

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

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
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May 19, 2015

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

Dear Mr. Dodaro:

In July 2014, the Committee on Energy and Commerce launched an investigation into the handling of select agents at federal laboratories, which included a request to the Government Accountability Office (GAO) regarding federal laboratory biosafety and biosecurity. As you know, the committee's investigation and its request to GAO for a concurrent review was prompted by several highly publicized reports of federal laboratories experiencing lapses in the management of dangerous pathogens. One of these incidents occurred on July 1, 2014, at the Bethesda, Maryland National Institutes of Health (NIH) campus, where the Food and Drug Administration (FDA) had been renting laboratory space. FDA personnel reported that they had unexpectedly found six vials of potentially live smallpox (*Variola*) virus stored in cardboard boxes, along with 321 vials of other pathogens dating back to the 1940s and 1950s.

Through its investigation, the committee sent information and document request letters to the Centers for Disease Control and Prevention (CDC), the NIH, and the FDA. The agencies provided responsive information that we believe merits review by the GAO, and we therefore request an expansion of your ongoing inquiry that takes into account this new information and other evidence.

We are forwarding for your consideration information, documents, and photographs obtained from the committee's investigation that lead us to believe the safety and security lapses involved with the lack of control over smallpox vials stored in cardboard boxes were more severe than previously disclosed.

Below is a summary detailing the background about the smallpox vials matter, the response from CDC, the response from the NIH, the response from FDA, and the key documents and photographs. The documents and photographs are included as attachments to this letter.

### Background on the Smallpox Vials

On July 1, 2014, as part of an effort to clean out and organize material in preparation for the move of FDA's laboratories from the NIH campus to the FDA's White Oak campus, FDA personnel working in Building 29A discovered cardboard boxes in a common cold storage room that FDA stated "had previously been overlooked." These boxes contained a total of 327 vials of laboratory samples, including six vials of *Variola*, the agent of smallpox. Immediately, the FDA personnel who found the material reported the finding to the FDA Center for Biologics Evaluation and Research Associate Director for Research, who immediately notified the Responsible Official (RO) for the NIH Select Agent Program. The boxes were transferred to the NIH RO, who secured the materials until CDC and the Federal Bureau of Investigation (FBI) were able to remove the contents. Subsequent testing of the samples by the CDC showed that the smallpox virus was still viable in two of the six vials.

On July 28, 2014, the committee sent requests to the CDC, NIH, and FDA for documents and information relating to the handling of select agents by federal laboratories. These requests included particular questions about the smallpox vials and other dangerous pathogens discussed above. Each of the agencies provided responses and new details related to the smallpox matter.

### CDC Response Provided August 22, 2014

The CDC reported to the committee that prior to the discovery of the unsecured pathogens on July 1, 2014, neither the NIH nor the FDA had notified the CDC about the smallpox vials as required by federal law and regulations.

### *Notification Requirements*

On July 12, 2002, CDC published a notice stating that facilities should complete a "notification of possession" form by September 10, 2002, based on an inventory of its facility and consulting with others (e.g., principal investigators), as necessary, to obtain information required for the form. The "notification of possession" form was to be submitted to the Department of Health and Human Services (HHS) under the Public Health Security and Bioterrorism Act. In addition, the HHS federal select agent regulations (42 CFR Part 73) became effective on February 7, 2003, and required the registration of the possession, use, and transfer of select agents and toxins, including *Variola major* and *Variola minor* viruses.

### *FDA and NIH Failure to Comply*

CDC reported to the committee that FDA and NIH submitted the required "notification of possession" of select agent forms to HHS in 2002, but the NIH's and FDA's notification forms did not indicate that they were in possession of any smallpox virus. It is notable that *Variola major* (smallpox virus) was explicitly listed on the form as a select agent for which notification

was required, but neither NIH nor FDA identified their possession of it. The registration application submitted to the Federal Select Agent Program by NIH, as required under the select agent regulations, likewise did not acknowledge possession of *Variola* viruses.

Pursuant to 42 CFR §73.9 (a)(6), the Responsible Official required to register select agents must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with these requirements. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected. In addition, under 42 CFR §73.9 (c)(1), the Responsible Official must immediately report the identification and final disposition of certain enumerated select agents or toxins, including the smallpox virus.

As to CDC's role, the CDC's Division of Select Agents and Toxins (DSAT) regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public health and safety.

CDC clarified its response letter to the committee that the NIH, not the FDA, was responsible for compliance with the federal select agent regulations. In emails sent from CDC staff to majority committee staff on August 25, 2014, the CDC explained that although FDA was using the lab space at NIH, NIH's Responsible Official – not FDA – was responsible for the space in question. One email specifically indicated that the CDC's DSAT said that NIH's RO was responsible because the building where the vials were located was an NIH building. Thus, CDC suggested the *Variola* should have been on the NIH registration application to the Federal Select Agent Program in 2003. The building was registered with the Federal Select Agent Program, but not the space where the vials were found. CDC also reported that the NIH's Responsible Official in 2003, the Director of the NIH Division of Occupational Health and Safety, has served continuously and is still the current NIH RO.

Although the CDC's DSAT and the Department of Agriculture's Animal and Plant Health Inspection Service conducted inspections of FDA laboratories on the NIH campus, documents from NIH showed the inspections did not cover the laboratories associated with the cold storage room in Building 29A, 3<sup>rd</sup> floor, C corridor because the laboratories were not using select agents.

#### NIH Response Provided September 17, 2014

The NIH reported that the FDA laboratories in Building 29A that conducted research involving infectious disease agents and other materials were registered with the NIH Institutional Biosafety Committee (IBC) to the Building 29 complex laboratories. Registration of these laboratories with the NIH IBC led to annual NIH safety surveys (inspections) of the areas identified as conducting these types of research by the Principal Investigator (PI). The NIH only conducted safety surveys of laboratories registered by PIs. The cold room in question, where the smallpox vials were found, was not registered with the NIH.

The NIH reported that it had no records of transfer of smallpox and other pathogen samples when the office that had custody over the vials was transferred from NIH to the FDA in 1972.

#### FDA Response Provided September 18, 2014

The FDA acknowledged responsibility for complying with applicable federal requirements governing the possession, use, and transfer of all select agents being stored in FDA lab facilities on the NIH campus. FDA further stated that “[t]hese requirements were established long after the recently discovered vials labeled as containing smallpox virus were prepared and placed in storage in Building 29A. Because FDA’s internal procedures did not clearly assign responsibility for inventorying the contents of common cold storage areas in Building 29A, the vials were not discovered until July 1, 2014, when a thorough search was conducted in preparation for the relocation of FDA’s Building 29A laboratories from Bethesda to FDA’s main campus in Silver Spring, Maryland.”

Committee staff later learned more about the specific location of the cold storage room, which was identified as Room 3C16 in Building 29A on the NIH campus.<sup>1</sup> According to FDA, researchers from the FDA’s Laboratory of DNA Viruses and Laboratory of Retroviral Research were using the cold storage room. Any of the labs on the 3<sup>rd</sup> floor C corridor would have been permitted to access and store materials in the cold storage room 3C16. Although, at the time, FDA did not have a centralized standard operating procedure describing a more comprehensive inventory of cold storage rooms, each PI who used the cold storage room was responsible for taking inventory of his or her own specimens.

#### Documents and Photographs

Documents produced by NIH to the committee appear to show that cold storage room 3C16 was inspected by NIH safety inspectors as part of NIH inspections of nearby FDA labs. The inspection reports dated back to 2006 show that the NIH Division of Occupational Health and Safety used a General Laboratory Safety Survey last revised on March 15, 2006. The survey included a checklist with a separate category, “Cold Room,” that included the following checklist entry: “No cardboard storage” with “Yes,” “No,” and “N/A” as check-off options. In a November 21, 2014 bipartisan committee staff briefing, the NIH Responsible Official stated that NIH inspectors would look at a cold storage room depending on the protocol.

The “no cardboard storage” policy in cold storage rooms was consistent with known biosafety practices at NIH and academia. For example, the National Cancer Institute-Frederick Fact Sheet, “Biosafety Technical Bulletin: Cold Rooms and Mold,” dated November 2011 stated that “[s]ince cold rooms are typically shared spaces, an established protocol should be adopted by all users to reduce the chance of mold growth in the space. At a minimum, . . . DO NOT store cardboard, . . . in cold rooms.” (Capital letters in original).

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<sup>1</sup> Majority and minority committee staff made an on-site visit at NIH on September 19, 2014 to the third floor C corridor in Building 29A to confirm the room number for the cold room, view the cold room (size and condition), and understand the layout of the corridor and neighboring labs.

The NIH conducted two different safety inspections on October 11, 2011, both of which indicated there was cardboard storage in the cold room, 3C16. The first inspection completed on October 21, 2011, was for the FDA laboratory located in Building 29A, Room 3C22 (a lab on the 3<sup>rd</sup> floor C corridor permitted access to the cold storage room 3C16). The NIH inspector wrote the following comment regarding the cold room: “Please remove all cardboard from the cold room.”<sup>2</sup> This statement, taken at face value, was not limited to just cardboard associated with the lab, but all cardboard in the cold room. Given that interpretation, it is unknown why the cardboard boxes containing the smallpox would not have been discovered at that time as part of the removal process. If the statement was intended to apply only to cardboard belonging to the lab, it still begs the question of which cardboard the inspector was referring to, and how – without looking at, or inside, the boxes – the inspector differentiated that cardboard from the cardboard boxes that were not labeled and not clearly marked (see attached photos) which contained smallpox and other select agent materials. More significantly, assuming a narrow interpretation, it is unclear why the NIH inspector would have ignored any remaining cardboard in the cold storage room because of the broad safety concerns about mold.

The second inspection, which was conducted by a different NIH inspector, also found cardboard in the cold storage room. This inspection was conducted for the laboratory located in Building 29A, Room 3C12. The NIH inspector checked “No” on “No cardboard storage” in the cold room, meaning there was cardboard there where there should not have been. The PI was the same for both of these labs.

According to an NIH inspection completed on October 24, 2012 for the FDA laboratory located in Building 29A, Room 3C22, the NIH inspector noted explicitly that the Cold Room was located at “N29A/3C16” and for the “No cardboard storage” item checked “Yes.” The Safety Survey completed September 26, 2013, for the same FDA lab also checked “Yes” for “No cardboard storage.” Since the 2012 and 2013 inspections indicated no cardboard in the cold storage room, it must be asked whether the inspectors missed the presumably remaining boxes of smallpox altogether, whether the inspectors saw but ignored the cardboard boxes because they were not connected to the lab, or whether the cardboard boxes containing smallpox were temporarily moved. It appears that the 2012 and 2013 inspections for the Room 3C12 lab did not examine the cold storage room because the inspection report indicated “N/A” for cold room storage, which probably meant that the research protocol for the lab at those times did not involve materials stored in the cold room.

CDC provided three photographs of the boxes found at the NIH by CDC personnel. (See attachments). The first is of the boxes that were found at NIH, in a larger box in which they were placed after they were found. The second picture is of the inside of one of the boxes. The third photo is of the inside of a box that contained two vials of *Variola* (label can be seen on top vial).

During the November 21, 2014 bipartisan committee staff briefing, the NIH RO confirmed that the vials of smallpox and other pathogens were contained in cardboard boxes and brought over to her office in a larger Xerox cardboard box. In addition, the RO acknowledged

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<sup>2</sup> A subsequent 2012 NIH inspection confirmed that the cold room associated with the 3C22 lab was the cold storage room 3C16. Previous NIH inspections of this lab indicated that the “cold room storage” category was not applicable to this lab.

that the NIH's knowledge gap about the presence of the smallpox vials and other pathogens was not in compliance with federal select agent regulations. The RO was also shown the NIH inspection surveys related to the cold room and the CDC photos of the cardboard boxes containing the smallpox vials. She acknowledged the questions raised by this evidence.

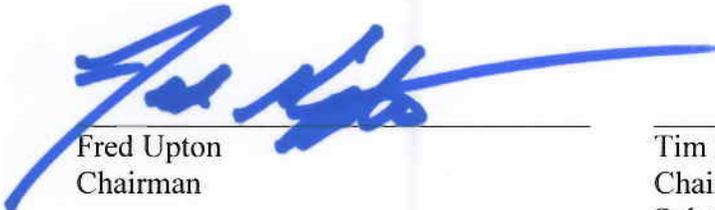
Questions Raised for Further Review

We believe the information and evidence developed from the investigation provides a basis to believe that there were additional lapses and concerns involved with the retention of the smallpox samples than just the failure to account for undiscovered, and presumably abandoned, materials. We request that GAO examine the following questions:

1. Did the NIH inspectors see and ignore (or simply miss) the cardboard boxes containing smallpox and other select agents during the 2011 inspections of the cold room?
2. Given the findings of the 2012 and 2013 inspections, did the FDA scientists know about, and act upon, the NIH instruction in the NIH inspection survey to remove all cardboard from the cold storage room? If so, did the FDA scientists remove some cardboard from the cold storage room without noticing and removing the cardboard boxes containing the smallpox, even though the NIH inspector directed that all cardboard be removed from the cold storage room?
3. Why did the NIH inspections in 2012 and 2013, which stated there was no cardboard in the cold storage room where the smallpox vials were discovered, not discover the cardboard boxes containing smallpox and other pathogens?
4. Is it likely that cardboard boxes stored for decades in a cold room would have exhibited evidence of mold? What would be the likely condition of cardboard boxes stored in a cold room for decades? Is it likely that cardboard boxes stored for such periods of time would look like the boxes shown in the CDC photos?

Your assistance on these questions is appreciated. If you have any questions regarding this request, please contact Alan Slobodin with the committee staff at (202) 225-2927.

Sincerely,



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Fred Upton  
Chairman



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Tim Murphy  
Chairman  
Subcommittee on Oversight and Investigations

Letter to The Honorable Gene L. Dodaro  
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Attachments

cc: The Honorable Frank Pallone, Jr., Ranking Member  
The Honorable Diana DeGette, Ranking Member  
Subcommittee on Oversight and Investigations