

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

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**MEMORANDUM**

**September 21, 2016**

**To: Subcommittee on Oversight and Investigations Democratic Members and Staff**

**Fr: Committee on Energy and Commerce Democratic Staff**

**Re: Hearing on “Bioresearch Labs and Inactivation of Dangerous Pathogens”**

On **Friday, September 23, 2016, at 9:00 a.m. in room 2322 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing titled “Bioresearch Labs and Inactivation of Dangerous Pathogens.” The hearing will build on the Committee’s recent oversight of high-containment laboratories and will focus on a recent GAO report on inactivation protocols for select agents.

**I. BACKGROUND**

The Centers for Disease Control and Prevention (CDC) and the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS) jointly regulate laboratories that conduct research on dangerous “select agents” through the jointly operated Federal Select Agent Program (FSAP). Select agents are substances and pathogens deemed by the government to pose a threat to human or animal health.<sup>1</sup> 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.<sup>2</sup> APHIS is responsible for those select agents that pose a threat to animal or plant health.<sup>3</sup>

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<sup>1</sup> Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188.

<sup>2</sup> Federal Select Agent Program, *FSAP Policy Statement: Registration of Select Agents and Toxins* (Aug. 25, 2014) (online at [www.selectagents.gov/regpolicystatement.html](http://www.selectagents.gov/regpolicystatement.html)).

<sup>3</sup> U.S. Department of Agriculture, *History of APHIS* (accessed Sept. 19, 2016) (online at [www.aphis.usda.gov/aphis/banner/aboutaphis/SA\\_APHIS\\_History](http://www.aphis.usda.gov/aphis/banner/aboutaphis/SA_APHIS_History)).

The federal government also oversees laboratory safety through best practices guidance in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual. These principles are incorporated into the Select Agent regulations and inspections.<sup>4</sup> The BMBL establishes four biosafety levels (BSLs 1 - 4) for work with pathogens and toxins, depending on the infectivity, severity, and transmissibility of the disease, and the nature of the work being conducted. High-containment biological laboratories operate at the highest levels, BSL-3 and BSL-4.<sup>5</sup> 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.<sup>6</sup>

The Federal Select Agent Program has come under scrutiny in recent years following several inadvertent releases of select agents from government high-containment laboratories. In response, several government panels, including the Federal Experts Security Advisory Panel (FESAP), the Fast Track Action Committee on the Select Agent Regulations (FTAC-SAR), and a CDC internal review have released recommendations on safety and security of working with select agents.<sup>7</sup>

These panels made several recommendations to revise select agent regulations, improve the culture of biosafety and biosecurity at laboratories, and enhance oversight and communications with regulated entities. All three reviews recommended increased transparency and public engagement surrounding the FSAP.<sup>8</sup> In response, the FSAP released its first public annual report on data regarding regulation of select agents and toxins in June 2016.<sup>9</sup>

## II. PAST COMMITTEE WORK

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<sup>4</sup> U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories* (Dec. 2009) (online at [www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf](http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf)).

<sup>5</sup> U.S. Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), 5th Ed. (2009) (online at [www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf](http://www.cdc.gov/biosafety/publications/bmb15/BMBL.pdf)).

<sup>6</sup> Congressional Research Service, *Oversight of High-Containment Biological Laboratories: Issues for Congress* (May 4, 2009) (online at [www.absa.org/leg/0905CRSHighContainmentLabs.pdf](http://www.absa.org/leg/0905CRSHighContainmentLabs.pdf)).

<sup>7</sup> U.S. Department of Health and Human Services, *Report of the Federal Experts Security Advisory Panel* (Dec. 2014) (online at [www.phe.gov/s3/Documents/fesap.pdf](http://www.phe.gov/s3/Documents/fesap.pdf)); The White House, *Fast Track Action Committee Report: Recommendations on the Select Agent Regulations Based on Broad Stakeholder Engagement* (Oct. 2015) (online at [www.phe.gov/s3/Documents/ftac-sar.pdf](http://www.phe.gov/s3/Documents/ftac-sar.pdf)); Centers for Disease Control and Prevention, *90-Day Internal Review of the Division of Select Agents and Toxins* (Oct. 2015) (online at [www.cdc.gov/phpr/dsat/full-report.htm](http://www.cdc.gov/phpr/dsat/full-report.htm)).

<sup>8</sup> *Id.*

<sup>9</sup> Federal Select Agent Program, *2015 Annual Report of the Federal Select Agent Program* (June 2016) (online at [www.selectagents.gov/resources/FSAP\\_Annual\\_Report\\_2015.pdf](http://www.selectagents.gov/resources/FSAP_Annual_Report_2015.pdf)).

Starting in 2007, the Subcommittee has held several hearings on biosafety issues, focusing on oversight as well as safety and security regulations for high-containment laboratories. In both October 2007 and September 2009, GAO testified that the rapidly expanding number of laboratories handling dangerous agents lacked national safety and security standards and expressed concern for the inadequate oversight of these facilities.<sup>10</sup>

In July 2014, the Subcommittee held a hearing on a series of accidental exposures at government laboratories to select pathogens, including anthrax, smallpox, and a highly pathogenic avian flu.<sup>11</sup> In July 2015, the Subcommittee heard from both the Department of Defense (DoD) and CDC on their investigations into inadvertent shipments of live anthrax from the Army's Dugway Proving Ground in Utah.<sup>12</sup>

The Subcommittee held a hearing in April 2016 on a GAO report that assessed the policies and oversight mechanisms of high-containment laboratories.<sup>13</sup> The April 2016 GAO 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.<sup>14</sup>

### **III. AUGUST 2016 GAO REPORT ON INACTIVATION PROTOCOLS**

At the Committee's request, GAO conducted an evaluation of the issues related to the inactivation of pathogens in high-containment laboratories. GAO is releasing its findings in a report entitled, "High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk."<sup>15</sup>

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<sup>10</sup> House Committee on Energy and Commerce, *Hearing on Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States*, 110th Cong. (Oct. 4, 2007); House Committee on Energy and Commerce, *Hearing on Federal Oversight of High Containment Bio-Laboratories*, 111th Cong. (Sept. 22, 2009).

<sup>11</sup> House Committee on Energy and Commerce, *Hearing on Review of CDC Anthrax Lab Incident*, 113th Cong. (July 16, 2014).

<sup>12</sup> House Committee on Energy and Commerce, *Hearing on Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax*, 114th Cong. (July 28, 2015).

<sup>13</sup> 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).

<sup>14</sup> 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).

<sup>15</sup> United States Government Accountability Office, *High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk* (Aug. 2016) (GAO-16-642).

The report considered the extent to which incidents involving incomplete inactivation occurred from 2003 through 2015, the challenges that may affect the implementation of inactivation in high-containment laboratories, and the extent to which the FSAP referred violations and enforced regulations related to incidents involving incomplete inactivation.<sup>16</sup>

GAO found that weaknesses remain in the federal government's oversight of inactivation and related research.<sup>17</sup> In particular, HHS and USDA do not know the extent to which incomplete inactivation occurs and whether incidents are being properly identified and addressed, because (1) laboratories are not required to identify such incidents on reporting forms for select agents, (2) a lack of reporting requirements entirely for some pathogens, and (3) the absence of a clear, consistent definition of inactivation.

GAO found that gaps in scientific knowledge and limited guidance presented challenges to the implementation of inactivation at high-containment laboratories. GAO also found that the FSAP did not consistently refer incidents involving incomplete inactivation for further investigation and enforcement for violations of select agent regulations.<sup>18</sup>

The GAO report makes six recommendations, including that the CDC, NIH, and APHIS develop clear definitions of inactivation, revise procedures for incident reporting, and create comprehensive and consistent guidance regarding inactivation protocols.<sup>19</sup> Additionally, GAO recommends coordinated efforts to close gaps in the science of inactivation and viability testing in high-containment laboratories. Finally, GAO recommends that the agencies develop and implement consistent criteria for referring violations and enforcing regulations regarding incomplete inactivation incidents.

#### **IV. WITNESSES**

The following witnesses have been invited to testify:

**Dr. Timothy M. Persons**  
Chief Scientist  
Government Accountability Office

**Dr. Daniel Sosin**  
Deputy Director and Chief Medical Officer  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention

**Dr. Steve Monroe**  
Associate Director for Laboratory Science and Safety

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<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

Centers for Disease Control and Prevention

**Mr. Mark Davidson**

Associate Deputy Administrator  
Veterinary Services  
U.S. Department of Agriculture

**Mr. Jeff Potts**

BioRisk Manager  
National Institutes of Health  
Office of Research Services

**Major General Barbara R. Holcomb**

Commanding General, U.S. Army Medical Research and Materiel Command at Fort Detrick  
Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology  
Chief, U.S. Army Nurse Corps  
Department of the Army  
The Pentagon