

**Questions for Dr. Lawrence Tabak
Principal Deputy Director
National Institutes for Health**

November 14, 2024: Select Subcommittee on the Coronavirus Pandemic hearing titled
“Preparing for the Next Pandemic: Lessons Learned and The Path Forward”

Questions from Rep. Michael Cloud

1. Both EcoHealth Alliance and Dr. Peter Daszak personally have now been debarred by HHS due to their failures to comply with NIH grant protocol.

- a. How many individuals and organizations receiving NIH funding have been debarred in the past five years?

NIH Response:

The HHS Suspension and Debarment Official (SDO) has suspended EcoHealth Alliance (EHA) and Dr. Peter Daszak and proposed them for debarment. The HHS SDO successfully debarred 11 individuals and 1 organization within the last five years that were previously supported on NIH funded projects.

- b. Does NIH maintain that this was an isolated incident as opposed to an indication of systemic failure?

NIH Response:

NIH uses rigorous oversight processes when managing awards and engaging with recipient organizations. When NIH identifies potential compliance concerns, NIH takes swift, appropriate action. NIH fully complied with the two recent HHS Office of Inspector General (OIG) audits that focused on the grant awarded to EHA or on the HHS Suspension and Debarment Office. NIH closed all of the OIG recommendations. NIH also notes that it has undertaken hundreds of compliance reviews resulting in extensive consequences for certain grant recipients and for certain scientists supported by NIH grants, when warranted and appropriate. This has led to actions taken on hundreds of scientists (usually from their institutions) and tens of millions of dollars from award funds being recovered.

- c. Does this incident indicate that NIH’s oversight system failed in initially awarding the grant?

NIH Response

No. At the time of the initial award, NIH followed all of the appropriate pre-award risk assessment procedures. to assess risks associated with the entity prior to making an award. Oversight begins once an award has been made. At

the time of the first Research Performance Progress Report (RPPR), NIH was not aware of any potential concerns with regard to post award performance.

- d. Does the fact that NIH waited to debar EcoHealth and Daszak until after this Subcommittee's investigation of their failures to comply with NIH protocol became public indicate that NIH's oversight system failed in allowing them to continue receiving funds until that point?

NIH Response

For HHS agencies, only the HHS SDO has authority to suspend and debar individuals and entities from participating in federal programs. Moreover, the HHS SDO has not debarred EcoHealth or Dr. Daszak; rather the HHS SDO has suspended them and proposed them for debarment. Any proposed debarments by the HHS SDO are subject to the Office of Management and Budget guidelines to agencies on government-wide debarment and suspension (non-procurement) in 2 CFR 180.¹

While NIH does not have authority to debar or suspend individuals and entities from participating in federal programs, NIH took proper oversight action against the non-compliant award by suspending the grant. Thereafter, NIH placed specific award conditions on all EHA grants, which removed certain administrative flexibilities (e.g. advanced payment options) and required a reimbursement option where the recipient must submit a request, to include justifications and invoices, to be reimbursed for all activities concerning their grant projects for activities that were conducted prior to the date that the HHS SDO suspended EcoHealth and Dr. Daszak from participating in federal programs (under the suspension and debarment procedures outlined within 2 CFR Part 180). NIH requested additional documentation from EHA to support details that were outlined in their RPPR for grant #R01AI110964. EHA did not provide the requested documentation, and, after multiple requests, NIH submitted a debarment referral package to the HHS SDO to support the suspension and proposed debarment.

- e. What improvements does NIH plan to implement to its grant award and oversight systems to ensure that this does not happen again?

NIH Response

NIH takes its stewardship over the nation's investment in biomedical research very seriously and routinely considers processes and measures for strengthening its oversight of federal funds. NIH implements additional oversight measures when appropriate to ensure a recipient's documented efforts to strengthen administrative processes meet the NIH's expectations. NIH actively monitors recipients' progress and any potential concerns, and is committed to ensuring NIH meets its collective goal of supporting rigorous science to improve human health. Relatedly, NIH responded to and closed all recommendations from the OIG in its audit of the EHA grant.

¹ www.ecfr.gov/current/title-2/subtitle-A/chapter-I/part-180

Selected examples of NIH actions to improve controls in grant oversight systems include:

- Strengthen the interim RPPR process and ensure the RPPRs are submitted, read, reviewed, and (as appropriate) approved.
- Automated reminder emails to principal investigators and NIH grants staff (including the program officer) when an interim RPPR has not been submitted.
- Automated reminder emails to NIH program officers to accept/rescind interim RPPRs within 14 days of submission.
- Flags on Type 2 (renewal) applications when an interim RPPR has not been submitted or accepted.
- “Red Bar” flags on Type 2 (renewal) applications when an interim RPPR has not been submitted or accepted. This flag prevents awarding of Type 5 (non-competing continuation) in the year following a Type 2 renewal if interim RPPRs are not submitted and approved.

2. Applications for NIH grants are reviewed by an Advisory Council or Board of the relevant Institute.

- a. Are the names of the individuals who make this decision publicly disclosed?

NIH Response:

Applications for NIH research funding undergo two levels of review: (1) peer review; and (2) review by NIH National Advisory Councils or Boards (NAC).²

First, a panel of peer reviewers (primarily non-federal scientists) with appropriate expertise assesses applications based on their scientific and technical merit. For applications discussed by the panel, the product of the first level of review is an impact score, indicating the likelihood of a sustained, powerful influence on the field; a summary statement with critiques addressing regulatory criteria (Significance, Innovation, Investigators, Approach, Environment) and other criteria required by the funding opportunity; and a summary of the discussion that informed the impact score. All peer reviewers not in conflict with the application take part in discussion and scoring.

Second, NACs arrive at funding recommendations based on the outcome of peer review and the mission and priorities of the Institute, Center, or Office (ICO). The ICO director makes the final funding decisions.

While the peer review groups and NACs do not make funding decisions, the rosters of peer review groups and NACs are available on the NIH website as well as the General Services Administration FACA database.³ Peer review group rosters are posted on the NIH Scientific Review Group SRG Roster Index.⁴ NAC rosters can be found on the committee website of the relevant ICO.

² grants.nih.gov/policy-and-compliance/policy-topics/peer-review

³ www.facadatabase.gov/FACA/s/

⁴ public.era.nih.gov/pubroster/rosterIndex.era

- b. Is any information on how they made their decision publicly disclosed?

NIH Response:

Peer review groups and NACs do not make funding decisions. As it relates to their review, peer review and NAC deliberations of funding applications are made in closed session. Federal Register Notice announcements cite exemptions 552b(c)(4) and 552b(c)(6) of the Government in the Sunshine Act, since the applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications. The disclosure of such information would constitute a clearly unwarranted invasion of personal privacy.

While first level peer review meetings are closed, NIH publishes the review criteria for the funding opportunity. NIH Scientific Review Officers, who are the designated federal officers during peer review meetings, diligently work to ensure peer reviewers follow the review criteria.

NACs have sessions that are both open and closed to the public. Minutes from open meetings and the ICO's scientific priorities can be found on the ICO website.

NIH gives each applicant the peer review group's summary statement of their application. However, as noted in the NIH Guide Notice NOT-OD-22-044, peer reviewers and NAC members agree to terms prohibiting them from disclosing information about committee deliberations, discussions, evaluations, or other confidential documents other than as authorized by NIH during or for the peer review meeting.⁵

- c. Is there any way of holding these individuals accountable if they fail to exercise due diligence in reviewing these grant applications?
- i. If so, how often have those mechanisms been used? Has anyone involved in the decision to fund EcoHealth faced disciplinary measures?

NIH Response:

As explained in NOT-OD-22-044, if NIH determines that a situation involves a breach of integrity, including confidentiality or security, in NIH peer review process, NIH, in coordination with other offices, may take actions including, but not limited to:

- Notifying or requesting information from an individual's institution.
- Terminating review service for a reviewer or NAC member.
- Deferring or withdrawing an application submitted by the individual's institution.
- Terminating grant, cooperative agreement, fellowship or R&D contract awards to the individual's institution.
- Notifying the NIH Office of Management Assessment (OMA) with

⁵ grants.nih.gov/grants/guide/notice-files/NOT-OD-22-044.html

possible referral to the U.S. Department of Health and Human Services Office of Inspector General (OIG) and the U.S. Department of Justice (DOJ) for further appropriate action.

- Providing a referral for government-wide suspension or debarment.
- Notifying other, appropriate Federal agencies.

NIH Scientific Review Officers enforce review criteria and standards before and during the review meeting. NIH will not invite reviewers back to serve if they do not adhere to the rules, including disclosing conflicts of interest.⁶

3. Do you own individual stock in Pfizer, Moderna, or any other pharmaceutical company?

NIH Response:

No.

- a. If so, which companies?

4. Since the beginning of 2020, have you received a royalty payment from any pharmaceutical company?

NIH Response:

No.

- a. If so, which companies?

- b. What was the amount of each payment?

⁶ grants.nih.gov/policy-and-compliance/policy-topics/peer-review/coi