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ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

April 18, 2016

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

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

On **Wednesday, April 20, 2016, at 10:15 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing titled "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse." The hearing will focus on a recent U.S. Government Accountability Office (GAO) report titled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety." The report builds on the Committee's past work on oversight of high-containment labs and accidental releases or unintentional shipments of live pathogens at government facilities.

I. BACKGROUND

The Centers for Disease Control and Prevention (CDC) and the Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) regulate laboratories that conduct research on dangerous "select agents." Select agents are those substances and pathogens deemed by government to pose a threat to human or animal health.[1] The CDC's Division of Select Agents and Toxins (DSAT) is responsible for registration and oversight of all laboratories that possess, use, or transfer select agents that could pose a threat to human health. APHIS is responsible for those select agents that pose a threat to animal or plant health.

The federal government also oversees laboratory safety through best practices guidance in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), and its principles are

[1] Public Health Security and Bioterrorism Preparedness and Response Act of 2002, P. L. No. 107-188.

incorporated into the Select Agent regulations and inspections.[2] BMBL establishes four biosafety levels for work with pathogens and toxins, depending on the infectivity, severity, and transmissibility of the disease, as well as the nature of the work being conducted. High-containment biological laboratories operate at the highest levels, BSL-3 and BSL-4. BSL-3 laboratories handle dangerous biological agents and toxins for which there is a vaccine and/or treatment, while BSL-4 laboratories handle dangerous biological agents and toxins for which there is no vaccine and no known treatment.[3] The number of BSL-3 and BSL-4 labs increased significantly after the anthrax attacks in 2001, which spurred interest and funding in biological research.[4] This expansion has taken place at federal and state government facilities as well as in the academic and private sectors.

II. PREVIOUS COMMITTEE WORK

Following the rapid expansion of the number of high-containment labs, the subcommittee held hearings on inadequate oversight in October 2007 and September 2009.[5] GAO testified at both hearings on oversight failures and noted the lack of national safety and security standards for these labs handling dangerous pathogens.

In July 2014, the subcommittee held a hearing on a series of accidental exposures to select agents, including anthrax, smallpox, and a highly pathogenic avian flu, at government laboratories. CDC, APHIS, and GAO testified on their investigations of these incidents and on improvements to safety procedures to prevent such incidents in the future.[6]

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[2] U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories (Dec. 2009) (online at www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf); Congressional Research Service, *Science and Technology Issues in the 114th Congress* (Apr. 7, 2015).

[3] *See* Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 5th Ed. (2009) (online at www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf).

[4] Congressional Research Service, *Oversight of High-Containment Biological Laboratories: Issues for Congress* (May 4, 2009) (R40418).

[5] Subcommittee on Oversight and Investigations, *Hearing on Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*, 110th Cong. (Oct. 4, 2007) (Serial No. 110-70); Subcommittee on Oversight and Investigations, *Hearing on Federal Oversight of High Containment Bio-Laboratories*, 111th Cong. (Sept. 22, 2009) (Serial No. 111-66).

[6] Subcommittee on Oversight and Investigations, *Hearing on Review of CDC Anthrax Lab Incident*, 113th Cong. (July 16, 2014).

In July 2015, the subcommittee held a hearing on the Department of Defense's (DoD) inadvertent shipment of live anthrax from the Army's Dugway Proving Ground in Utah.[7] Subsequent investigations by DoD found that such shipments had been occurring for over a decade, largely due to a lack of standardized inactivation procedures and failure to follow inactivation protocols.[8] DoD and CDC have conducted further review of these incidents and made institutional changes to improve oversight.

III. GAO REPORT ON THE NEED FOR STRONGER OVERSIGHT AT HIGH-CONTAINMENT LABORATORIES

At the committee's request, GAO conducted a study of the high-containment laboratories at eight departments and 15 agencies to assess their policies and oversight mechanisms for securing hazardous biological agents. GAO is releasing its findings in a report entitled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety."[9]

GAO assessed the departments and agencies by six key elements: rules and guidelines for incident reporting; defined roles and responsibilities for personnel; trainings on the handling of hazardous biological agents; inventory of these agents; ongoing inspections; and adherence to the BMBL.[10] GAO also examined the response by HHS and DoD to recent incidents involving mishandling of select agents. GAO concluded that the majority of agencies and departments had policies that were not comprehensive or up-to-date. GAO also concluded that, although HHS and DoD have made progress in implementing recommendations from internal reviews to prevent further security lapses, they have not set deadlines for implementation of these changes. This lack of time frames is inconsistent with federal internal control standards for ensuring prompt resolution of audit findings and other reviews.

To ensure that the departments and agencies that handle select agents have comprehensive and up-to-date policies, GAO made 33 recommendations.[11] GAO advises that those departments and agencies they have examined should develop inventory control policies and reporting protocols to senior officials for incident reports in high-containment labs. In

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[7] Subcommittee on Oversight and Investigations, *Hearing on Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax,* 114th Cong. (July 28, 2015).

[8] Memo from Frank Kendall, Undersecretary of Defense for Acquisition, Technology and Logistics, to Deputy Secretary of Defense re Report of the Comprehensive Review of Department of Defense Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* (Anthrax) Spores (July 22, 2015).

[9] Government Accountability Office, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety* (Mar. 2016) (GAO-16-305).

[10] *Id.*

[11] *Id.*

addition, they recommend analysis of inspection reports, revision of out-of-date policies, and establishment of departmental time frames for revision of these policies. The relevant departments and agencies concurred with the majority of GAO's recommendations.

IV. WITNESSES

Major General Brian Lein
Commanding General, U.S. Army Medical Research and Material Command at Fort Detrick
Department of Defense

Dr. Steve Monroe
Associate Director for Laboratory Science and Safety
Centers for Disease Control and Prevention

Dr. Segaran Pillai
Director
Office of Laboratory Science and Safety
U.S. Food and Drug Administration

Dr. Lawrence A. Tabak
Principal Deputy Director
National Institutes of Health

Mr. John Neumann
Director, Natural Resources and Environment
U.S. Government Accountability Office