

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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**MEMORANDUM**

**July 24, 2015**

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

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

**Re: Hearing on “Continuing Concerns with the Federal Select Agent Program:  
Department of Defense Shipments of Live Anthrax”**

On Tuesday, July 28, 2015, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigation will hold a hearing titled “Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax.” The hearing will review the circumstances surrounding the May 2015 inadvertent shipment of live anthrax from the Department of Defense’s Dugway Proving Grounds and broadly examine the Federal Select Agent Program.

**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.” The select agents are those that the government has deemed 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. APHIS is responsible for those select agents that pose a threat to animal or plant health.

The Select Agent Program requires that facilities that possess, use, or transfer an agent on the list register with the CDC or APHIS, have lab workers checked by the FBI, comply with specific security and biosafety requirements, and submit to regular government inspections.<sup>2</sup> “Non-viable” or “nonfunctional” agents and toxins are exempt from the Select Agent

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

<sup>2</sup> *Id.*; 42 C.F.R. Part 73.

regulations.<sup>3</sup> An entity must use a scientifically validated method to render a select agent non-viable or a select toxin nonfunctional. This means that the method must be scientifically sound and will produce consistent results each time the method is used such that the expected result can be ensured.<sup>4</sup>

Misuse, unauthorized possession, and transfer of select agents is subject to potential criminal penalties and FBI investigations.<sup>5</sup> When regulatory violations of select agent regulations occur, CDC-DSAT refers the matter to the Department of Health and Human Services Office of the Inspector General (HHS OIG) for potential civil enforcement action, which might include monetary penalties against violating labs or institutions. CDC-DSAT has separate authority to deny, revoke, or suspend a laboratory's registration under the Select Agent Program.<sup>6</sup> CDC-DSAT can also require entities with systemic biosafety and security deficiencies to enter into a Performance Improvement Plan (PIP) to come into compliance with Select Agent regulations.<sup>7</sup>

A 2010 executive order led to revised regulations that designated those agents presenting the greatest risks of deliberate misuse as "Tier 1" agents. These regulations also established additional personnel suitability, physical security, and information security standards for accessing Tier 1 select agents and toxins.<sup>8</sup>

The federal government also 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.<sup>9</sup> 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

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<sup>3</sup> Centers for Disease Control, *Non-Viable Select Agents and Nonfunctional Select Toxins and Rendering Samples Free of Select Agents and Toxins* (online at [www.selectagents.gov/guidance-nonviable.html](http://www.selectagents.gov/guidance-nonviable.html)) (accessed July 22, 2015).

<sup>4</sup> *Id.*

<sup>5</sup> 18 U.S.C. 175; 18 U.S.C. 175b.

<sup>6</sup> 42 C.F.R. 73.8.

<sup>7</sup> Federal Select Agent Program, *FAQs* (accessed July 20, 2015).

<sup>8</sup> Exec. Order No. 13546 (July 2, 2010).

<sup>9</sup> 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](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)); Congressional Research Service, *Science and Technology Issues in the 114<sup>th</sup> Congress* (Apr. 7, 2015).

there is no vaccine and no known treatment.<sup>10</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>11</sup>

## II. PREVIOUS COMMITTEE HEARINGS

In October 2007, the Oversight and Investigations Subcommittee held the first in a series of hearings on biosafety issues, focusing on risks from the increasing number of high-containment bio-laboratories.<sup>12</sup> At that hearing, the U.S. Government Accountability Office (GAO) identified concerns with rapid increases in the number of BSL-3 and BSL-4 labs and the inadequate oversight of these facilities, noting that no single federal agency was responsible for tracking their numbers or their locations.<sup>13</sup>

In September 2009, the Subcommittee held its second hearing in the series on biological research laboratories.<sup>14</sup> GAO recommended that the National Security Advisor and the appropriate executive departments identify a single entity to oversee high-containment laboratories and develop standards for their design, construction, commission, and operation.<sup>15</sup> GAO re-evaluated high-containment laboratories in February 2013, reporting that, despite previous recommendations to do so, national safety and security standards still had not been established.<sup>16</sup>

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<sup>10</sup> 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](http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)).

<sup>11</sup> Congressional Research Service, *Oversight of High-Containment Biological Laboratories: Issues for Congress* (May 4, 2009) (R40418).

<sup>12</sup> 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).

<sup>13</sup> Subcommittee on Oversight and Investigations, Testimony of Dr. Keith Rhodes, Chief Technologist, Center for Technology and Engineering, U.S. Government Accountability Office, *Hearing on Germs, Viruses, and Secret: The Silent Proliferation of Bio-Laboratories in the United States*, 110th Cong. (Oct. 4, 2007) (Serial No. 110-70).

<sup>14</sup> Subcommittee on Oversight and Investigations, *Hearing on Federal Oversight of High Containment Bio-Laboratories*, 111th Cong. (Sept. 22, 2009) (Serial No. 111-66).

<sup>15</sup> Government Accountability Office, *High-Containment Laboratories: National Strategy for Oversight Is Needed* (Sept. 2009) (GAO-09-574).

<sup>16</sup> Government Accountability Office, *High-Containment Laboratories: Assessment of the Nation's Need Is Missing* (Feb. 2013) (GAO-13-466R).

In July 2014, the Subcommittee held a hearing on an anthrax exposure incident at a CDC laboratory and subsequent CDC, APHIS, and GAO investigations.<sup>17</sup> The investigations found that the lab had used inadequate inactivation protocols, that scientists were improperly trained in inactivation procedures, and that the lab lacked proper oversight and supervision. In May 2015, bipartisan Committee leaders requested that GAO study inactivation and attenuation protocols.

### III. DEPARTMENT OF DEFENSE'S INADVERTENT SHIPMENT OF ANTHRAX

As part of its Chemical and Biological Defense Program, the Department of Defense (DoD) develops vaccines, drugs, diagnostics, and personal protective equipment to counteract and protect against chemical and biological threats.<sup>18</sup> The Department regularly ships both live and dead biological materials to private labs, academia, and other federal labs to study and develop potential countermeasures.

On May 22, 2015, a private laboratory contacted the CDC regarding a shipment it had received from the Army's Dugway Proving Ground in Utah. The lab tested the shipment and discovered that a sample unexpectedly contained live *Bacillus anthracis* (anthrax), a Tier 1 select agent. The lab was working to develop a new diagnostic test to identify biological threats and was intending to receive inactivated anthrax.<sup>19</sup> Although the samples were irradiated and shipped with "death certificates" through commercial shipping services, such as FedEx, the samples were not inactivated in the process.<sup>20</sup> As a result, a number of labs received live anthrax.

To date, DoD has reported that 86 labs in 20 states, the District of Columbia, and seven foreign countries have received insufficiently inactivated anthrax shipments from Dugway.<sup>21</sup> Over 30 individuals received post-exposure prophylaxis, and 21 remain on the medication as a preventative measure.<sup>22</sup> There have been no suspected or confirmed cases of anthrax infection in potentially exposed lab workers, and the agencies state that there is no known risk to the general public.<sup>23</sup>

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<sup>17</sup> Subcommittee on Oversight and Investigations, *Hearing on Review of CDC Anthrax Lab Incident*, 113th Cong. (July 16, 2014).

<sup>18</sup> U.S. Department of Defense, *Anthrax Frequently Asked Questions* (June 9, 2015) (online at [www.defense.gov/home/features/2015/0615\\_lab-stats/ANTHRAX\\_FAQ\\_CBD.pdf](http://www.defense.gov/home/features/2015/0615_lab-stats/ANTHRAX_FAQ_CBD.pdf)).

<sup>19</sup> Centers for Disease Control and Prevention, *CDC investigating unintentional DoD shipment of anthrax* (May 29, 2015) (press release).

<sup>20</sup> Alison Young, *Army Lab Cited Eight Years Ago for Failing to Properly Kill Anthrax Samples*, USA Today (June 12, 2015).

<sup>21</sup> U.S. Department of Defense, *Department of Defense Laboratory Review* (accessed July 15, 2015).

<sup>22</sup> *Id.*

<sup>23</sup> Alison Young, *Army Lab Cited Eight Years Ago for Failing to Properly Kill Anthrax Samples*, USA Today (June 12, 2015).

Bipartisan Committee leaders requested briefings from the CDC and DoD immediately following the news of this latest incident.<sup>24</sup> Committee members then wrote to CDC and the HHS OIG to request information on biosafety issues and inspections of the laboratory at Dugway Proving Ground.<sup>25</sup>

Following a May 28, 2015, *USA Today* report that CDC had referred 79 labs for potential enforcement actions to the HHS OIG since 2003, the members again wrote to the HHS OIG for information about enforcement of the federal select agent program.<sup>26</sup>

On July 23, 2015, DoD released an internal review of the root causes and circumstances related to the accidental release of inactivated anthrax to these labs. DoD's review found that DoD personnel did appear to follow inactivation protocols correctly, but that there is "insufficient technical information in the broader scientific community" to guide researchers on anthrax inactivation. The review also found that each DoD laboratory has safety protocols and inactivation procedures in place, but they are not uniform across all DoD labs. The review offered a series of recommendations, including establishing standardized, peer-reviewed anthrax spore inactivation and sample testing protocols based on improved scientific data. It also recommended that additional quality control measures be put in place and that program management be enhanced.

In a memo accompanying the review, Undersecretary of Defense for Acquisition, Technology, and Logistics Frank Kendall stated that the technical leadership at Dugway should have been aware of the inadequacies in the inactivation process and sample testing process. Consequently, the report calls for a "thorough formal investigation" of the institutions and individuals responsible for the shipments at Dugway.

The CDC is conducting a separate investigation to work with the labs that received samples to determine if the labs received other live samples and will assess worker safety, laboratory analysis, and handling of laboratory waste.<sup>27</sup> The CDC also launched a separate review in July to assess its regulation of safety and security at high-containment labs.<sup>28</sup> The

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<sup>24</sup> Letters to Ashton Carter, Secretary, Department of Defense and Thomas Frieden, Director, Centers for Disease Control and Prevention from Reps. Upton, Pallone, Murphy, and DeGette (May 28, 2015).

<sup>25</sup> Letters to Thomas Frieden, Director, Centers for Disease Control and Prevention, and Daniel Levinson, Inspector General, Department of Health and Human Services from Reps. Upton, Pallone, Murphy, and DeGette (June 12, 2015).

<sup>26</sup> Letter to Daniel Levinson, Inspector General, Department of Health and Human Services from Reps. Upton, Pallone, Murphy, and DeGette (July 6, 2015).

<sup>27</sup> Centers for Disease Control and Prevention, *CDC investigating unintentional DoD shipment of anthrax* (May 29, 2015) (press release).

<sup>28</sup> Alison Young, *CDC to review oversight of bioterror labs after USA Today investigation*, *USA Today* (July 21, 2015).

review will be conducted by Stephen Redd, director of the CDC's Office of Public Health Preparedness and Response, and is expected to take 90 days.

#### **IV. WITNESSES**

The following witnesses have been invited to testify:

**Dr. D. Christian Hassell**

Deputy Assistant Secretary of Defense for Chemical and Biological Defense  
Department of Defense

**Dr. Dan Sosin**

Deputy Director  
Office of Public Health Preparedness and Response  
Centers for Disease Control and Prevention

**Gregory Demske**

Chief Counsel  
Office of the Inspector General  
Department of Health and Human Services

**Dr. Marcia Crosse**

Director  
Healthcare  
Government Accountability Office