

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

July 28, 2014

The Honorable Francis Collins, M.D.  
Director  
National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dear Dr. Collins:

Pursuant to Rules X and XI of the U.S. House of Representatives, the committee is investigating the handling of select agents by federal laboratories. In particular, the committee has questions about whether the National Institutes of Health (NIH) complied with federal select agent regulations with regard to dangerous pathogens discovered at a Food and Drug Administration (FDA) lab on the NIH campus, and NIH's oversight of FDA laboratories on its campus.

Recently, workers from the FDA discovered six vials of smallpox in a cold storage room in an FDA lab, located in Building 29A on the NIH campus. It appears these vials are about six decades old and were sitting in a cardboard box. Subsequent testing of the samples from two of the six vials showed the smallpox virus was still viable. Since smallpox was declared eradicated in the early 1980s, world health authorities believed that the only smallpox samples were safely stored at the Centers for Disease Control and Prevention (CDC) in Atlanta, and the Vector Institute at Novosibirsk, Russia. This was also reportedly the first time unaccounted-for smallpox samples were discovered since storage of smallpox samples was limited to CDC and the Vector Institute.

In addition to the smallpox vials, the FDA disclosed last week that the FDA workers also found 12 boxes and 327 vials holding an array of other pathogens, such as dengue, spotted fever, influenza, and Q fever. The discovery of these select agents in a cold storage room raises very serious questions about the NIH's ability to control, secure, and account for dangerous biological materials on the NIH campus and ensure compliance with federal select agent regulations.

To assist the committee's inquiry, please respond to the following questions and provide the following documents and information by August 15, 2014:

1. The smallpox samples and the other discovered vials of pathogen are dated well before 1972. The lab facility where these vials were discovered was reportedly transferred from the NIH to the FDA in 1972. Did the NIH transfer the ownership of the biological samples to the FDA? If yes, provide copies of documents related to the transfer of ownership of biological materials or samples in the labs. If not, were these vials still legally the property of the NIH? Provide the legal basis for the conclusion.
2. Has the NIH ever had a Memorandum of Understanding (MOU) with, or including, the FDA relating to the FDA laboratories on the NIH campus? If so, provide copies of any MOUs since the 1972 transfer or around the time of the 1972 transfer.
3. Does the NIH have a responsibility to conduct inspections of the FDA laboratories on the NIH campus to ensure the laboratory is meeting the specific level of biosafety designated to that facility and research to ensure safe handling of biological agents?
4. Have the FDA laboratories in Building 29A ever been inspected by the NIH? If so, please provide copies of any inspections conducted since 2002.
5. Have the FDA laboratories in Building 29A ever been inspected by the CDC and/or the Department of Agriculture's Animal and Plant Health Inspection Services (APHIS)? If so, please provide copies of any inspections conducted since 2002.
6. Have the FDA laboratories in Building 29A ever been inspected or audited by another federal agency or any other kind of external review group? If so, please provide copies of any inspections or audits conducted since 2002.
7. Provide a list of all NIH and FDA laboratories in Building 29A prior to June 1, 2014 with the associated area of research.
8. Does the NIH have a responsibility to account for all select agents being stored in any facility on the NIH campus?
9. Has the NIH conducted any inventory checks of select agents of any lab in Building 29A, including the FDA labs?
10. Was it ever the practice of NIH scientists to maintain collections of pathogens? If yes, when? Has the NIH ever found collections of pathogens in storage at NIH laboratories?
11. Provide a list of NIH officials responsible for overseeing the FDA labs on the NIH campus.
12. Did the NIH ever conduct an inventory check accounting for all select agents on the NIH campus after 9/11 and the anthrax mailings? If not, why not? If so, were the FDA labs in Building 29A included? If the FDA labs were not included, why not?

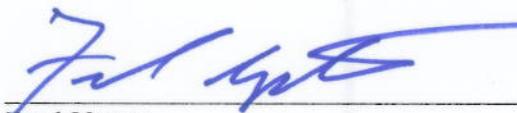
13. Please identify all instances of discovery of select agents in unregistered locations at NIH since 2002. Include the dates, the locations, identity of the select agents, and actions taken.

In addition, the committee is concerned about the NIH's handling of the National Science Advisory Board for Biosecurity (NSABB). In light of recent incident at federal laboratories involving the improper handling of select agents, the role of NSABB has assumed even greater importance and visibility. We note that this advisory panel has not been convened in nearly two years, that the Board's charter was changed in March so that the Board no longer has responsibility to review research that might be repurposed for bioterrorism or bioweapons, and that 11 of the 23 panel members were suddenly dismissed by NIH official and executive director of the NSABB, Mary Groesch, on a Sunday evening (July 13, 2014). These circumstances raise serious questions about the rationale and motives behind the dismissals of the panel members and the change in the Board's charter. To assist the committee's inquiry, please provide by August 15, 2014:

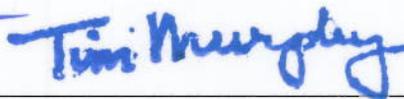
1. All emails since January 1, 2012 in the possession of Mary Groesch relating to the NSABB, including the dismissal of the 11 members of the Board, the change in the Board's charter, and why the Board has not met in nearly two years.

Your prompt assistance is appreciated. An attachment to this letter provides additional information on how to respond to the committee's request. If you have any questions, please contact Alan Slobodin of the committee staff at (202) 225-2927.

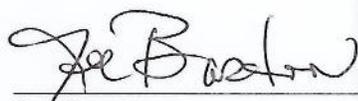
Sincerely,



Fred Upton  
Chairman



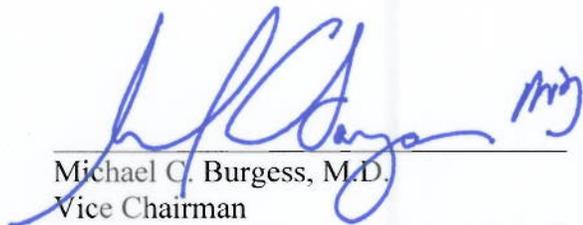
Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations



Joe Barton  
Chairman Emeritus



Marsha Blackburn  
Vice Chairman

A handwritten signature in blue ink, appearing to read "Michael C. Burgess" with a stylized flourish at the end.

Michael C. Burgess, M.D.  
Vice Chairman  
Subcommittee on Oversight and Investigations

Attachment

cc: The Honorable Henry A. Waxman, Ranking Member

The Honorable Diana DeGette, Ranking Member  
Subcommittee on Oversight and Investigations