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ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

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August 1, 2023

The Honorable Gene Dodaro
Comptroller General
U.S. Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Mr. Dodaro:

The COVID-19 pandemic highlighted the debate about the risks and benefits of a type of potentially high-risk research called “gain-of-function” research involving pathogens with pandemic potential. However, this term is not well understood and is often misused. “Gain-of-function” is a broad term that covers research that, among other things, involves genetically altering an organism, which may include increasing a pathogen’s ability to cause a pandemic. The White House Office of Science and Technology Policy (OSTP) has recommended that federal agencies adopt an appropriate review process if they conduct or fund “gain-of-function” research that could increase a potential pandemic pathogen’s ability to cause a pandemic. SARS-CoV-2, which causes COVID-19 disease, is an example of a pandemic pathogen.

The Department of Health and Human Services (HHS), the Department of Defense (DOD) and other federal departments fund and/or oversee some high-risk research, which may include “gain-of-function research.” Some in the scientific community argue that the riskier types of “gain-of-function” research are needed to better understand how viruses evolve in order to develop medical countermeasures for emerging pathogens. Others argue that the risks outweigh any potential benefits. The Government Accountability Office (GAO) reported in January 2023 that HHS oversight of high-risk research has serious gaps.¹

As “gain-of-function” research could entail biosafety, biosecurity, and public health risks, the risks and benefits of this research must be evaluated to determine which types of studies

¹ U.S. Government Accountability Office (GAO), Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens GAO-23-105455 (January 2023), [Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens | U.S. GAO](#)).

should go forward and under what conditions. Further, until we know the tangible outcomes of “gain-of-function” research, we cannot know if the benefits outweigh the risks.

We request that GAO follow up its January 2023 report on high-risk research and review the following:

- (1) What terms and definitions do federal agencies use to refer to “gain-of-function” research, what gaps, if any, exist among the different definitions, and what potential changes are under consideration for those definitions?
- (2) What are the benefits and risks of different types of “gain-of-function” research?
- (3) What tangible outcomes, such as the development of medical countermeasures, have resulted from the different types of federally funded “gain-of-function” research, including the enhancement of potential pandemic pathogens?
- (4) What are the risks associated with gain of function research, and to what extent can lab safety protocols mitigate these risks? Are there particular challenges with overseeing the mitigation of such risks for gain of function research conducted abroad?

If you have any questions, please contact Alan Slobodin or John Strom of the Majority Committee staff at (202) 225-3641. Thank you for your attention to this request.

Sincerely,



Cathy McMorris Rodgers
Chair
Energy and Commerce Committee



Brett Guthrie
Chair
Subcommittee on Health



H. Morgan Griffith
Chair
Subcommittee on Oversight and Investigations

cc: Frank Pallone Jr., Ranking Member, Energy and Commerce Committee
Anna Eshoo, Ranking Member, Subcommittee on Health
Kathy Castor, Ranking Member, Subcommittee on Oversight and Investigations