



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

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July 24, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled “Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax.”

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On July 28, 2015, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, “Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax.”

In late May 2015, the Department of Defense (DoD) acknowledged 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. These shipments revealed that Dugway’s process for inactivating anthrax with radiation was not fully effective, and that sterility testing used to validate and ensure that the inactivation process was working had failed to detect the live anthrax spores. After learning about these problems, DoD determined that the scope of the live anthrax distribution was more widespread, and has occurred over nearly a ten-year period. The DoD internal review so far shows live anthrax has been shipped to 86 facilities spanning 7 foreign countries, 20 States, and the District of Columbia, with 21 personnel on post-exposure prophylaxis.

The Dugway shipments are the most recent instance of a series of high-profile incidents involving the mishandling of dangerous pathogens known as select agents.<sup>1</sup> This hearing builds on both the Committee’s prior work on the Federal Select Agent Program (FSAP), and the U.S. Government Accountability Office’s (GAO) work in response to Committee requests.<sup>2</sup> A year ago, the Committee held a hearing on a different anthrax incident, specifically an incident that occurred in June 2014 at the Centers for Disease Control and Prevention (CDC) laboratory where

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<sup>1</sup> Over the last year, the Committee has been examining the following incidents: (1) June 2014 CDC inadvertent transfer of live anthrax between CDC labs resulting in the potential exposure of 81 CDC staff and the closure of a bioterrorism rapid response lab; (2) Spring 2014 CDC inadvertent shipment of highly pathogenic H5N1 influenza to a USDA lab with a two-month lag time before CDC leadership had been made aware of the incident; (3) July 2014 FDA report of finding vials of smallpox and 327 other vials of dangerous biological agents that had never registered or accounted for but were allegedly housed in a storage room in an NIH building for more than 40 years without anybody knowing about it; and (4) December 2014 CDC inadvertent transfer of potentially live Ebola virus from a biosafety level 4 lab to a lower biosafety level 2 lab.

<sup>2</sup> See, e.g., “Review of CDC Anthrax Lab Incident,” Hearing before the Subcommittee on Oversight and Investigations, House Energy and Commerce Committee, Serial No. 113-160 (July 16, 2014); and “Germs, Viruses, and Secrets: the Silent Proliferation of Bio-Laboratories in the United States,” 110<sup>th</sup> Congress (October 4, 2007).

as many as 84 CDC employees were exposed to live anthrax, because established safety practices were not followed. 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.<sup>3</sup> The hearing also examined other incidents, including a spring 2014 cross-contamination involving H5N1 influenza virus at the CDC influenza laboratory and the discovery of decades-old vials of smallpox in a Federal Drug Administration (FDA) lab on the National Institutes for Health (NIH) campus that were only discovered while employees were preparing for the lab's move to the FDA's main campus in White Oak, Maryland.

Last year's hearing on the CDC anthrax incident and recent GAO reports emphasized three general themes: (1) no single entity in the Federal government is in charge of overseeing high-containment laboratories that handle select agents; (2) current oversight of high-containment laboratories is fragmented; and (3) CDC as a regulator of the FSAP presents a conflict of interest because CDC funds labs in the FSAP and has not effectively policed its own labs in handling select agents. GAO is currently undertaking reviews in response to bipartisan committee requests on Federal agency management of select agents<sup>4</sup> and scientific issues related to the inactivation of select agents.<sup>5</sup>

The purpose of this hearing is to address the following: (1) whether Dugway shipments of live anthrax and the overall performance record of labs handling select agents make a sufficient case that the FSAP needs to be substantially strengthened and reformed, and if so, (2) what changes and reforms to the FSAP will lead to substantial improvements in performance?

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<sup>3</sup> 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.

<sup>4</sup> Letter from The Honorable Fred Upton, Chairman, House Energy and Commerce Committee; The Honorable Henry Waxman, Ranking Member; The Honorable Tim Murphy, Chairman, Subcommittee on Oversight and Investigations; The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations; The Honorable Joseph R. Pitts, Chairman, Subcommittee on Health; and The Honorable Frank Pallone, Ranking Member, Subcommittee on Health to The Honorable Gene L. Dodaro, Comptroller General, Government Accountability Office (July 31, 2014).

<sup>5</sup> Letter from The Honorable Fred Upton, Chairman, House Energy and Commerce Committee; The Honorable Frank Pallone, Ranking Member; The Honorable Tim Murphy, Chairman, Subcommittee on Oversight and Investigations; and The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations to The Honorable Gene L. Dodaro, Comptroller General, Government Accountability Office (May 7, 2015).

## I. WITNESSES

- Dr. D. Christian Hassell, Deputy Assistant Secretary of Defense for Chemical and Biological Defense, Department of Defense;
- Dr. Dan Sosin, Deputy Director for the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention;
- Gregory Demske, Counsel to the Inspector General, Office of Inspector General, U.S. Department of Health and Human Services; and,
- Dr. Marcia Crosse, Director, Healthcare, Government Accountability Office.

## II. BACKGROUND

### A. Federal Select Agent Program

#### *Creation of the Federal Select Agent Program*

The FSAP was established by the Antiterrorism and Effective Death Penalty Act of 1996, following the Oklahoma City bombing in 1995. 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 2 years to determine if agents need to be added to or deleted from the list.<sup>6</sup> 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.<sup>7</sup> The USA Patriot Act also made it a criminal offense for any individual to knowingly possess any biological agent, toxin, or delivery system in type or quantity not justified by a peaceful purpose.<sup>8</sup>

Congress later enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which (1) expanded the select agent program to include not only the regulation of the transfer, but also the use and possession of select agents and (2) increased safeguards and security requirements.<sup>9</sup> The 2002 Act also establishes civil money penalties for persons violating the regulations and additional criminal penalties for knowingly possessing a

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<sup>6</sup> Federal Select Agent Program, About Us, <http://www.selectagents.gov/about.html>.

<sup>7</sup> USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).

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

<sup>9</sup> 42 U.S.C. § 262a.

select agent or toxin without registering it or knowingly transferring a select agent or toxin to an unregistered person.<sup>10</sup>

### ***DSAT's and APHIS's Regulatory Role***

The 2002 Act requires HHS to regulate select agents. Within HHS, this responsibility has been assigned to CDC, Division of Select Agents and Toxins (DSAT).<sup>11</sup> CDC regulates select agents that could pose a severe threat to public health and safety. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regulates select agents and toxins that could pose a severe threat to animal or plant health. CDC and APHIS establish select agent regulations and monitor and enforce compliance with Federal select agent regulations.<sup>12</sup>

DSAT regulates and inspects 284 labs and other entities for the possession, use, or transfer of biological select agents and toxins (BSAT), in accordance with HHS select agent regulations.<sup>13</sup> CDC laboratories that possess BSAT fall under this regulatory responsibility.<sup>14</sup> As of July 10, 2014, there are 324 entities registered with the FSAP for possession, use, or transfer of select agents.<sup>15</sup> There are 11,034 individuals with active approvals to access select agents at FSAP-registered entities.<sup>16</sup> There are 472 CDC staff with active security risk assessment approvals to access select agents.<sup>17</sup> About 15 percent of entities registered to work with select agents were subject to inspection overlap (multiple Federal agencies inspecting within a 2-year period).<sup>18</sup>

All inspections include review of biosafety practices, security, incident response, training, and records management. Since 2005, DSAT has conducted 9 inspections at the CDC Roybal campus that included the BSL-3 laboratories in Building 18. Four of these inspections were done jointly with APHIS. In September 2012, CDC reported that APHIS agreed to assume lead responsibility for inspections of CDC laboratories that are regulated under the FSAP.<sup>19</sup>

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<sup>10</sup> *Id.*

<sup>11</sup> For FY 2013, CDC DSAT spent \$13,682,997.

<sup>12</sup> Federal Select Agent Program, About us, <http://www.selectagents.gov/about.html>.

<sup>13</sup> 42 C.F.R. part 73.

<sup>14</sup> CDC FY 2015 Congressional Justification, 310. CDC's website on the FSAP states there are 347 entities registered and inspected by the Federal Select Agent Program.

<sup>15</sup> E-mail from CDC staff to Committee staff, July 11, 2014. CDC's website, however, states there are 347 entities registered and inspected by the Federal Select Agent Program.

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

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

<sup>18</sup> GAO, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program," GAO-13-154 (January 2013) <http://www.gao.gov/products/GAO-13-154>.

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

### ***HHS OIG's Law Enforcement Role***

Section 19 of the select agent regulations requires that incidents of theft, loss, or release of select agents and toxins be reported to either DSAT or APHIS select agent regulators. DSAT refers cases of significant regulatory non-compliance to HHS Office of Inspector General (OIG) for investigation and to assess whether the imposition of civil money penalties would be appropriate. To date, the DSAT has made 68 referrals to HHS OIG for potential FSAP enforcement actions. Out of those referrals, the OIG found violations in 30 of the 68 referrals. The OIG resolved 20 cases with civil monetary penalty settlements and issued 10 notice of violation letters. The OIG also closed 3 referrals for 1 Federal entity after the OIG's Office of Audit Services issued an audit report to the entity with audit findings that addressed the violations in the referral. For the 20 entities receiving civil monetary penalties, the OIG collected more than \$2.4 million for violations of the 2002 Act. However, about 75 percent of the total amount was imposed on only 2 entities, with an average settlement amount for the other 18 entities of approximately \$54,000.<sup>20</sup> HHS OIG has not imposed civil monetary penalties on any Federal government agency entity, even though Federal government agency entities are the leading offenders with multiple violations.

### ***The FBI's Role***

The Federal Bureau of Investigation (FBI) has several roles in the FSAP.<sup>21</sup> First, the FBI screens scientists who submit applications to participate in the program pursuant to the USA Patriot Act for reliability. The FBI conducts a database check against 11 restricted persons categories, but no interviews or other background investigations are involved. The entity in the Federal select agent program would be responsible for the suitability assessment. The FBI estimates doing 30,000 reliability assessments with less than 300 denied.

Second, the FBI helps protect the FSAP by raising security awareness in the research community, and helping coordinate security in the event of theft, loss, or release of a select agent. For example, the FBI helped secure and transport the smallpox vials discovered last year on the NIH campus. The FBI can also assist CDC, USDA, and the entity in accounting for select agents that may be stolen, lost, or released. The FBI has a Weapons of Mass Destruction (WMD) directorate with WMD coordinators in 56 field offices who serve as local resources as part of a response.

Third, the FBI serves as a criminal back-stop to the FSAP, conducting criminal investigations when necessary. In the event of a theft, loss, or release, the FBI conducts a Threat Credibility Evaluation—with the FBI labs, CDC, and possibly others—to determine whether there is any intent to use the select agent as a weapon, so inherently dangerous it has no legitimate research purpose, or if an entity is egregiously non-compliant (such as an entity decertified from the FSAP that refused to transfer or destroy its select agents<sup>22</sup>). While the FBI

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<sup>20</sup> Letter from Inspector General Daniel Levinson, Department of Health and Human Services Office of Inspector General, to The Honorable Fred Upton, Chairman, Committee on Energy & Commerce, et. al (July 20, 2015); E-mail from HHS OIG staff to Committee staff, July 21, 2015.

<sup>21</sup> Information in this section is derived from a bipartisan committee staff briefing from the FBI on July 20, 2015.

<sup>22</sup> This example is an illustration, and not an actual case.

has investigated and prosecuted crimes related to select agents, there have been only a handful of cases and only 1 has involved a legitimate researcher, who was prosecuted for misleading authorities about missing vials of bubonic plague in 2003.

**B. Reaction to the May 2015 Anthrax Incident**

In late May 2015, DoD acknowledged that Dugway, an Army facility in Utah, had inadvertently shipped live anthrax to a commercial laboratory in Maryland as well as to other contract labs. DoD has since determined that the scope of the live anthrax distribution was more widespread, and over nearly a ten-year period.

***Department of Defense Review***

On July 23, 2015, DoD publicly released the results of its review of its safety practices for generating and handling inactivated anthrax.<sup>23</sup> According to DoD's report, on May 22, 2015, a private company notified CDC that inactivated anthrax in its possession was live. CDC's ensuing investigation determined that the live anthrax originated at Dugway. Ultimately, DoD found live anthrax had been shipped to 86 facilities spanning 7 foreign countries, 20 States and the District of Columbia, with 21 personnel on post-exposure prophylaxis.<sup>24</sup>

DoD's review was unable to definitively determine the root cause for how and why Dugway shipped live anthrax. One of the stated reasons DoD was unable to identify a root cause is the "absence of specific scientific community standards" for inactivating anthrax and "continuing scientific uncertainty regarding the survival, injury, and repair of spores exposed to gamma radiation."<sup>25</sup> That said, DoD found that deficiencies in sample sizes and inadequate validation procedures after irradiation may have contributed to undetected live anthrax. Further, although its labs had safety protocols and procedures, DoD found that these procedures were not standardized.<sup>26</sup>

DoD's review made a series of recommended corrective actions. Broadly, DoD recommends enhancing quality assurance, implementing a more extensive scientific peer review process, and improving program management for inactivating and conducting viability testing of anthrax.<sup>27</sup> More specific recommendations include standardizing anthrax inactivation protocols across DoD laboratories, establish and manage an environmental surface sampling program, conduct audits and inspections of DoD laboratories utilizing select agents, revise the death certificate process, and prioritize research and development for those pathogens where

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<sup>23</sup> Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* Spores, "Inadvertent Shipment of Live *Bacillus anthracis* Spores by DoD" (July 13, 2015).

<sup>24</sup> *Id.*

<sup>25</sup> *Id.* at 4.

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* at 18.

information is lacking.<sup>28</sup> Regarding the last recommendation, DoD noted that all the laboratories failed to recognize the importance of knowledge gaps.<sup>29</sup>

### ***FSAP Entity Inspection Report***

From May 26 to May 28, 2015, following the discovery that live anthrax was shipped, CDC inspectors from DSAT conducted an inspection and issued a report.<sup>30</sup> In its report, the DSAT inspectors observed that the Standard Operating Procedures (SOP) for the irradiation of anthrax spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator, which resulted in inactivation failures. As a result, the DSAT inspectors recommended that Dugway provide an updated SOP where all steps in the preparation of the spore suspensions have been verified to not inhibit their inactivation. The DSAT inspectors also observed that the method used for inactivation, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation before creating spore suspensions that would be released from the facility. The report recommended that Dugway provide documentation validating the method of inactivation to ensure that each preparation does not contain viable spores or cells after irradiation. Ultimately, as a result of live anthrax being shipped across the world, the report ordered Dugway to suspend any shipment “inactivated” anthrax preparations, and that they are to be considered select agents until proven otherwise.<sup>31</sup>

### ***USA TODAY Investigation***

Shortly after DoD acknowledged that one of its facilities shipped live anthrax to contract labs, USA TODAY released its findings after its extensive investigation of America’s biolabs. Its investigation uncovered hundreds of life threatening accidents and revealed many labs’ repeated failures to correct past observation, biosafety, and security concerns.<sup>32</sup> Such disregard for safety protocol poses a major public health problem. For example, a 25-year-old researcher died due to a San Francisco VA Medical Center lab’s failure to “adequately supervise and protect workers in the research lab” and train workers about warning signs of infection.<sup>33</sup> Since 2012, at least 50 incidents of failures to fulfill safety protocol have occurred.<sup>34</sup> One lab with a history of non-compliance was cited for 9 of the same violations on 4 consecutive inspections over the span of 1 year.<sup>35</sup> Another lab received a letter from CDC in February of 2014, alerting that it “has failed to address safety issues over the course of the last four years.”<sup>36</sup> Despite these repeated transgressions, CDC inspectors have allowed some of these labs to continue their

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<sup>28</sup> *Id.* at 18-22.

<sup>29</sup> *Id.* at 22.

<sup>30</sup> DSAT and APHIS Entity Inspection Report: Life Science Test Facility (June 5, 2015).

<sup>31</sup> *Id.*

<sup>32</sup> Alison Young and Nick Penzenstadler, *Inside America’s Secretive Biolabs*, USA TODAY, May 28, 2015, <http://www.usatoday.com/story/news/2015/05/28/biolabs-pathogens-location-incidents/26587505/>.

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> Alison Young, *CDC to Review Oversight of Bioterror Labs after USA TODAY Investigation*, USA TODAY, July 21, 2015, <http://www.usatoday.com/story/news/2015/07/21/cdc-review-oversight-bioterror-labs-after-usa-today-investigation/30458589/>.

<sup>36</sup> *Id.*

work.<sup>37</sup> USA TODAY also reported that CDC is launching a comprehensive review of how it regulates its bioterror labs.<sup>38</sup>

### **C. The Federal Select Agent Program's Performance**

The DoD shipments may reflect broader concerns with Federal laboratories, especially because safety incidents at high-containment labs have not been isolated events. As DoD acknowledged in its review of the live anthrax shipments, laboratory biosafety protocols and procedures are not standardized amongst DoD laboratories due to the fact that laboratories are managed under multiple chains of command.<sup>39</sup> Further, there is a lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures.<sup>40</sup> These key findings, along with ongoing work by government watchdogs, indicate that these laboratories need better oversight and national standards and protocols.

#### ***GAO Reports***

The GAO has conducted comprehensive work on the oversight of high-containment laboratories. In 2009, GAO noted that the number of high-containment laboratories was increasing in different sectors throughout the United States.<sup>41</sup> The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.<sup>42</sup> And since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.<sup>43</sup> In fact, aspects of the FSAP—particularly those provided by HHS and the USDA—depend on entities' monitoring themselves and reporting incidents to the regulators. For example, with respect to a certification that a select agent had been rendered sterile (that is, noninfectious), DSAT officials told GAO, that “the burden of validating non-viability and non-functionality remains on the individual or entity possessing the select agent, toxin, or regulated nucleic acid.”<sup>44</sup> DSAT does not approve each entity's scientific procedure. Instead, DSAT strongly recommends that “an entity maintain information on file in support of the method used for rendering a select agent non-viable . . . so that the entity is able to demonstrate that the agent . . . is no longer subject to the select agent regulations.”<sup>45</sup> For these reasons, GAO has continued to recommend a government-wide strategy for the requirements of high-containment laboratories and the need for national standards for designing, constructing, commissioning, and maintaining such laboratories.<sup>46</sup>

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<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> Action Memo for Deputy Secretary of Defense following the Report of the Comprehensive Review of Department of Defense Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* (Anthrax) spores (July 22, 2015).

<sup>40</sup> *Id.*

<sup>41</sup> GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

<sup>42</sup> *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> Testimony of Nancy Kingsbury, Managing Director, Applied Research and Methods, GAO, Hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations, “Review of CDC Anthrax Lab Incident,” Serial No. 113-160, 39-40 (July 16, 2014).

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*



### ***2011 HHS OIG Report***

In 2011, the HHS OIG issued a report after a nationwide review of Federal laboratories' compliance with select agent regulations.<sup>47</sup> The review included labs at CDC, NIH, and FDA. The OIG found some of the labs had weaknesses that allowed access to select agents by unapproved individuals. These same labs did not maintain accurate inventory and/or access records as required. For example, during a reorganization of laboratory space at CDC, a scientist found two select agent vials stored in a drawer in a laboratory area that was not listed on the lab's certificate of registration and was not secured as select agents. The OIG found that most laboratories reviewed did not ensure that approved individuals received select agent training. One CDC lab did not provide biosafety and security training to 88 of its 168 approved individuals before granting them access to select agent areas. Plans for two labs reviewed did not meet one or more regulatory requirements for developing and implementing security plans. The incident response plan for two labs did not function as intended. At one FDA lab, emergency announcements could not be heard over the public address system in select agent laboratory and storage areas.

Finally, the OIG found that DSAT did not effectively monitor and enforce certain Federal select agent regulations at the laboratories. Specifically, DSAT inspections did not always identify noncompliance with Federal select agent regulations, and DSAT personnel entered incorrect select agent registration information into its national registry database for one laboratory. According to the OIG, these weaknesses may have contributed to the labs not being in full compliance, "which may have put public health and safety at increased risk."<sup>48</sup>

The OIG has also found that 11 of 15 representative universities investigated did not fully comply with the select agent regulations. The OIG determined that none of the 8 representative State, local, private, or commercial laboratories investigated were in full compliance.<sup>49</sup>

#### **D. CDC Lab Research**

High containment laboratories, which conduct research on bioweapon agents, have proliferated since the 2001 anthrax attacks in which spores mailed to news media offices and 2 U.S. senators killed 5 people and infected 17 others.<sup>50</sup> 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.<sup>51</sup> GAO had

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<sup>47</sup> HHS OIG, "Nationwide Review of Federal Laboratories' Compliance with Select Agency Regulations" (July 2011), redacted version available at <http://docs.house.gov/meetings/IF/IF02/20140716/102479/HHRG-113-IF02-20140716-SD014.pdf>.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> 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.

<sup>51</sup> 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>.

recommended in 2009<sup>52</sup> that the National Security Advisor make a single Federal agency responsible for assessing lab standards, 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.”<sup>53</sup>

CDC and NIH have established 4 main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.<sup>54</sup> 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 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.

CDC works to protect Americans from rare but deadly pathogens like Hantavirus pulmonary syndrome, Ebola and Marburg viral hemorrhagic fevers, rabies, monkeypox, smallpox, and anthrax.<sup>55</sup> Because the pathogens that cause these diseases are so deadly, with many of them considered bioterrorism threats that are regulated as Tier 1 select agents, CDC maintains biosafety level BSL-3 and BSL-4 laboratories. These labs support epidemiologic investigations, research, and prevention efforts to reduce the public health threat of these hazardous and infectious high-consequence pathogens. According to an April 2014 U.S. government report to the United Nations, CDC reported spending a total of more than \$30 million in 2013 on select agent research.<sup>56</sup>

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<sup>52</sup> GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

<sup>53</sup> 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>.

<sup>54</sup> 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/>

<sup>55</sup> CDC FY 2015 Congressional Justification 101.

<sup>56</sup> See United States of America, Confidence Building Measure Return covering 2013, Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Submitted to the United Nations on April 15, 2014, at 79-90 [http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/7B8EB5C27800D7A9C1257CC3005010BE/\\$file/BWC\\_CB\\_M\\_2014\\_UnitedStates\\_PUBLIC.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/7B8EB5C27800D7A9C1257CC3005010BE/$file/BWC_CB_M_2014_UnitedStates_PUBLIC.pdf).

### **E. Safety Stand-Down**

On August 18, 2014, in response to biosafety lapses that occurred in 2014 – including the smallpox incident where FDA lab employees discovered decades-old vials of smallpox in its lab on NIH’s campus – the White House announced a Safety Stand-Down for Federal laboratories. In a memorandum, Lisa Monaco, Assistant to the President for Homeland Security and Counterterrorism, and John Holdren, Assistant to the President for Science and Technology, urged all Federal departments and agencies that worked with infectious agents to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. All Federal agencies that possessed, used, or transferred select agents were urged to perform a Safety Stand-Down, including an immediate sweep of their facilities to verify that all select agents in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

During the Safety Stand-Down, Federal agencies conducted sweeps at over 4,000 facilities across the United States and in U.S. facilities abroad, which included examining inventory and documentation for over 40 million samples. As a result of this review, the White House reported on December 16, 2014, that there were 27 instances in which select agents were not properly registered with the FSAP. Agencies reported the adjudication and final disposition for the materials, and there were no indications of human exposure to the select agents.

The U.S. Government is conducting parallel Federal and non-Federal reviews that will result in specific recommendations to strengthen the government’s biosafety and biosecurity practices and oversight system for Federally funded activities. Through the Federal Experts Security Advisory Panel (FESAP), a coordinated Federal review is being conducted to: (1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for select agents; (2) identify actions and any regulatory changes necessary to improve biosafety and biosecurity; and (3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer select agents. In addition, the National Science and Technology Council has established an interagency Fast Track Action Committee to conduct a comprehensive review of the impact that the select agent regulations have had on science, technology, and national security.

### **III. ISSUES**

The following issues may be examined at the hearing:

- How can oversight of select agents be improved?
- Were the safety breaches an isolated incident, or part of a pattern at DoD labs?
- What lessons can be derived from the investigations of this incident?
- Are there broader implications from this incident beyond DoD about the oversight of select agents and of all high-containment labs throughout the U.S.?

- Is Congressional action necessary? If so, what actions?
- What are the most effective ways to improve biosafety?

#### **IV. STAFF CONTACTS**

If you have any questions regarding this hearing, please contact Alan Slobodin, Jessica Donlon, or Brittany Havens of the Committee staff at (202) 225-2927.