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ONE HUNDRED SEVENTEENTH CONGRESS
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October 24, 2022

Lawrence A. Tabak, D.D.S., PhD.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

Dr. Tabak,

We write to request information on why NIH provided new funding to EcoHealth Alliance (EcoHealth), and why NIH is considering a resumption of funding for work under a suspended grant to EcoHealth, given EcoHealth's documented failures to comply with NIH grant terms and the outstanding questions concerning EcoHealth's conduct.

NIH records show that on September 22, 2022, the NIH funded EcoHealth through a new award grant 1R01AI163118-01A1 after suspending EcoHealth's grant R01AI110964 for more than two years (R01 award). Funding this new award grant and NIH's intentions to resume funding for EcoHealth under the R01 award as indicated in the August 19, 2022, letter¹ to Republican Committee Leader Rodgers seem inexplicable given NIH's previous findings of EcoHealth's noncompliance with grant terms and the serious concerns about EcoHealth raised in our four letters without a response from NIH.²

¹ Letter from Michael Lauer, M.D., Deputy Director for Extramural Research, NIH to Representative Cathy McMorris Rodgers (August 19, 2022).

² See Letter from Representatives Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith *et al* to Francis Collins, M.D., Ph.D., Director, NIH (June 10, 2021) (concerns about EcoHealth's inadequate oversight, EcoHealth's delinquent financial reports, and possible NIH funding of EcoHealth for duplicative research); Letter from Representatives Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith to Francis Collins, M.D., Ph.D., Director, NIH (October 27, 2021) (concerns over gain-of-function research supported by EcoHealth grant); Letter from Representatives Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith to Lawrence A. Tabak, D.D.S., PhD., Acting Director, NIH (February 24, 2022) (concerns over withheld data and possible double billing, missing laboratory notebooks and electronic files related to humanized mice research at the Wuhan lab, and EcoHealth's private donations that may not have been reported to NIH); Letter from Representatives Cathy McMorris Rodgers, Brett Guthrie, Morgan Griffith to Lawrence A. Tabak, D.D.S., PhD., Acting Director, NIH (April 25, 2022) (concerns over whether EcoHealth intentionally withheld certain data relating to mice deaths and other material information during the peer review process for EcoHealth's grant renewal application).

In an October 4, 2022, interview with the WASHINGTON POST, in response to a question about funding of this new grant by the National Institute of Allergy and Infectious Diseases (NIAID) to EcoHealth, NIAID Director Dr. Anthony Fauci stated that EcoHealth “adequately addressed” NIH “administrative things” presumably related to noncompliance in the R01 award. He pointed this out to show there would be no mechanism to arbitrarily cut off funding for EcoHealth and that NIH could be legally vulnerable if it took such an action (“If they [EcoHealth] ever brought that to court, they could sue us, and win that in a microsecond.”).³ However, this assertion begs the question of how NIH determined EcoHealth had adequately addressed noncompliance issues given the history of this grant.

The NIH suspended the EcoHealth R01 award on July 8, 2020, over avowed concerns about the adequacy of EcoHealth’s oversight of its sub-grantee, the Wuhan Institute of Virology (WIV) and its noncompliance with specific regulatory and NIH grant policy requirements.⁴ As the NIH noted in the suspension letter, “[w]e have concerns that WIV has not satisfied safety requirements under the award, and that EcoHealth Alliance has not satisfied its obligations to monitor the activities of its subrecipient to ensure compliance.”

In October 2021, NIH confirmed that EcoHealth did not comply with the NIH’s safety rule on excessive virus growth in an experiment involving humanized mice infected with chimeric viruses.⁵ On August 19, 2022, the NIH stated that EcoHealth failed to include the terms and conditions required in Federal awards in WIV’s subaward agreement to ensure access to any documents, papers, or other records of the non-Federal entity (WIV) pertinent to the Federal award.⁶ The NIH found that EcoHealth’s deficient subaward agreement represented “material failures to comply with the terms of its award.”⁷ As a result of these failures, EcoHealth did not secure lab notebooks and electronic files associated with the humanized mice experiment, and did not obtain these materials from the WIV after NIH requested them.⁸ Neither of these violations can be remedied by corrective actions. In fact, the NIH terminated the WIV sub-grant, but seemed to treat EcoHealth as if it was an unwitting victim rather than an NIH grantee with numerous responsibilities over its sub-grantee, the WIV, as NIH has maintained for two years.

As a grantee, EcoHealth was required to “monitor the activities of the subrecipient as necessary to ensure that the subaward is used for authorized purposes, in compliance with

³ Dr. Fauci’s comments are included in this video of the interview. https://twitter.com/emilyakopp/status/1577401562246389760?s=12&t=r1XJ8G_aar1YFZE2TihPng See also Kellie Schmitt, Dr. Anthony Fauci talks to WaPo’s Dan Diamond on the pandemic and where we go from here, Center for Health Journalism (October 6, 2022) <https://centerforhealthjournalism.org/2022/10/06/dr-anthony-fauci-talks-post-s-dan-diamond-pandemic-and-where-we-go-here>

⁴Letter from Michael S. Lauer, M.D., Deputy Director for Extramural Research to Drs. Aleksei Chmura and Peter Daszak, EcoHealth Alliance (July 8, 2020).”

⁵ NIH October 20, 2021, letter

⁶ Letter from Michael Lauer, M.D., Deputy Director for Extramural Research, NIH to Representative Cathy McMorris Rodgers (August 19, 2022).

⁷ *Id.*

⁸ *Id.*

Federal statutes, regulations, and the terms and conditions of the subaward . . .”⁹ 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.”¹⁰ NIH records document that EcoHealth drew down grant payments thereby acknowledging acceptance of the terms and conditions of the award, including monitoring the activities of the subrecipient to ensure the subaward was used for authorized purposes.¹¹ We would further note that EcoHealth charged the grant for supervising its sub-grantee. However, the Principal Investigator of the R01 award, Dr. Peter Daszak, strongly suggested in comments to THE INTERCEPT that EcoHealth was not actively monitoring the WIV but instead was passively relying on annual updates from the WIV:

Here's what happens, it's a very standard procedure. We are subcontracting to a lab in China to do some work. Every year we have to file a report to NIH to tell them what we've done for the year, how we've spent the money, and whether we've achieved the goals of the grant. So, we contact our subcontractees and we say, 'Send us the information. Let us know what successes you've had this year and whether you've had problems and issues. Put it all in a report and send it to us.'¹²

In addition, Dr. Daszak admitted that he had never actually seen the WIV's database of viral samples and sequences that went offline in September 2019, and that his staff had no access to it.¹³ Dr. Daszak had previously written to NIH that EcoHealth's biosafety oversight of the WIV consisted of semiannual meetings with the lead investigators and assessments of compliance with all conditions of the award. Biosafety experts have said that this falls short of the level of oversight one would want for this kind of work.¹⁴

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.¹⁵ This was particularly true when NIH identified possible gain-of-function research concerns in an experiment proposed by EcoHealth and conducted by the WIV. We would note that in a July 7, 2016, letter to EcoHealth, 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

⁹ 45 C.F.R. § 75.352(d).

¹⁰ NIAID, Notice of Award, EcoHealth Alliance, Grant Number 1R01A1110964-01, *Understanding the Risk of Bat Coronavirus Emergence* (May 27, 2014).

¹¹ https://www.usaspending.gov/award/ASST_NON_R01A1110964_7529

¹² Sharon Lerner and Mara Hvistendahl, Peter Daszak Answers Critics and Defends Coronavirus Research, *The Intercept* (March 11, 2022), Peter Daszak Answers His Critics, Defends EcoHealth Alliance (theintercept.com)

¹³ *Id.*

¹⁴ *Id.*

¹⁵ 45 CFR § 75.352.

Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.¹⁶

However, EcoHealth violated this grant policy. In an October 20, 2021, letter to Representative McMorris Rodgers, the NIH stated:

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 log 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.** (Emphasis added).¹⁷

The fact that the WIV apparently completed the humanized mice experiment with excessive virus growth without any reported stoppage and without EcoHealth notifying the NIH about the excessive virus growth is consistent with EcoHealth's detachment from the WIV's activities under the sub-grant of the R01 award. It appears EcoHealth was ignorant in real-time about the conduct of this experiment, and that this ignorance was a byproduct of a deliberately detached relationship with the sub-grantee. Thus, scientists at the WIV could have been exposed to and infected by an out-of-control virus (with a 75 percent death rate in one group of mice with human lung cells) without the experiment being stopped, without EcoHealth knowing in real-time, and without NIH being notified immediately.

Further, EcoHealth did not have a copy of the laboratory notebooks and electronic files associated with the experiment. Since EcoHealth told NIH it did not have these records, EcoHealth apparently accepted the WIV's annual information without any substantiating records. By drawing down the NIH grant funds, EcoHealth accepted the NIH grants terms which required EcoHealth to actively monitor and supervise the WIV. By its own admission and its failures to actively monitor the WIV's humanized mice experiment without any substantiating documentation, the available information suggests to us that EcoHealth acted with deliberate ignorance or reckless disregard concerning the conduct of the WIV's humanized mice experiment.

NIH's own findings and EcoHealth's own statements and actions suggest EcoHealth violated the False Claims Act (FCA) when it accepted NIH grant terms by drawing down NIH grant funds but materially failed to comply with the terms of the grant. Recent Department of Justice (DOJ) FCA settlements with an NIH grantee demonstrate that these "administrative things" include requirements on NIH grantees to make factual representations to NIH without deliberate ignorance or reckless disregard.¹⁸ In addition, NIH grantees must make full disclosure to the NIH. As DOJ has noted, "Full disclosure is essential not only in validating scientific

¹⁶ Letter from Jenny Greer and Erik J. Stemmy, Ph.D., NIAID/NIH to Mr. Aleksei Chmura, EcoHealth Alliance (July 7, 2016)(obtained via Freedom of Information Act by White Coat Waste Project).

¹⁷ Letter from Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, NIH to Representative Cathy McMorris Rodgers, Ranking Member, House Committee on Energy and Commerce (October 20, 2021).

¹⁸U.S. Department of Justice Press Release, *Department of Justice Reaches \$5.5 Million Settlement With Van Andel Research Institute To Resolve Allegations of Undisclosed Chinese Grants to Two Researchers* (December 19, 2019).

research, but also in the intense competition for scientific funding from the federal government. NIH's application process is intended to yield information that is critical to the agency's responsible stewardship of billions of taxpayer dollars."¹⁹ We are troubled that NIH has not provided, and we are not aware of, any evidence of how EcoHealth provided full disclosure of the experiment without substantiating records and thus adequately addressed these critical requirements with the R01 award.

EcoHealth was lax in its oversight of the WIV, no ordinary sub-grantee. The WIV conducted research with Chinese military researchers. This relationship is not disputed by the Biden administration.²⁰ The WIV was headed by a Chinese communist party official.²¹ As far as we are aware, the undocumented humanized mice experiment has not resulted in a publication in scientific literature. Thus, as a result of EcoHealth's deliberate ignorance and negligence, no scientific publication was produced by the NIH grant money to the broader scientific community. At the same time, China retains control over the experiment materials, and benefitted from the humanized mice sent from the U.S., the federal grant money, the know-how conveyed through the EcoHealth relationship, and whatever information that could be derived from the work enabled by EcoHealth that could help the interests of the Chinese military. It is not clear to us how these outcomes from the EcoHealth R01 award benefitted the American people. It is more apparent how these outcomes could have been to the detriment of the American people.

We question whether EcoHealth honored its position of trust as an NIH grantee. As Michael Shannon, former NIH Director of Management Assessment, noted for the record for a June 29, 2022, hearing before the Subcommittee on Health, "the American people have a covenant with research institutions: we provide you the funds and you are good stewards and deliver benefits to humanity from the research. There are three basic cornerstones of this understanding:

1. The grantee will account for what was done with taxpayer dollars and publish the research results. New scientific information will be shared and accessible. Other scientists have an opportunity to reproduce the results.
2. The grantee will conduct the research as safely as possible to protect the lab workers and the public. The grantee will comply with the safety conditions set by the NIH. This is of even greater importance when the research involves high-risk viruses.
3. The grantee will account for their research activities each year on deadline."²²

¹⁹ U.S. Department of Justice Press Release, *Department of Justice Reaches Million-Dollar Settlement With Van Andel Research Institute To Resolve Allegations Of Undisclosed Foreign Ties to NIH Grants* (September 1, 2021).

²⁰U.S. Department of State, Fact Sheet: Activity at the Wuhan Institute of Virology, Office of the Spokesperson (Jan.15, 2021) *available at* <https://2017-2021.state.gov/fact-sheet-activity-at-the-wuhan-institute-of-virology/index.html>. We sent two letters to Secretary of State Antony Blinken on this specific issue, without this point being disputed.

²¹This was disclosed in a 2013 email that the senior Chinese Communist Party official in charge at the Wuhan Institute of Virology was Zhi-ming Yuan. [usrtk.org/wp-content/upl](https://www.usrtk.org/wp-content/upl)

²² Responses to Questions for the Record, Michael Shannon, Executive/President of Government Solutions, IPTalons, Inc., Subcommittee on Health, Hearing on "Investing in Public Health: Legislation to Support Patients, Workers, and Research," (June 29, 2022).

At this point, we do not see the evidence of how EcoHealth met any of these elements. EcoHealth failed to obtain the laboratory notebooks and electronic files associated with the WIV humanized mice experiment, thereby failing to meet the cornerstones of information being shared and accessible. Further, there is no scientific publication we are aware of.

With regard to the safe conduct of research, EcoHealth failed to comply with the virus growth policy. With regard to accounting for their research activities each year on deadline, EcoHealth's Year 5 progress report for the R01 award was not submitted to the NIH until two years after the deadline.

Given this information, please respond to the following by November 7, 2022:

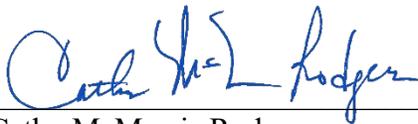
1. Name each and every lawyer or law firm(s) involved in advising Dr. Fauci in the legal ramifications associated with not renewing the R01 award.
2. What is the NIH precedent for resuming funding to suspended grantees under these circumstances? Please provide details on specific examples.
3. How much was EcoHealth paid under the grant to oversee the laboratory work of the WIV during Year 4 and Year 5 of the R01 award?
4. Isn't it true that under the terms and conditions, EcoHealth's drawdown of grant funds constitutes a claim that EcoHealth would monitor its sub-grantee in compliance with the terms of the grant? What certifications did EcoHealth make to the NIH?
5. Did EcoHealth comply with the requirements to monitor the WIV? If so, what is the basis for this conclusion? If not, what is the basis for this conclusion?
6. Why has NIH continued to provide funding for EcoHealth Alliance's international research activities?
7. How will NIH validate the information regarding EcoHealth Alliance's oversight and compliance activities for its subawardees?
8. It is unclear how the additional terms and conditions that NIH has described will ensure that future issues with obtaining laboratory notebooks and data resulting from NIH funded activities will not reoccur. How will NIH ensure that EcoHealth Alliance will comply with these additional terms and conditions?
9. Did the NIH ever ask EcoHealth why it failed to include the terms and conditions required in Federal awards in WIV's subaward agreement to ensure access to any documents, papers, or other records of the non-Federal entity (WIV) pertinent to the Federal award? If so, what was EcoHealth's rationale? Did EcoHealth ever attempt to include such terms and conditions? Did the WIV refuse to agree to the inclusion of the terms and conditions? Did EcoHealth proceed with the subaward despite such a

refusal if it occurred? If the NIH did not ask EcoHealth about the rationale for not including these terms and conditions, why did the NIH not ask?

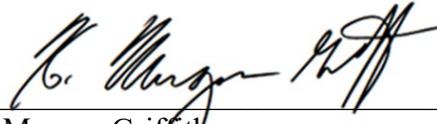
10. Did the NIH confer with any other federal agency about EcoHealth Alliance before making the most recent award? If so, please identify the agencies, the date of contact, and the issues discussed.

If you have questions about this correspondence, please contact Alan Slobodin of the Minority Committee Staff.

Sincerely,



Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce



H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and
Investigations
Committee on Energy and Commerce



Brett Guthrie
Republican Leader
Subcommittee on Health
Committee on Energy and Commerce

Cc: The Honorable Frank Pallone, Chair, House Energy and Commerce Committee
The Honorable Anna Eshoo, Chair, Subcommittee on Health
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Christi Grimm, HHS Inspector General