

United States Senate
WASHINGTON, DC 20510-0908

September 15, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Secretary Becerra:

We write today regarding the troubling issues raised by the recent Senate Committee on Homeland Security and Governmental Affairs' Emerging Threats and Spending Oversight Subcommittee hearing *Revisiting Gain of Function (GOF) Research: What The Pandemic Taught Us and Where Do We Go From Here*.¹ This hearing revealed concerning issues associated with the Potential Pandemic Pathogen Care and Oversight (P3CO) review that must be addressed to protect the country from another deadly pandemic.

The hearing found that although the P3CO Review Group is supposed to add a layer of oversight for GOF research, its effectiveness to-date has been questionable, primarily because it is a voluntary process in which U.S. Department of Health and Human Services (HHS) agencies self-select research projects for the P3CO risk assessment review.² Additionally, the P3CO Review Group operates largely in secret, lacking critical transparency required when evaluating potential hazardous research, unless that research is classified. Senators heard during the recent hearing that the P3CO review process amounts to self-policing on the part of NIH, and only evaluates the estimated results of proposed research in all HHS operations.

According to the HHS website, only three research projects have undergone review since its inception in 2017.³ However, the website was last updated in September 2021, so the current number of research project reviews is unknown. We are concerned that some projects should have been reviewed were not.

¹ <https://www.hsgac.senate.gov/subcommittees/etso/hearings/revisiting-gain-of-function-research-what-the-pandemic-taught-us-and-where-do-we-go-from-here>

² <https://www.washingtonpost.com/nation/interactive/2021/a-science-in-the-shadows/>

³ <https://www.phe.gov/s3/dualuse/Pages/ResearchReview-PPP.aspx>

We are also aware that the Ranking Members of the House Energy and Commerce Committee and the Health and Oversight subcommittees wrote to you in April 2022 and have not yet received a reply.⁴ Please provide to us a copy of your response to the Energy and Commerce ranking members and also provide written responses to the following questions:

1. Please provide a list of all members on the P3CO Review Group, including the federal agencies for which such members work.
2. Why has NIH not publicly disclosed the names of members of the P3CO Review Group, and does NIH have plans to publish their names?
3. What safeguards are in place to ensure and protect the independence of the members of the P3CO Review Group to guard against potential conflicts of interest? Are reviews of NIH grants solely performed by HHS permanent or contract staff members?
4. In 2014, the HHS framework required a review of certain flu or coronavirus strains that would be “transmissible among mammals” and might accidentally cause human infections. In 2017, the P3CO policy was announced which narrowed to cover only pathogens “likely capable of wide and uncontrollable spread in human populations.” Why were references to transmissibility among mammals removed in the 2017 revision?
5. Other than HHS personnel, which national security agencies are represented on the P3CO panel?
6. Please provide a full list of all P3CO experiments that have been reviewed, approved or denied.
 - a. What was funded, who received funding, and how much funding was provided to the researchers?
 - b. Please describe all research project inquiries that did not continue through the P3CO process, including dates and status of those projects.
 - c. Please describe the process by which the P3CO’s recommendations are reviewed for proper implementation by HHS divisions, such as NIH.

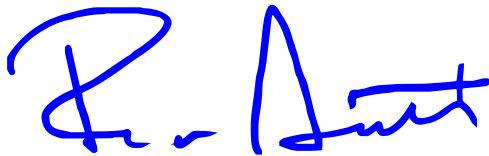
⁴ <https://republicans-energycommerce.house.gov/wp-content/uploads/2022/04/4.19.22-Letter-to-HHS-Secretary-Becerra.pdf>

The Honorable Xavier Becerra
September 15, 2022
Page Three

7. Please provide all documents, meeting notes, and calendar dates of P3CO Review Group meetings.
8. Are members of the P3CO review process required to sign nondisclosure agreements (NDA)?
9. Did the P3CO approve grants for research that was conducted at the Wuhan Laboratory of Virology?
10. Please provide a list of all Gain-of Function research currently being funded by the U.S. taxpayer domestically and internationally.
 - a. For each research project listed, please identify the city, state, province, and country where the research is being performed, as applicable.

The American people deserve nothing less than full accountability and transparency from their government. I appreciate your attention to this sensitive matter.

Sincerely,



Rick Scott
United States Senator



Roger Marshall, M.D.
United States Senator



Rand Paul, M.D.
United States Senator