



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

September 21, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Bioresearch Labs and Inactivation of Dangerous Pathogens”

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, September 23, 2016, at 9:00 a.m. in 2322 Rayburn House Office Building, entitled “Bioresearch Labs and Inactivation of Dangerous Pathogens.” The Subcommittee will hear testimony on the Government Accountability Office’s (GAO) recent report on the need for improving the Federal Select Agent Program’s oversight of incomplete inactivation,¹ as well as the steps taken by the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), the National Institutes of Health (NIH), and the Department of Defense (DOD) to strengthen their policies. In recent years, the Subcommittee has examined numerous safety lapses at bioresearch high-containment labs.

I. WITNESSES

- Timothy M. Persons, Ph.D., Chief Scientist, GAO;
- Daniel Sosin, M.D., Deputy Director and Chief Medical Officer for the Office of Public Health Preparedness and Response, CDC;
- Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety, CDC;
- Mark Davidson, DVM, Associate Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, USDA;
- Jeff Potts, MPH, CBSP, ARO, BioRisk Manager, NIH; and
- MG Barbara R. Holcomb, Commanding General, U.S. Army Medical Research and Materiel Command and Fort Detrick, MD; Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology; and Chief, U.S. Army Nurse Corps, Department of the Army.

¹ The Select Agent Program is operated by the Departments of Health and Human Services and Agriculture to oversee certain dangerous pathogens, known as select agents. Inactivation can be defined as a process used in laboratories to render pathogens unable to cause disease, but retaining characteristics of interest for future use, such as for vaccine development.

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, the inactivation of dangerous pathogens in high-containment laboratories.² Inactivation is the process to render highly dangerous pathogens incapable of causing disease, but still useful for research purposes. Several incidents involving the shipment of live pathogens, thought to be inactivated, have recently occurred, potentially exposing people to dangerous pathogens that cause infectious diseases, such as the bacterium that causes anthrax. In a May 7, 2015 bipartisan request (and coincidentally, about two weeks before the discovery of inactivation problems at a DOD lab), the Committee asked GAO to evaluate issues related to inactivation of pathogens in high-containment labs.³

a. 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 infecting seventeen others.⁴ 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.⁵ GAO had recommended in 2009 that the National Security Advisor make a single Federal agency responsible for assessing lab standards,⁶ but in its 2013 report, GAO noted that the National Security Staff and the Office of Science and Technology Policy (OSTP) rejected the recommendation as “unnecessarily broad and cumbersome.”⁷

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.⁸ 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

² GAO, “High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk,” GAO-16-642 (August 2016).

³ Letter from The Honorable Fred Upton, Chairman of the House Energy and Commerce Committee the Honorable Frank Pallone, Jr., the Honorable Tim Murphy, and the Honorable Diana DeGette to the Honorable Gene L. Dodaro, Comptroller General, GAO, (May 7, 2015) available at: <https://energycommerce.house.gov/hearings-and-votes/hearings/review-cdc-anthrax-lab-incident>

⁴ 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.

⁵ 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>.

⁶ GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

⁷ 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>.

⁸ 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/bmb15/>

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 labs was increasing in different sectors throughout the United States.⁹ The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.¹⁰ Since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.¹¹ GAO has continued to recommend a government-wide strategy for the requirements of high-containment labs and the need for national standards for designing, constructing, commissioning, and maintaining such laboratories.¹²

b. Subcommittee’s previous oversight

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 eighty-four CDC employees were exposed to live anthrax because established safety practices were not followed.¹³ 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.¹⁴

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.¹⁵ 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

⁹ GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Review of CDC Anthrax Lab Incident: Hearing before the Subcommittee on Oversight and Investigations, House Comm. on Energy & Commerce*, 113th Cong. (2014).

¹⁴ 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.

¹⁵ *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).

process was working had failed to detect the live anthrax spores. This past April, the Subcommittee held a hearing on the need for comprehensive and stronger oversight at high-containment laboratories, specifically at NIH, CDC, and DOD.

c. 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 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 or deleted from the list.¹⁶ 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.¹⁷ This 2001 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.¹⁸

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.¹⁹ The 2002 Act also established 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 such items to an unregistered person.²⁰

d. GAO Report on Inactivation of Dangerous Pathogens

The recent safety lapses at DOD and CDC involved the shipment of live pathogens that were not completely inactivated, and therefore, potentially exposed people to dangerous pathogens that cause infectious diseases, including the bacterium that causes anthrax. As previously noted, the Committee requested last year that GAO evaluate issues related to inactivation of pathogens in high-containment laboratories and examine the extent to which incomplete inactivation incidents occurred. The GAO also reviewed the extent to which the Federal Select Agent Program referred violations and enforced regulations related to incidents involving incomplete inactivation.

¹⁶ Federal Select Agent Program, About Us, <http://www.selectagents.gov/about.html>.

¹⁷ USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).

¹⁸ *Id.*

¹⁹ 42 U.S.C. § 262a.

²⁰ *Id.*

GAO found that the total number of incidents involving incomplete inactivation that occurred from 2003 through 2015 is unknown.²¹ GAO specifically noted that, according to the Select Agent Program, ten incidents occurred from 2003 through 2015. However, GAO identified an additional eleven incidents that the program did not initially identify.²²

One key reason is that the Select Agent Program—operated by the Departments of HHS and USDA—does not require laboratories to identify such incidents on reporting forms. Because the program cannot easily identify incidents involving incomplete inactivation, it does not know the frequency or reason they occur, making it difficult to develop guidance to help mitigate future incidents.²³

Gaps in scientific knowledge and limited guidance were found by GAO to affect the implementation of inactivation in high-containment labs. GAO noted that there is limited federal guidance for researchers on the development and validation of inactivation protocols. Validation helps ensure protocols are scientifically sound and produce consistent results. Due to limited guidance, laboratories varied in their interpretation of validated methods of inactivation, resulting in researchers applying differing levels of rigor.²⁴

GAO also found that the Select Agent Program did not consistently refer incidents involving incomplete inactivation for further investigation and enforcement for violations of select agent regulations. Specifically, it found that the program referred incidents involving incomplete inactivation at various laboratories, but did not refer two incidents in 2014 that occurred at HHS.²⁵ In responding to a draft of this report, the program provided a draft, joint CDC-APHIS (Animal and Plant Health Inspection Service) document that provides some guidance on when to refer violations and options for enforcement actions; however, program officials did not provide GAO with a time frame or plan for finalizing and implementing this draft document.

Furthermore, a previous finding by GAO, that existing federal oversight of high-containment laboratories is fragmented and self-policing, was highlighted when it noted that the program does not have a consistent, written set of criteria for handling incidents. Without such criteria, the program risks inconsistent enforcement of select agent regulations.²⁶

GAO made six recommendations to HHS and to USDA to mitigate the risk to human and animal health due to incidents involving incomplete inactivation of dangerous pathogens used in high-containment labs, and to improve the Select Agent Program's oversight of inactivation. With respect to both HHS and USDA, GAO recommended that the Secretary of Health and

²¹ GAO, "High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk," GAO-16-642 (August 2016).

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

Human Services direct CDC and NIH, and that the Secretary of Agriculture direct APHIS, in their respective parts, to:

- Develop clear definitions of inactivation for use within their respective guidance documents that are consistent across the Select Agent Program, NIH's oversight of recombinant pathogens, and the *Biosafety in Microbiological and Biomedical Laboratories* manual;²⁷
- Revise reporting forms within their respective areas of oversight to help identify when incidents involving incomplete inactivation occur and analyze the information reported to help identify the causes of incomplete inactivation to mitigate the risk of future incidents;
- Coordinate research efforts and take actions to help close gaps in the science of inactivation and viability testing across high containment laboratories;
- Create comprehensive and consistent guidance for the development, validation, and implementation of inactivation protocols—to include the application of safeguards—across the Select Agent Program, NIH's oversight of recombinant pathogens, and the *Biosafety in Microbiological and Biomedical Laboratories* manual;
- Develop and implement consistent criteria and documentation requirements for referring violations to investigative entities and enforcing regulations related to incidents involving incomplete inactivation.

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

- Direct the Directors of CDC and NIH, when updating the *Biosafety in Microbiological and Biomedical Laboratories* manual, to include guidance on documenting the shipment of inactivated material.

III. ISSUES

The following issues may be examined at the hearing:

- How serious are the science gaps in the inactivation of dangerous pathogens? Is there sufficient scientific information to support the complete inactivation of all dangerous pathogens, especially the historical challenge of completely inactivating anthrax?
- How should gaps in scientific understanding of inactivation be addressed?

²⁷ *Id.*

- What steps are being taken by key Federal agencies to know when incomplete inactivation occurs and how to properly identify, analyze, and respond to such incidents?
- How will the Federal Select Agent Program ensure that its oversight of the inactivation process, as well as over other program requirements, is applied consistently, particularly between federal and nonfederal laboratories?

IV. STAFF CONTACTS

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