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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

October 31, 2017

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Concerns over Federal Select Agent Program Oversight of Dangerous Pathogens"

On **Thursday, November 2, 2017, 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 "Concerns over Federal Select Agent Program Oversight of Dangerous Pathogens." The hearing will focus on a recent U.S. Government Accountability Office (GAO) report titled, "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens." 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] Currently, 66 agents and toxins are regulated under this criteria.[2] 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.

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

[2] Federal Select Agent Program, Select Agents and Toxin List (online at https://www.selectagents.gov/SelectAgentsandToxinsList.html) (last accessed Oct. 27, 2017).

The federal government oversees laboratory safety through best practices guidance in the Biosafety in Microbiological and Biomedical Laboratories (BMBL), and its principles are incorporated into the Select Agent regulations and inspections.[3] 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.[4]

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.[5] This expansion has taken place at federal and state government facilities as well as in the academic and private sectors. Currently, 276 entities are registered with the Federal Select Agent Program (FSAP). Of these, 32 percent are in academia; 29 percent are in non-federal government agencies; 18 percent are affiliated with commercial entities; 15 percent are associated with the federal government; and six percent are associated with private laboratories.[6]

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.[7] 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 needed improvements to

[3] 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).

[4] *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).

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

[6] Federal Select Agent Program, *2016 Annual Report of the Federal Select Agent Program* (Oct. 2017).

[7] 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).

safety procedures to prevent such incidents in the future.[8] 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.[9] In September 2016, the subcommittee held a hearing on the protocols for inactivation of dangerous pathogens in bioresearch laboratories.[10]

III. INVESTIGATION INTO 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 released its findings in a March 2016 report entitled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety."[11] This report made 33 recommendations to eight executive departments and agencies to revise out-of-date policies, ensure that the results of oversight activity are reported to senior officials, and develop plans with timeframes for implementing safety recommendations.[12] The subcommittee held a hearing on this report in April 2016.[13] At that hearing, the relevant departments and agencies concurred with the majority of GAO's recommendations.

In response to a request from the committee, in October of this year GAO released a follow-up report entitled "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens."[14] The report identifies what GAO refers to as "five key elements of effective oversight in areas where low-probability adverse events can have significant and far-reaching effects."[15] These elements include: (1) independence of the oversight authority; (2) the ability to perform reviews; (3) technical

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

[9] 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).

[10] Subcommittee on Oversight and Investigations, *Hearing on Bioresearch Labs and Inactivation of Dangerous Pathogens*, 114th Cong. (Sept. 23, 2016).

[11] 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).

[12] *Id*.

[13] House Committee on Energy and Commerce, *Hearing on How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse*, 114th Cong. (Apr. 20, 2016).

[14] Government Accountability Office, *High-Containment Laboratories: Coordinate Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens* (Oct. 2017) (GAO-18-145).

[15] *Id*.

expertise to perform safety and security assessments; (4) appropriate transparency of the oversight authority; and (5) clear and sufficient enforcement ability.

GAO's report concludes that FSAP does not fully satisfy these five elements. Of particular note, GAO found that while FSAP has taken steps to increase independence by reducing conflicts of interest, CDC and APHIS inspectors may still conduct inspections of laboratories located within their own agencies. In addition, FSAP does not regularly submit to third-party reviews of its program. GAO also found that both CDC and APHIS face challenges hiring and retaining sufficient staff, which creates a risk that inspectors may lack adequate technical expertise to conduct inspections.[16] Finally, GAO expressed an overarching concern that "the program lacks joint strategic planning documents to guide its shared oversight efforts across CDC and APHIS."[17]

GAO issued 11 recommendations, including five designed to improve FSAP's independence; two to improve the program's ability to perform reviews; two to improve its transparency; and two to improve its technical expertise and overcome fragmentation. CDC and APHIS concur with all of GAO's recommendations.

IV. WITNESSES

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[16] *Id.*

[17] *Id.*