



441 G St. N.W.
Washington, DC 20548

June 15, 2023

The Honorable Brett Guthrie
Chair
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Dear Chair Guthrie:

This letter responds to your June 1, 2023, request that I address a question for the record related to the Subcommittee's May 11, 2023, hearing on preparing for and responding to future public health security threats. If you have any questions about this response or need additional information, please contact me at (202) 512-8552 or DeniganMacauleyM@gao.gov.

Sincerely yours,

A handwritten signature in cursive script that reads "Mary Denigan-Macauley".

Mary Denigan-Macauley
Director, Health Care

Enclosure

Attachment 1—Additional Questions for the Record

The Honorable Gus Bilirakis

- 1) **In a 2023 report, the GAO identified three recommendations to HHS for improving oversight of potential pandemic pathogens, including creating a standard for determining research “reasonably anticipated to create, transfer or use enhanced potential pathogens” for departmental review, increase transparency of the review process and reviewers, and assess the risks posed by the current DSAT exemptions for public health emergencies.**
 - **In reviewing HHS’s policies and programs, what steps does GAO recommend Congress take to ensure gaps in enhanced potential pandemic pathogen oversight are being addressed?**

In our 2023 report, we made three recommendations to improve HHS's oversight of high risk research, including developing and documenting a standard for “reasonably anticipated”, increasing transparency, and assessing the risk of statutory limitations. HHS neither agreed nor disagreed with our first two recommendations and agreed with the third. At the time of our review, HHS had sought input from the National Science Advisory Board for Biosecurity (NSABB) on the scope and effectiveness of HHS’s oversight of research with enhanced potential pandemic pathogens. In responding to our first two recommendations, HHS cited the then-ongoing work of the NSABB in evaluating HHS’s research oversight policies and developing recommendations, and noted that the department expected NSABB’s work to inform its future actions. The NSABB issued a report in March 2023 including recommendations to revise federal policies. Congress could request HHS to provide status updates on both the GAO and NSABB recommendations to ensure progress is made in improving oversight of research involving enhanced potential pandemic pathogens.