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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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WASHINGTON, DC 20515-6115
Majority (202) 225-3641
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March 27, 2023

The Honorable Robert M. Califf, M.D., MACC
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dr. Califf,

Pursuant to Rules X and XI of the U.S. House of Representatives, the Committee is investigating the adequacy of the Food and Drug Administration (FDA) oversight of FDA-funded research that may pose significant biosafety or biosecurity risks.

On January 19, 2022, we sent a request to FDA for a list of all proposed, approved, or ongoing research work that your agency is funding in the area of coronaviruses (especially SARS CoV-2) or viruses related to SARS, MERS, or SARS CoV-2. One of the informational requests in Question 3 of our January 19, 2022, letter asked: "Does the research involve virus manipulation, passaging of a virus, genetically modified animals, or making any mutations to a virus?" Although the FDA provided a spreadsheet listing some information about FDA-funded coronavirus research projects, the spreadsheet did not respond to Question 3.

After Republican Committee staff followed up, the FDA staff acknowledged in a January 31, 2023, email response that some FDA research studies did involve virus manipulation, passaging of a virus, genetically modified animals, or making any mutations to a virus:

> To your question about viral manipulation in the referenced studies – standard techniques in molecular biology, including manipulation of viral sequences and use of animal models, were used in some studies to better understand differences in disease pathology caused by the different SARS-CoV-2 strains (Wuhan and Omicron) that arose naturally. None of the research studies were undertaken to make the virus intentionally more virulent.

However, the FDA did not provide further specifics about these studies. To put these studies in context and to be able to assess the adequacy of FDA's oversight of potential risks in such experiments, we are requesting additional information. In light of the Committee's interest

in biosafety and adequate oversight of laboratory research studies that may pose significant biosafety or biosecurity risks, please respond to the following by April 10, 2023:

1. Please provide a list of all coronavirus research studies referenced in the January 31, 2023, email.

2. What is the biosafety level of the facility being used for these experiments? What biocontainment measures are being taken with these experiments?

3. Have FDA laboratories introduced any mutations or insertions of genes associated with pathogenesis or transmission into SARS CoV2? If so, what were the studies? What was the purpose for such studies? Can such insertions contribute to increasing pathogenesis or transmission? If so, please explain.

4. Have FDA laboratories introduced mutations or insertions of genes that encode for resistance to medical countermeasures, or increase pathogenesis or transmission in influenza virus or other respiratory viruses or human pathogens? If so, what were they? What were the reasons for such study?

5. Do all laboratory research studies undergo Institutional Biosafety Committee (IBC) or Dual Use Research of Concern (DURC) review at the FDA? If not, why not? How many studies have undergone IBC review since the inception of the process? How many studies have undergone DURC review since the inception of the process? For the studies referenced in the January 31, 2023, email, please identify the studies and specify whether the study (1) underwent IBC review, and/or (2) underwent DURC review.

6. Please provide a list of all studies that have undergone IBC review at the FDA since October 1, 2013.[1]

7. Please provide a list of all studies that have undergone DURC review at the FDA since October 1, 2013.

8. Who at the FDA oversees the FDA IBC and DURC process? When were the DURC review processes instituted? Please provide the policies and/or procedures related to the IBC and DURC processes.

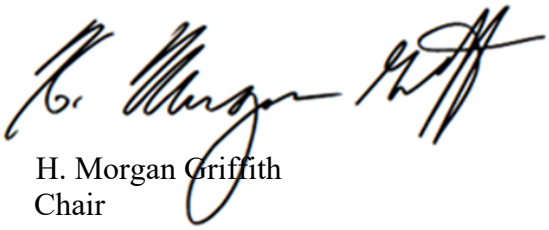
If you have any questions, please contact Alan Slobodin of the Majority Committee staff at (202) 225-3641. Thank you for your attention to this request.

[1] FDA's website indicates that the FDA IBC became operational as of September 30, 2013. https://www.accessdata.fda.gov/scripts/fdatrack/view/track_project.cfm?program=operations&id=Operations-ESEM-Institutional-Biosafety-Committee

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