U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY AND COMMERCE

April 18, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse."

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, April 20, 2016, at 10:15 a.m. in 2322 Rayburn House Office Building, entitled "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse." The Subcommittee will hear testimony on the Government Accountability Office's (GAO) recent report on the need for comprehensive policies and stronger oversight at high-containment laboratories,[1] as well as the steps taken by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Department of Defense (DOD) to strengthen their policies. In recent years, the Subcommittee has examined numerous safety lapses at high-containment laboratories.

I. WITNESSES

- John Neumann, Director, Natural Resources and Environment, Government Accountability Office;
- Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, National Institutes of Health;
- Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety, Centers for Disease Control and Prevention;
- Segaran Pillai, Ph.D., Director, Office of Laboratory Science and Safety, Office of Commissioner, Office of Chief Scientist, U.S. Food and Drug Administration; and
- MG Brian C. Lein, Commanding General, U.S. Army Medical Research and Material Command and Fort Detrick and Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, Department of the Army, U.S. Department of Defense.

II. BACKGROUND

The purpose of this hearing is to examine the conclusions of a recent GAO report on the need for more comprehensive policies for and stronger oversight of high-containment

[1] Laboratories that conduct research on hazardous biological agents are assigned one of four biosafety levels (BSL). Labs at BSL-3 and BSL-4, the highest risk of the four levels, are known as "high-containment laboratories."

laboratories.[2] The Committee requested this report in July 2014 after several incidents involving the mishandling of hazardous biological agents raised questions about Federal policies for managing hazardous biological agents in high-containment laboratories. In this bipartisan request, the Committee asked GAO to analyze the policies and procedures in place at Federal agencies to ensure the proper management of pathogens and the steps taken to improve their inventory management of pathogens. The Committee also requested GAO assess how the agencies evaluate the effectiveness of their policies and procedures relating to pathogen management.[3]

The Subcommittee has previously held multiple hearings on security lapses at high-containment laboratories. In July 2014, the Subcommittee on Oversight and Investigations held a hearing examining an incident that occurred in June 2014 at the CDC laboratory where as many as 84 CDC employees were exposed to live anthrax, because established safety practices were not followed.[4] The incident led CDC Director Thomas Frieden to shut down the Bioterror Rapid Response and Advance Technology (BRRAT) laboratory until certain issues were resolved and issued a moratorium on transfers of biological material leaving any CDC high-containment lab until adequate measures were in place.[5] The hearing also examined other incidents, including a spring 2014 cross-contamination involving H5N1 influenza virus at the CDC influenza laboratory and the discovery of decades-old vials of smallpox in a FDA lab on the NIH campus that were only discovered while employees were preparing for the lab's move to the FDA's main campus in White Oak, Maryland.

In July 2015, the Subcommittee held a hearing on the Department of Defense's acknowledgement that the Dugway Proving Ground (Dugway), an Army facility in Utah, had inadvertently shipped live anthrax to a commercial laboratory in Maryland as well as to other contract labs.[6] These shipments revealed that Dugway's process for inactivating anthrax with radiation was unreliable, and that sterility testing used to validate and ensure that the inactivation process was working had failed to detect the live anthrax spores.

a. Federal Select Agent Program

Following the Oklahoma City bombing in 1995, the Antiterrorism and Effective Death Penalty Act of 1996 established the Federal Select Agent Program (FSAP). This law required

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[2] GAO, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," GAO-16-305 (March 2016).
[3] Letter from Hon. Fred Upton, Chairman, Hon. Tim Murphy, Hon. Joseph Pitts, Hon. Henry Waxman, Ranking Member, Hon. Diana DeGette, and Hon. Frank Pallone, Jr., H. Comm. on Energy & Commerce, to Hon. Gene Dodaro, Comptroller Gen., U.S. Gov't Accountability Office (July 31, 2014).
[4] *Review of CDC Anthrax Lab Incident: Hearing before the Subcomm. on Oversight and Investigations, H. Comm. on Energy & Commerce*, 113th Cong. (2014).
[5] On June 8, 2015, the BRRAT Laboratory received approval from CDC's internal Laboratory Safety Improvement Workgroup and CDC leadership to reopen. The lab is currently conducting laboratory training and validation of new laboratory procedures in preparation of resuming fall operations.
[6] *Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax: Hearing before the Subcomm. on Oversight & Investigations, H. Comm. on Energy & Commerce*, 114th Cong. (2015).

the Department of Health and Human Services (HHS) to identify a list of organisms and toxins (known as select agents) that could potentially be used for bioterrorist attacks and to regulate their transfer, though not their possession. The FSAP regulates 65 select agents and toxins. The select agent list is reviewed at least every two years to determine if agents need to be added to or deleted from the list.[7] Examples of some select agents are anthrax, tularemia, smallpox, and plague.

The September 11, 2001 terrorist attacks and the 2001 anthrax mailings increased the Federal government's interest in the threat of bioterrorism. The USA Patriot Act made it a criminal offense for certain restricted persons, including some foreign aliens, persons with criminal records, and those with mental defects, to transport or receive select agents.[8] The USA Patriot Act also made it a criminal offense for any individual knowingly to possess any biological agent, toxin, or delivery system in type or quantity not justified by a peaceful purpose.[9]

Congress later enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which (1) expanded the select agent program to include the regulation of the transfer and the use and possession of select agents and (2) increased safeguards and security requirements.[10] The 2002 Act also establishes civil money penalties for persons violating the regulations and additional criminal penalties for knowingly possessing a select agent or toxin without registering it or knowingly transferring a select agent or toxin to an unregistered person.[11]

b. High Containment Laboratories

High containment laboratories, which conduct research on bioweapon agents, have proliferated since the 2001 anthrax attacks in which spores were mailed to news media offices and two U.S. senators, killing five people and infected 17 others.[12] In February 2013, GAO reported to the bipartisan leadership of the Committee that there was an increased risk of laboratory accidents given weaknesses in lab oversight and the lack of national safety standards.[13] GAO had recommended in 2009[14] that the National Security Advisor make a single Federal agency responsible for assessing lab standards, but in its 2013 report, GAO noted that

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[7] Federal Select Agent Program, About Us, http://www.selectagents.gov/about.html.
[8] USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).
[9] *Id*.
[10] 42 U.S.C. § 262a.
[11] *Id.*
[12] In 2009, there were over 240 entities with at least 1,362 BSL-3 laboratories in the United States registered under the Federal select agent program. This expansion has continued. As already noted in the memorandum, CDC reported to the Committee that there are 324 entities registered.
[13] GAO, "High-Containment Laboratories: Assessment of the Nation's Need Is Missing," GAO-13-466R (February 25, 2013) http://gao.gov/assets/660/652308.pdf.
[14] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.

the National Security Staff and the Office of Science and Technology Policy (OSTP) rejected the recommendation as "unnecessarily broad and cumbersome."[15]

CDC and NIH have established four main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.[16] Each biosafety level is associated with specific physical and procedural protections. In general, the more dangerous the pathogen is to public health, the higher its recommended biosafety level. Procedures deemed unlikely to produce disease in healthy humans should be conducted at BSL-1. Those that may cause disease in healthy humans, but for which immunization or antibiotic treatment is available, should be conducted at BSL-2. Procedures that may cause serious or potentially lethal diseases as a result of pathogen inhalation should be conducted at BSL-3. Procedures that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease should be conducted at BSL-4. Generally, the term "high-containment laboratory" refers to BSL-3 and BSL-4 laboratories.

The GAO has conducted comprehensive work on the oversight of high-containment laboratories. In 2009, GAO noted that the number of high-containment laboratories was increasing in different sectors throughout the United States.[17] The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.[18] And since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.[19] GAO has continued to recommend a government-wide strategy for the requirements of high-containment laboratories and the need for national standards for designing, constructing, commissioning, and maintaining such laboratories.[20]

c. GAO Report on High-Containment Laboratories

In the wake of the recent safety lapses, DOD, HHS, and other agencies undertook multiple reviews to strengthen the policies surrounding and oversight of high-containment laboratories. Last year, the Committee requested that GAO review biosafety and biosecurity policies for the eight departments and fifteen component agencies that own and operate the Federal government's high-containment laboratories. GAO also examined any oversight policies at each department and component agency. GAO found a number of deficiencies in the policies for high-containment laboratories.

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[15] GAO, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program," GAO-13-154 (January 2013) http://gao.gov/assets/660/651730.pdf.
[16] Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, Biosafety in Biomedical and Microbiological Laboratories (BMBL), 5th edition, 2009. http://www.cdc.gov/biosafety/publications/bmbl5/
[17] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.
[18] *Id.*
[19] *Id.*
[20] *Id.*

GAO found that most of the departments and agencies did not have comprehensive policies for managing hazardous biological agents.[21] That is, the policies lacked at least one of six elements identified by GAO as critical to safely manage high-containment laboratories:

- Establishing appropriate lines of reporting for incidents involving hazardous biological agents;
- Defining roles and responsibilities of department, agency, or laboratory personnel;
- Establishing training for personnel handling hazardous biological agents;
- Ongoing monitoring during normal laboratory operations; and
- Requiring adherence to, or referencing, the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) guidance.[22]

GAO determined DOD's policies not to be comprehensive because some elements only applied to DOD's select agent-registered laboratories and not all high-containment laboratories. DOD's component agencies, including the Army, had policies that were missing one or more elements or applied only to select agent-registered laboratories. GAO specifically noted that DOD and its component agencies only had inventory control policies for select agent-registered laboratories, and that requirements for training and inspections in the Air Force's and Navy's policies only applied to select agent-registered laboratories.[23] GAO further found that the Army and Navy did not routinely report the results of internal inspections to either senior agency or senior department officials.[24] The Air Force reported to GAO that they routinely report the results of inspections to senior agency officials, but not senior department officials.[25] DOD officials told GAO that they did not require high-containment laboratories not registered with the select agent program to report the results of any agency inspections to DOD, and had no plans to implement such a requirement.[26]

GAO found that HHS did not have comprehensive policies because HHS did not have department-level policies for managing hazardous biological agents, and neither the CDC nor the FDA had all six elements in their agency-level policies. Specifically, CDC's policies for training and inspection only applied to select agent-registered laboratories, and CDC and FDA policies did not contain requirements for incident reporting to senior department officials. GAO found that NIH's policies for laboratory management to be comprehensive.[27] GAO further found that CDC, FDA, and NIH did not routinely report the results of internal inspections to either senior

[21] GAO, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," GAO-16-305 (March 2016) at 12.
[22] *Id*.
[23] *Id*. at 15.
[24] *Id*. at 31.
[25] *Id*.
[26] *Id*.
[27] *Id*. at 16.

agency or senior department officials.[28] CDC and NIH did inform GAO that the results of select agent inspections are reported to senior agency officials, but not senior department officials.[29] CDC reported that, beginning in January 2016, following the creation of a laboratory safety oversight office, laboratories would begin reporting the results of inspections to senior agency officials.[30] FDA told GAO that it is contemplating whether to create an ongoing oversight role for the Laboratory Safety Practices and Policies Workgroup, which was established to conduct the laboratory sweeps for the White House's August 2014 safety stand-down.[31]

GAO detailed recent policy changes taken by the relevant departments to strengthen inventory control management controls. DOD is working with its component agency laboratories to establish a database to centralize the select agent inventory of all DOD laboratories into one system.[32] At HHS, each relevant component agency strengthened its inventory management controls in the last year in the wake of numerous select agent lapses:

- CDC developed a new procedure for scientists separating from the agency to account for biological research specimens in February 2015. CDC also launched a centralized electronic system to manage hazardous biological agents in all infectious disease laboratories, and expects to expand the system to all labs within two years.[33]

- FDA introduced electronic inventory control and management system to track the agency's biological, radiological, and chemical materials in October 2015. FDA plans to fully implement this system in the first quarter of fiscal year 2017.[34]

- NIH revised its safety audit inspection checklists to include documentation of inventory spot-checks during annual inventory audits in March 2015. NIH also established a database to record all hazardous biological agents in long-term storage in September 2014.[35]

GAO also analyzed the progress made by HHS and DOD to implement recommendations from laboratory safety reviews conducted after the 2014 and 2015 safety lapses. CDC reported implementing 91 recommendations from 209 total recommendations across all internal and external reviews. FDA reported implementing six of thirty recommendations from its external laboratory safety review. NIH reported implementing nine of ten recommendations from its external laboratory safety review.[36] DOD reported implementing one recommendation from its July 2015 report on the anthrax safety lapse, and was taking steps to implement the remaining 21 recommendations. DOD also convened a committee to review the May 2015 anthrax incident,

[28] *Id*. at 31.
[29] *Id*. at 32.
[30] *Id*. at 31.
[31] *Id*.
[32] *Id*. at 28.
[33] *Id*.
[34] *Id*.
[35] *Id*.
[36] *Id*. at 36.

which issued a report in July 2015 with 19 recommendations. Further, CDC, DOD, and the Army lack some time frames for implementing each of the recommendations. This is inconsistent with Federal internal control standards that departments and agencies should establish policies and procedures for ensuring that the findings of audits and other reviews are promptly resolved.[37]

GAO made a number of recommendations to each department or agency that has high-containment laboratories. With respect to the Department of Defense, GAO recommended, in part, that the Secretary:

- Revise existing department policies to contain specific requirements for inventory control for all high-containment laboratories, not just for select agent-registered laboratories;

- Routinely analyze agencies' inspection results and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues, and share the lessons learned with relevant personnel;

- Require routine reporting of the results of inspections and laboratory incidents at non-select agent registered laboratories to senior department officials; and

- Develop timeframes for the remaining recommendations from the July 2015 review.

With respect to HHS, GAO recommended that the Secretary, in part:

- Develop department policies for managing high-containment laboratories that contain requirements for reporting laboratory incidents to senior department officials;

- Develop department policies with specific requirements for training and inspections for all high-containment laboratories, not just the select agent registered laboratories;

- Direct the Director of NIH to review and update the agency's policies for high-containment laboratories; and

- Require routine reporting of the results of inspections to senior department and agency officials.

III. ISSUES

The following issues may be examined at the hearing:

- GAO's findings that HHS and DOD must create more comprehensive policies and enhance oversight to improve safety at high-containment laboratories;

[37] *Id.* at 40-41.

- Steps taken by DOD and HHS component agencies in the wake of recent safety lapses to enhance laboratory safety at high-containment laboratories; and

- How to improve oversight of select agents, and the Federal Select Agent Program.

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, Jen Barblan, or Ryan Coble at (202) 225-2927.