, and also early in the morning. We will end that grant very quickly. 42			

On April 18, 2020, Dr. Lauer was told by his supervisor, Dr. Tabak, to send a letter to EcoHealth that would instruct them to terminate all funding to the WIV.⁴³ Dr. Lauer sent this letter the next day, on April 19.⁴⁴ On April 24, 2020, Dr. Lauer was told by his supervisor, Dr.

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⁴² Remarks by President Trump, Vice President Pence, and Members of the Coronavirus Task Force, Press Briefing, The White House (Apr. 17, 2020).

⁴³ Lauer TI, *supra* note 12, at 40.

⁴⁴ Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Peter Daszak, Ph.D., et. al., Pres., EcoHealth Alliance, Inc. (Apr. 19, 2020).

Tabak, to send a letter to EcoHealth terminating its entire grant. ⁴⁵ Dr. Lauer was not involved in the discussions or drafting of ether letter and did not have knowledge of how the decision originated. Importantly, however, Dr. Lauer agreed with the letters' content and justifications. He testified:

Dr. Michael Lauer (Nov. 2, 2023)

- Q. Did you review the letter before it was sent?
- A. Yes.
- Q. And did you agree with its contents and the justifications provided in it?
- A. Yes.⁴⁶

Through the Committees' investigation, evidence discovered suggests that the decision to terminate the EcoHealth grant originated from Mr. Meadows. According to Dr. Tabak:

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. So like I said, this is Majority Exhibit 7. It's an April 19th, 2020 letter from Dr. Lauer to EcoHealth and Columbia -- I believe Columbia was on there by mistake -- but primarily to EcoHealth, notifying EcoHealth that they're not to provide funds to the Wuhan Institute of Virology anymore pursuant to a couple regulations and OMB provisions. Were you aware of this letter at the time it was sent?
- A. I was.
- Q. Did you have any discussions with anyone about this letter prior to it being sent?
- A. Yes.
- Q. Who?
- A. I discussed this letter with Dr. Lauer and I discussed this letter with Dr. Collins. I don't know if I discussed it with anyone else.
- Q. Do you remember how this -- the drafting process of this letter, how it came to be?

⁴⁵ Lauer TI, supra note 12, at 48.

⁴⁶ Lauer TI, *supra* note 12, at 49.

- A. Okay. So this was done with the help of a senior administrative official. That's really all I could say.
- Q. Can you give me a little bit more generality about that? A grants officer? A program officer? Who was the –
- A. A senior administrative official.
- Q. Who is that?
- A. That's –
- Q. The who isn't deliberative.

- A. Mr. Charrow.
- O. The Office of General Counsel at HHS?
- A. Correct.
- Q. All right. Is this the first time or the days preceding this that you became aware of efforts to suspend or terminate or otherwise alter the EcoHealth grant?
- A. I don't remember the dates. I remember the -- but I remember the event that was time-sensitive. Former President Trump was to give a news conference of some sort, and apparently he wanted to articulate that this had been suspended, and so that was the time sensitivity.
- Q. And who communicated that sensitivity to you?

- A. Mr. Charrow.
- Q. Okay. And do you know who had communicated with Mr. Charrow?

A. I was told who it was, but I don't have any evidence of who it was.

Q. Who were you told who it was?

- A. Okay. My secondhand knowledge is that it was the White House chief of staff.
- Q. Mark Meadows?
- A. Correct.
- Q. Thank you. I want to then -- well, I'm going to summarize the timeline then leading up to April 19th without getting into any of the discussions of how April 19th happened. Your understanding -- and, granted, some of this is secondhand -- is a conversation took place between Chief of Staff Meadows and Mr. Charrow, who then had a conversation with you, and then you had a conversation with Dr. Lauer that resulted in this letter?

A. That is correct.⁴⁷

This sequence of events was confirmed by Dr. Fauci. He testified:

Dr. Anthony Fauci (Jan. 8, 2024)

- Q. This is a letter sent from Dr. Lauer to Drs. Chmura and Daszak from April 24th, 2020 -- so 5 days after this one was sent -- that terminates the entire grant "Understanding the Risk of Bat Coronavirus Emergence." Were you previously aware of this letter?
- A. Let me read it. Hold on. I was aware that the grant was terminated. I'm not -- I don't recall this particular letter that I saw at the time. I think I was shown -- I don't think I was shown this, but I don't recall seeing this letter at the time it was sent.
- Q. You testified in June of 2020 before the House Committee on Energy and Commerce. You were asked about this grant and the cancellation and said, "Why was it canceled? It was canceled because the NIH was told to cancel it. I don't know the reason, but we were told to cancel it." Do you have any recollection of who told you to cancel it?

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⁴⁷ Tabak TI, *supra* note 21, at 53-58.

- Q. All right. I'll relay to you what Dr. Tabak told us was the chain of events, and you can just tell me if that's accurate to the best of your recollection. Dr. Tabak testified that Chief of Staff Mark Meadows called the Office of General Counsel at HHS, who then called Dr. Tabak, who then called Dr. Lauer, who was instructed to cancel the grant. Is that consistent with your memory?
- A. Yes. 48

By April 17, the White House had been reviewing both the EcoHealth grant and other grants that involved China to ensure they were in compliance with all applicable grant terms and conditions. After this review, Mr. Meadows identified EcoHealth and its subgrant to the WIV as being problematic and instructed HHS to first terminate the subaward and then the entirety of the grant. Dr. Lauer, the NIH official in charge of grant compliance, testified that he was unaware of EcoHealth or that it was out of compliance prior to April 19.⁴⁹ If not for the actions of the Trump Administration, this grantee and grant may have been allowed to continue without proper oversight.

B. NIH Compliance Actions

Between April 19, 2020 and April 26, 2023, NIH conducted an investigation into EcoHealth's compliance with its grant terms. This investigation primarily focused on (1) EcoHealth's late Year 5 Report, (2) an experiment that showed excessive viral growth, and (3) EcoHealth's relationship with the WIV. Below is a list of compliance actions levied by NIH against EcoHealth. The full letters are attached to this report as supplementary materials. The initial two letters (April 19, 2020 and April 24, 2020) were discussed above.

1) April 19, 2020: Letter from Dr. Lauer to EcoHealth

2) April 24, 2020: Letter from Dr. Lauer to EcoHealth

3) May 22, 2020: Letter from Counsel for EcoHealth to Dr. Lauer

4) July 8, 2020: Letter from Dr. Lauer to EcoHealth

In this letter, Dr. Lauer, because of legal issues surrounding NIH's decision to terminate the full grant on April 24, reinstates and then immediately suspends EcoHealth's grant. The suspension was pending EcoHealth's answers to a number of questions regarding activities in and around Wuhan at the time of the outbreak. NIH witnesses testified they agreed with sending this letter:

⁴⁸ Fauci TI, *supra* note 40, at 211-212.

⁴⁹ Lauer TI, *supra* note 12, at 22.

Dr. Michael Lauer (Nov. 2, 2023)

- Q. And did you believe at the time that NIH had the authority to ask these questions -- make these -- let me rephrase. Did you believe at the time that NIH had the authority to make these requests of a grantee?
- A. Yes.
- Q. Okay. And is that still your opinion, NIH had the authority to make these requests of a grantee?
- A. I'm comfortable that, you know, with what was happening at the time, the information I had available at the time, that we followed appropriate processes. 50

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. Did you agree with sending this letter?
- A. I did agree with sending it.⁵¹
- 5) August 13, 2020: Letter from Counsel for EcoHealth to Dr. Lauer
- 6) October 23, 2020: Letter from Dr. Lauer to Dr. Daszak
- 7) April 11, 2021: Letter from Dr. Daszak to Dr. Lauer
- 8) April 13, 2021: Letter from Dr. Lauer to Dr. Daszak
- 9) April 23, 2021: Letter from Dr. Daszak to Dr. Lauer
- 10) July 23, 2021: Letter from Dr. Lauer to Dr. Daszak

In this letter, Dr. Lauer identifies that EcoHealth's Year 5 Report is late for the first time. Dr. Lauer writes, "[w]e are also writing to notify you that a review of our records for R01AI110964 indicates that EcoHealth Alliance, Inc. is out of compliance with requirements..." Witness testimony indicates that neither NIH nor NIAID identified this late report until this letter was sent:

Dr. Erik Stemmy (Nov. 13, 2023)

⁵⁰ Lauer TI, *supra* note 12, at 53-54.

⁵¹ Tabak TI, *supra* note 21, at 62.

⁵² Letter from Dr. Michael Lauer, M.D., Dep. Dir. Extramural Research, Nat'l Insts. Of Health, to Peter Daszak, Ph.D., et. Al., President, EcoHealth Alliance, Inc. (July 23, 2021).

- 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 --

Dr. Emily Erbelding (Nov. 28, 2023)

Q. While you're flipping through it, this is a letter from Dr. Lauer to EcoHealth from July 23rd, 2021. And in it there's a lot, and it continues to request in order to review the WIV's records validating certain expenditures and monitoring safety and financial specifics. But then also on the second page indicates that EcoHealth has not submitted their year 5 annual report yet.

- Q. "We are also writing to notify you that a review of our records for R01 indicates that EcoHealth Alliance is out of compliance with requirements to submit the following reports," a financial report and then the Interim Research Performance Progress report.
- A. Okay. I see the paragraph you're referring to.
- Q. Were you involved at all in the drafting of this letter?
- A. No.
- Q. When did you first learn that the year 5 report was late?

⁵³ Stemmy TI, *supra* note 8, at 127-128.

A. I believe I learned of it when it came in, which was about a month after the date on this letter.⁵⁴

Dr. Michael Lauer (Nov. 2, 2023)

- Q. In this letter, it's also the first time you notify EcoHealth that they're now 22 months late on their year-five progress report. Is that correct?
- A. Yes.
- Q. Would that have been consistent with the timing that you testified to earlier, that the interim progress report would've come up with the year-seven funding?
- A. So –
- Q. Or was it later than what you would normally see?
- A. It's later than what we would normally see, but -- okay. Well, I'll answer your question. It's later than what we would normally see.
- Q. Okay. When did you learn that the year-five report was late?
- A. Shortly before we sent this letter.⁵⁵
- 11) October 20, 2021: Letter from Dr. Lauer to Dr. Daszak
- 12) October 26, 2021: Letter from Dr. Daszak to Dr. Lauer
- 13) November 5, 2021: Letter from Dr. Lauer to Dr. Daszak

In this letter, Dr. Lauer requests Dr. Daszak produce "original laboratory notebook entries" to verify certain experiments and determine if those experiments violated EcoHealth's grant terms and conditions—specifically the condition requiring notification to NIH of any experiment that exhibits excessive growth. According to witnesses, EcoHealth should have had access to these notebooks:

Dr. Emily Erbelding (Nov 28, 2023)

Q. Thank you. Yes. That's what I was asking. When Dr. Lauer -- he's asked for the notebooks a couple times. We've already discussed

⁵⁴ Erbelding TI, *supra* note 19, at 96-97.

⁵⁵ Lauer TI, *supra* note 12, at 66.

EcoHealth hasn't produced them. And it is EcoHealth's responsibility to produce them when requested. Is that correct?

- A. [Nonverbal response.]
- Q. You have to give an audible answer.
- A. Yes. Oh, I'm sorry. Yes. ⁵⁶

Dr. Michael Lauer (Nov. 2, 2023)

- Q. And, in your opinion, NIH had the authority to ask for those notebooks and files?
- A. Yes.
- Q. And, in your opinion, EcoHealth should've had access to those notebooks and files?
- A. Yes. 57

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. So, at the time of the EcoHealth enforcement actions, it would have been a requirement, if NIH requested lab notebooks, for EcoHealth to provide them?
- A. Yes, it would've been.⁵⁸

14) November 18, 2021: Letter from Dr. Daszak to Dr. Lauer

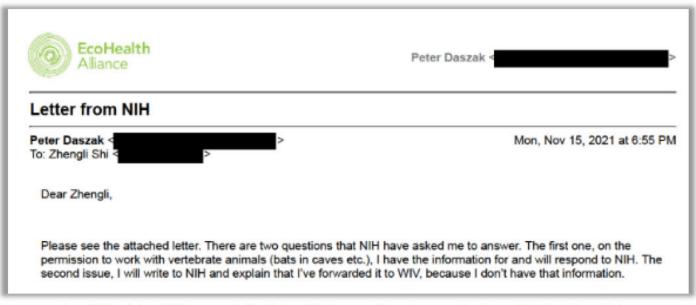
In this letter, Dr. Daszak said that, despite the requirement to do so, he does not have access to the requested laboratory notebooks. Specifically, Dr. Daszak states, "[w]e do not have copies of these, which were created by and retained by the WIV. Nonetheless, I have forwarded your letter to the WIV, and will let you know their response soon as the WIV replies to our request." It appears Dr. Daszak's never explicitly requested the notebooks from the WIV, but instead simply informed it of the request from NIH:

⁵⁶ Erbelding TI, *supra* note 19, at 101.

⁵⁷ Lauer TI, *supra* note 12, at 74.

⁵⁸ Tabak TI, *supra* note 21, at 100.

⁵⁹ Letter from Peter Daszak, Ph.D., President, EcoHealth Alliance, Inc., to Michael Lauer, M.D., Dep. Dir. Extramural Research, Nat'l Insts. of Health (Nov. 18, 2021).



As of the date of this report, the Select Subcommittee does not believe that Dr. Daszak has ever submitted the request for the laboratory notebooks.

15) January 6, 2022: Letter from Dr. Lauer to Dr. Daszak

16) January 6, 2022: Letter from Dr. Lauer to Dr. Daszak

17) January 21, 2022: Letter from Dr. Daszak to Dr. Lauer

18) August 19, 2022: Letter from Dr. Lauer to Dr. Daszak

These actions ended with the WIV's suspension and subsequent debarment. While this is an appropriate and deserved action, NIH must do more to hold EcoHealth accountable for its wrongdoing.

II. NIH Leadership Supported The Compliance Actions Levied Against EcoHealth.

On numerous occasions Dr. Daszak held President Trump responsible for the cancellation of the grant. In fact, Dr. Daszak testified:

Dr. Peter Daszak (Nov. 14, 2023)

- Q. Did you ever learn any information, either from government officials or nongovernment officials, that connected the statement of intent by then-President Trump to terminate the grant to the decision that was ostensibly made by NIH to terminate the grant?
- A. What I heard was that -- look, when President Trump says something, he usually does it. Let's face it. I mean, that's one

attribute of President Trump, that when he makes a statement like that he normally follows through.

- Q. And from what you heard and what you understand, do you believe that it was the HHS Secretary making the decision himself at that point, or through instructions from the President?
- A. Well, I think President Trump very clearly stated in that press conference, "We will end it very quickly." And within a week it was ended.
- Q. And is this, is your understanding of that formed through public reporting and your sort of connecting the dots, or have people directly told you that?
- A. So all of the above.⁶⁰

Notwithstanding Dr. Daszak's testimony, additional testimony regarding the grant cancellation is clear – NIH career public health officials supported and did not doubt the actions undertaken by NIH and Dr. Lauer. According to top career officials at NIH:⁶¹

Dr. Michael Lauer (Nov. 2, 2023)

- Q. All right. Thank you. I'm going to go back and ask some questions -- a blanket one I think you touched on, but maybe not directly: Would you sign and send a letter if you did not agree with the contents of the letter?
- A. No.⁶²

Dr. Hugh Auchincloss (Dec. 20, 2023)

Q. I want to first start by, as you know, NIH Office of Extramural Affairs started compliance efforts with regard to EcoHealth in April of 2020. Every letter sent by them was sent by Mike Lauer, who heads that office. When he testified in front of us, he said that he would not sign and send a letter that he disagreed with. Do you have any reason to doubt that assertion?

⁶⁰ Daszak TI, *supra* note 7, at 203-204.

⁶¹ Lauer TI, *supra* note 12, at 55; Auchincloss TI, *supra* note 25, at 147-148; Transcribed Interview of Francis Collins, M.D., former Dir., Nat'l Insts. of Health, at 145 (Jan. 12, 2024) (On filed with Select Subcomm. Staff) (hereinafter "Collins TI").

⁶² Lauer TI, *supra* note 12, at 55.

A. None. 63

Dr. Lawrence Tabak (Jan. 5, 2024)

- Q. So understanding there wasn't, if any, involvement prior to 2020, I'm going to shift ahead to the 2020 to present timeframe as it pertains to EcoHealth and start with one question. We had a similar interview with Dr. Lauer, and he testified at that interview that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?
- A. I have no doubt at all about that.⁶⁴

Dr. Francis Collins (Jan. 12, 2024)

- Q. Moving into 2020. Before we start with individual letters, we asked Dr. Lauer and he testified that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?
- A. No.
- Q. Do you agree with every enforcement action the NIH took against EcoHealth?
- A. Yes. 65

Dr. Fauci was the only official at the Director or Deputy Director level the Committees interviewed who was evasive regarding Dr. Lauer's integrity. Dr. Fauci testified:

Dr. Anthony Fauci (Jan. 8, 2024)

- Q. Okay. I want to shift to a time period a little closer -- it's still 2020, but it's at least closer than 2016 -- and ask a blanket question first. Dr. Lauer testified that he would not sign or send a letter that he disagreed with. Do you have any reason to doubt that assertion?
- A. He would not sign –
- Q. Or send a letter that he disagreed with.
- A. I can't speak for him. 66

⁶³ Auchincloss TI, supra note 25, at 147-148.

⁶⁴ Tabak TI, *supra* note 21, at 51.

⁶⁵ Collins TI, *supra* note 61, at 145.

⁶⁶ Fauci TI, supra note 40, at 210.

As discussed above, Mr. Meadows instructed HHS and NIH to terminate or suspend the grant to EcoHealth because of concerns that arose regarding the WIV and compliance. This instruction resulted in a multi-year effort to investigate and oversee EcoHealth's actions, including an investigation led by Dr. Lauer with the support of NIH leadership—notably Dr. Collins and Dr. Tabak. Contrary to Dr. Daszak's testimony and public reporting, the actions levied against EcoHealth were not political, but instead supported by facts and evidence and executed by career public health officials.

REINSTATEMENT

It is NIH policy to make every possible attempt to return grantees to compliant status. However, in the case of EcoHealth, NIH turned a blind eye to potential issues with the reinstatement of this grant. Evidence gathered by the Select Subcommittee suggests that Dr. Daszak omitted a material fact during the grant reinstatement process—a fact that may have changed whether EcoHealth's grant was reinstated or not. Further, evidence suggests that because of Dr. Daszak's actions, NIH is in violation of the terms of the debarment of the WIV.

Finding:

While negotiating the reinstatement of the grant, Dr. Daszak omitted the material fact that unanalyzed samples and sequences—that the U.S. paid for—are in the custody and control of the WIV. This omission was taken as fact by NIAID and NIAID took no steps to verify the actual location of the sequences and samples. If Dr. Daszak had not made this omission it would have provoked questions from NIAID regarding EcoHealth's ability to fulfill the aims of the reinstated grant. Finally, as a result of Dr. Daszak affirmations, NIH is currently violating the terms of the debarment of the WIV.

I. <u>Dr. Daszak Omitted A Material Fact To Secure EcoHealth's Grant Renewal.</u>

On April 26, 2023, NIAID reinstated EcoHealth's grant. ⁶⁷ This reinstatement was publicly announced by EcoHealth on May 8, 2023. ⁶⁸ In NIH's notification to Congress, it stated that EcoHealth had been organizing and implementing a corrective action plan to satisfy NIH's compliance efforts. NIH's goal during compliance investigations is to bring the grantee back into compliance and to design a corrective action plan to support that outcome. As Dr. Lauer testified to the Committees:

Dr. Michael Lauer (Nov. 2, 2023)

So, again, our philosophy -- and it's not just a philosophy; it's what's grounded in the uniform guidance regulations -- is that, when a recipient is out of compliance, the goal is to bring them back into compliance. And we can do that, as I said, through a variety of means -- through revising terms and conditions of award, through specific award conditions, through a corrective action plan. Because, ultimately, what we want is we want the recipient to be successful and we want them to be compliant with terms and conditions.⁶⁹

⁶⁷ See Grant Summary, R01AI110964, USASpending (last accessed Apr. 24, 2024).

⁶⁸ EcoHealth Alliance Receives NIH Renewal Grant for Collaborative Research to Understand the Risk of Bat Coronavirus Spillover Emergence, EcoHealth Alliance, Inc. (May 8, 2023).

⁶⁹ Lauer TI, supra note 12, at 80.

However, in the case of EcoHealth, one of the required conditions could not be remedied. NIH requested EcoHealth provide laboratory notebooks to establish what gain-of-function experiments involving coronaviruses were conducted with U.S. taxpayer dollars at the WIV. EcoHealth failed to provide these notebooks. As Dr. Lauer wrote in a letter to Congress: ⁷⁰

 However, NIH also identified one non-compliance requirement under the grant R01AI110964 (R01) that could not be remedied with SACs. NIH had requested EHA provide NIH the laboratory notebooks and original electronic files from the research conducted at WIV. Since EHA failed to provide these records and WIV was unable to fulfill its duties for the subaward, NIH notified EHA on August 19, 2022, that it would be terminating the WIV subaward for failure to meet award terms and conditions.

In a notification to EcoHealth sent on the same day, NIH wrote, "[t]he award R01AI110964 beginning on April 19, 2020, remains suspended pending the renegotiation of specific aims for the award without the involvement of the Wuhan Institute of Virology." The Select Subcommittee proceeded to gather evidence regarding the rationale for the renewal. One of the primary reasons for reinstating the grant to EcoHealth was its alleged access to sequences and samples previously paid for by the federal government and not yet analyzed. Dr. Erbelding testified:

Dr. Emily Erbelding (Nov. 28, 2023)

Q. And then I want to somewhat briefly parse out a little bit more on the samples. So you referenced earlier you and Dr. Lauer provided a briefing to a number of committees over the summer on the EcoHealth Alliance reinstatement. And one of the reasons given for reinstating the grant were that there were these bat samples collected from China and Southeast Asia with funding that still needed to be tested or sequenced, or I forget the exact language that was used.

Is that correct?

- A. Is it correct that I said that to the committee –
- Q. Yes.
- A. -- or --
- Q. Is that your understanding of the grant, the reason for the grant reinstatement?

⁷⁰ Letter from Michael Lauer, M.D., Dep. Dir. Of Extramural Research, Nat'l Insts. of Health, to Hon. Brad Wenstrup, Chairman, Select Subcomm. on the Coronavirus Pandemic, H. Comm. on Oversight & Accountability (Apr. 26, 2023).

⁷¹ Letter from Michelle Bulls, Dir., Office of Policy for Extramural Research Administration, Office of Extramural Research, Nat'l Insts. of Health, to EcoHealth Alliance, Inc. (Apr. 26, 2023).

- A. That was part of the reason, yes, that we wanted to get the most out of existing sequences from prior work. We wanted to get the most out of prior work.
- Q. What were the other rationales?
- A. Well, that they could address a scientific priority of NIAID in understanding how pandemics occur. I think that it would be -- that they had been scientifically productive in the past. That was another part of the rationale for reinstatement.
- Q. If you know, at the time of reinstatement, how many samples did EcoHealth have access to that remained untested?
- A. I don't know the number.
- Q. Did EcoHealth -- was it EcoHealth that told you that they had samples?
- A. They did -- they did give an approximate number. I don't recall what it was.
- Q. Did they tell you that the samples were in their possession?
- A. I believe I asked, You have access to these samples? Do you have access to these samples? I think that, to my -- to the best of my recollection, that's how I phrased the question. And I got an affirmative answer. That was, I think, the conversation.
- Q. You asked, do you have access, and they responded yes?
- A. This was Peter Daszak. Yes.
- Q. There wasn't an elaboration on the yes?
- A. I did not ask further questions. I took his representation as truthful.⁷²

Dr. Erbelding testified that, at the time of the reinstatement, NIAID believed that EcoHealth had access to sequences and samples the federal government had previously paid to have collected but that had yet to be analyzed. For reasons that are not clear to the Select Subcommittee, NIAID apparently never asked EcoHealth where the samples were located. Instead, NIAID relied solely on the representations of Dr. Daszak that the samples existed and that he had access to them. In reality, EcoHealth was relying on the WIV, an institute debarred for failing to produce laboratory notebooks, to provide them with virus samples and sequences that were the justification for reinstatement. Dr. Daszak testified:

⁷² Erbelding TI, *supra* note 19, at 55-56.

Dr. Peter Daszak (Nov. 14, 2023)

- Q. I have got a few quick questions on the reinstatement. And then one circle back on the intelligence community issue. So the reason you should know this, but Drs. Lauer and Erbelding gave us a congressional briefing a few months ago on the reinstatement and some of the decisions and, you know, additional terms put in place. One of the reasons -- one of scientific rationales for reinstating the grant is that there remains thousands of bat samples collected from China with funding basically paid for by the grant before it was suspended, but still need to be tested for the presence of the virus. Is that still the case?
- A. Well, we have new data from China on some of those -- on the results from some of those samples. We are currently analyzing it. Very important critical data. And yeah, I think it's -- we're getting there. It's good to have new information, but there are still many samples that we don't have direct control over.
- Q. Sure. Who is the custodian for those samples presently?
- A. Right now, they are in the Wuhan Institute of Virology. And theoretically, a sample collected in a foreign government belongs to the foreign government so yeah.
- Q. But the WIV has been debarred. They can't participate in this grant?
- A. Yeah. And they are not participating in this grant.
- Q. But they have custody of all the samples?
- A. But we have got information, data from the samples that has not yet been analyzed. We have that information here in the U.S.
- Q. But the Latinne paper, you said that was all your information?
- A. Since the Latinne paper, since the pandemic began, Wuhan Institute of Virology's staff has continued to sequence out some of those initial small fragments to get whole genome sequences, critical information. I agree with what Dr. Erbelding and Stemmy or whoever it was has said that that was paid for by U.S. taxpayers. It is our right to get that information. We've got it and we're now working on it to publish that information.
- Q. Is there information derived from the samples that you don't have?

- A. From what I hear, no. Not -- until they do more work on them. And then we have an understanding that we'll be able to get some access to those data too.
- Q. I'm trying to understand how this works. With the WIV debarred, and not talking to you anymore, which –
- A. Well, they do talk to us. I can talk to them. It's not illegal to talk to them.
- Q. No, no, no. But you said, like, we've asked them for the progress reports, they never answered an email.
- A. I asked them for the lab notes.
- Q. For the lab notes.
- A. Yeah, yeah.
- Q. But your -- I'm trying to understand how we have debarred them, but we're still paying them to process samples.
- A. No, no. There's no money going to Wuhan Institute of Virology at all. No money going to China.
- Q. So there's a bolus of data that left the WIV before they were suspend -- between -- before they were suspended that has yet to be analyzed, that has to be analyzed or that need -
- A. My understanding is that the debarment is they are not able to take Federal funds, now for 10 years. I think at least that is, what I understand, from what the phrase means. They have other samples. If they are going to do further work on those samples and they are willing to give us that information, that's a positive win for the U.S. taxpayer.
- Q. Sure.
- A. I'm going to take the opportunity and publish it, and I think that's a good thing.
- Q. So why do you think the difference? Why do you think the difference in the WIV is willing to give you access to the samples, the results of tests on these samples but not the laboratory notebooks?

- A. Well, you would have to ask WIV about that. I'm very delighted that we've been able to get that. Information out of WIV and out of China. It's a good thing.
- Q. And they are, functionally, doing it for free? We may have some prior claim on it because the initial sampling was done with our money.
- A. Yeah, unfortunately, the legalities of ownership are not good and not clear in this sort of issue. However, if we can get the data, we're going to get it and we're going to work it and we are going to make it public and we are going to try and get at much good information as we can out of it.⁷³

According to Dr. Erbelding, Dr. Daszak failed to inform NIH that a substantial number of samples or sequences—the same samples or sequences that were a primary purpose for reinstating EcoHealth's previously suspended grant—were in the custody and control of the WIV, a now debarred organization. It remains unclear how many samples or sequences that the federal government paid for still reside at the WIV.

Since access to sequences and samples was a substantial reason for reinstating EcoHealth's grant, it raises the question of whether NIH would have still reinstated the grant if it had knowledge of this issue. According to Dr. Erbelding, if she had that knowledge, it would have at least caused her to ask more questions regarding the reinstatement. Dr. Erbelding testified.⁷⁴

Dr. Emily Erbelding

- Q. I have one quick follow-up question, and then I'm going to ask some more about EcoHealth and their various efforts. If Dr. Daszak had told you that samples were still in the custody and control of the Wuhan Institute of Virology, would that have changed your calculus in reinstating the grant?
- A. I think it depends on -- we would have said those samples, we can't assume that they're going to be used. It would have depended upon what other samples he did have access to or he did have in other locations that were accessible.
- Q. So it would have at least prompted some follow-up questions or more information?
- A. Yes.

⁷³ Daszak TI, *supra* note 7, at 263-265.

⁷⁴ Erbelding TI, *supra* note 19, at 90.

- Q. All right. Thank you.
- A. I think so. 75

Witness testimony makes clear that Dr. Daszak omitted the material fact that the sequences and samples the federal government were paying for were, at least in part, under the custody and control of the WIV. Further, testimony suggests that if NIH had known this, it would have resulted in more questions regarding whether to reinstate the grant or not.

That NIAID would reinstate the EcoHealth grant without asking basic questions about the location of the not yet analyzed samples that supposedly justified the reinstatement is either gross incompetence or connivence by NIAID. Whatever the reasons, based on the totality of the evidence, it seems clear that NIAID leadership placed an unusually high-priority on ensuring that EcoHealth continued to receive funding despite compliance failures and lack of candor.

II. Because Of EcoHealth's Actions, NIH Is Currently In Violation Of The Debarment Of The WIV.

Dr. Daszak testified that to carry out the research objectives of his reinstated NIH grant he is currently requesting access to samples that are in the possession of the WIV. Contrary to Dr. Daszak's testimony, debarment is more than simply being barred from receiving federal funds. Debarment also has "nonprocurement" consequences. The nonprocurement terms that apply to the WIV are: ⁷⁶

Nonprocurement:

No agency in the Executive Branch shall enter into, renew, or extend primary or lower tier covered transactions to a participant or principal determined ineligible unless the head of the awarding agency grants a compelling reasons exception in writing. Additionally, agencies shall not make awards under certain discretionary Federal assistance, loans, benefits (or contracts there under); nor shall an ineligible person participate as a principal, including but not limited to, agent, consultant, or other person in a position to handle, influence or control Federal funds, or occupying a technical or professional position capable of substantially influencing the development or outcome of a funded activity; nor act as an agent or representative of other participants in Federal assistance, loans and benefits programs. Contact the award agency for questions regarding the extent of Nonprocurement transaction award ineligibility. The period of ineligibility is specified by the termination date. **Hide Details**

In addition to not being able to directly fund the WIV, the WIV also may not be "in a position to handle, influence or control Federal Funds, or occup[y] a technical or professional position capable of substantially influencing the development or outcome of a funded activity."⁷⁷ EcoHealth is relying on the WIV for access to sequences and samples it needs to meet its aims

⁷⁵ Erbelding TI, supra note 19, at 90.

Wuhan Institute of Virology, Chinese Academy of Sciences Capital Construction, SAM.gov

⁷⁷ Id.

pursuant to its federally funded grant. This puts the WIV in a position to substantially influence the outcome of this grant—for better or worse. This is a violation of the terms of the WIV debarment.

EcoHealth's reliance on the WIV also violates the spirit – if not the letter – of its renegotiated grant terms after the April 26, 2023 reinstatement. Part of the agreement for the reinstatement held that EcoHealth would not perform work in or with Chinese affiliated institutions. As stated in EcoHealth's special grant terms: ⁷⁸

In these modified specific aims, we have removed all on-the-ground work in China, all further field sampling of people or bats, and all recombinant virus culture or infection experiments. Work will now be conducted only

EcoHealth stated that it has "removed all on-the-ground work in China." Considering Dr. Daszak's testimony, this statement is, at a minimum, misleading.

A plain reading of the exclusion's terms relating to the WIV make NIAID's continued funding of EcoHealth's reinstated R01 grant a violation of the WIV's debarment.

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⁷⁸ Modified Project Summary/Abstract Section, EcoHealth Alliance, Inc. (May 8, 2023).

RECOMMENDATIONS

The evidence necessitates immediate action. As part of the Committees' investigation and pursuant to House Resolution 5, the Committees recommend the following actions to be carried out either through executive action or legislation.

I. Recommendations Regarding EcoHealth Alliance, Inc.

- 1. The National Institutes of Health must recommend, and the Department of Health and Human Services must initiate suspension and debarment proceedings against EcoHealth Alliance, Inc.
- 2. The National Institutes of Health must recommend, and the Department of Health and Human Services must initiate suspension and debarment proceedings against Dr. Peter Daszak, President of EcoHealth Alliance, Inc.
- 3. The Department of Justice should evaluate if Dr. Daszak violated any federal laws, including but limited to violations of
 - i. 18 U.S.C. 1001; or
 - ii. 31 U.S.C. 3729-3733.

II. Recommendations Regarding The Federal Government.

- 1. Evaluate whether to remove final approval authority for high-risk virology research proposals involving potential pandemic pathogens from NIAID and instead empower an independent oversight entity to review, approve, and oversee such experiments.
- 2. Impose increased transparency requirements for high-risk virology research involving potential pandemic pathogens so that NIAID, NIH, and entities like EcoHealth can no longer withhold critical information from Congress and the public.
- 3. Evaluate the allocated funding and resources for the NIH Office of Extramural Research to ensure adequate resources to ensure adequate NIH wide grant enforcement and proper investigations of grant compliance.
- 4. Consider whether NIAID should be divided into two institutes, one focusing on infectious disease and one focusing on allergies.
- 5. Evaluate whether NIAID leadership should be subject to term or years of service limits.
- 6. Evaluate whether the United States needs a single, unified regulatory scheme governing gain-of-function and dual use research, regardless of funding source.
- 7. Consider granting the Director of the NIH or the Secretary of HHS, in consultation with the Office of the Director of National Intelligence, authority to immediately suspend, pending investigation, a grant determined to be a threat to national security.
- 8. Incorporate a national security or intelligence community review into the grant making process for grants that involve, in any way, countries of particular concern or special watch list countries.

LIMITATIONS

The conclusions and supporting evidence contained in this report are limited by the cooperation of the various individuals and institutions that the Committees requested documents and information from. EcoHealth and HHS have substantially obstructed the Committees ability to conduct a fulsome investigation.

HHS has routinely and without valid reason objected to lines of questions posed by Committee staff during transcribed interviews. Further, HHS has—without consent of the Committees—set the terms of these interviews, often these terms restrict the Committees ability to ask all the necessary questions. Finally, HHS has, either by intent or incompetence, produced the requested documents and information at an unacceptable pace. This has restricted the number of documents in the responsive universe that the Committees had access to while drafting this report.

Like HHS, EcoHealth has also delayed and failed to produce all responsive documents the Committees requested. Further, the documents provided to the Committees appear to be incomplete and lacking specific e-mails contained within larger chains of communications. EcoHealth has also acted to affirmatively obstruct the Committees by failing to produce documents all together and instead directing the Committees to review unverifiable public productions via the Freedom of Information Act.

The actions by HHS and EcoHealth are unacceptable and may require further action. The Committees are evaluating the use of the compulsory process.