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

October 31, 2017

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Concerns over Federal Select Agent Program Oversight of Dangerous Pathogens"

The Subcommittee on Oversight and Investigations will hold a hearing on Thursday, November 2, 2017, at 10:15 a.m. in 2322 Rayburn House Office Building, entitled "Concerns over Federal Select Agent Program Oversight of Dangerous Pathogens." The Subcommittee will hear testimony on the Government Accountability Office's (GAO) recent report on the need for coordinated actions needed to enhance the Federal Select Agent Program's (FSAP) oversight of hazardous pathogens. In recent years, the Subcommittee has examined numerous safety lapses at high-containment laboratories and ways to enhance U.S. biosafety and biosecurity under the FSAP.[1]

I. WITNESSES

- Mary Denigan-Macauley, Ph.D., Acting Director, Health Care, Government Accountability Office;
- Samuel S. Edwin, Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention; and
- Freeda E. Isaac, DVM, Director, Agriculture Select Agent Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture.

II. BACKGROUND

The purpose of this hearing is to examine the conclusions of a recent GAO report on the coordinated actions needed to enhance the Federal Select Agent Program's oversight of hazardous pathogens.

The Committee requested this report in May 2015 after several incidents involving the mishandling of hazardous biological agents raised questions about Federal policies for managing hazardous biological agents in high-containment laboratories. In this bipartisan request, the Committee asked GAO to analyze the policies and procedures in place at Federal agencies to ensure the proper management of pathogens and the steps taken to improve their inventory

[1] The Select Agent Program is operated by the Departments of Health and Human Services and Agriculture to oversee certain dangerous pathogens, known as select agents.

management of pathogens. The Committee also requested that GAO assess how the agencies evaluate the effectiveness of their policies and procedures relating to pathogen management.[2]

The Subcommittee has previously held multiple hearings on security lapses at high-containment laboratories. In July 2014, the Subcommittee on Oversight and Investigations held a hearing examining an incident that occurred in June 2014 at the Centers for Disease Control and Prevention's (CDC) laboratory where as many as 84 CDC employees were exposed to live anthrax, because established safety practices were not followed.[3] 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.[4] 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 Food and Drug Administration (FDA) lab on the National Institutes of Health's (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.

In July 2015, the Subcommittee held a hearing on the Department of Defense's (DOD) acknowledgement 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.[5] These shipments revealed that Dugway's process for inactivating anthrax with radiation was unreliable, and that sterility testing used to validate and ensure that the inactivation process was working had failed to detect the live anthrax spores.

On April 20, 2016, the Subcommittee held a hearing on the GAO report on the need for comprehensive policies and stronger oversight at high-containment laboratories,[6] as well as the steps taken by the National Institutes of Health (NIH), the CDC, the FDA, and the DOD to strengthen their policies. GAO found that stronger oversight mechanisms for federal high-containment laboratories were needed at the individual federal department and component level.

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[2] Letter from Hon. Fred Upton, Chairman, Hon. Tim Murphy, Frank Pallone, Jr., Ranking Member, Hon. Diana DeGette, H. Comm. on Energy & Commerce, to Hon. Gene Dodaro, Comptroller Gen., U.S. Gov't Accountability Office (May 7, 2015). This letter requested an examination of the sufficiency of inactivation protocols and procedures for studying dangerous pathogens. The request included a part relating to how other countries addressed this issue, which was separated from the scope of the first report and deferred for later work. On July 28, 2016, GAO met with bipartisan committee staff and agreed that for part two of the inactivation request, we needed to broaden the scope and focus on current and alternative oversight structures for select agents in high-containment laboratories.

[3] *Review of CDC Anthrax Lab Incident: Hearing before the Subcomm. on Oversight and Investigations, H. Comm. on Energy & Commerce*, 113th Cong. (2014).

[4] 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.

[5] *Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax: Hearing before the Subcomm. on Oversight & Investigations, H. Comm. on Energy & Commerce*, 114th Cong. (2015).

[6] Laboratories that conduct research on hazardous biological agents are assigned one of four biosafety levels (BSL). Labs at BSL-3 and BSL-4, the highest risk of the four levels, are known as "high-containment laboratories."

On September 23, 2016, the Subcommittee heard testimony on GAO's report on the need for improving the Federal Select Agent Program's oversight of incomplete inactivation,[7] as well as the steps taken by CDC, the U.S. Department of Agriculture (USDA), the NIH, and the DOD to strengthen their policies.

a. Federal Select Agent Program

Following the Oklahoma City bombing in 1995, the Antiterrorism and Effective Death Penalty Act of 1996 established the Federal Select Agent Program. 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 66 select agents and toxins. The select agent list is reviewed at least every two years to determine if agents need to be added to or deleted from the list.[8] 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.[9] The USA Patriot Act also made it a criminal offense for any individual knowingly to possess any biological agent, toxin, or delivery system in type or quantity not justified by a peaceful purpose.[10]

Congress later enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which (1) expanded the FSAP to include the regulation of the transfer and the use and possession of select agents and (2) increased safeguards and security requirements.[11] The 2002 Act also established civil money penalties for persons violating the regulations and additional criminal penalties for knowingly possessing a select agent or toxin without registering it or knowingly transferring a select agent or toxin to an unregistered person.[12]

b. High Containment Laboratories

High containment laboratories, which conduct research on bioweapon agents, have proliferated since the 2001 anthrax attacks in which spores were mailed to news media offices

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[7] Inactivation can be defined as a process used in laboratories to render pathogens unable to cause disease, but retaining characteristics of interest for future use, such as for vaccine development.
[8] Federal Select Agent Program, About Us, http://www.selectagents.gov/about.html.
[9] USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).
[10] *Id.*
[11] 42 U.S.C. § 262a.
[12] *Id.*

and two U.S. senators, killing five people and infected 17 others.[13] 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.[14] GAO had recommended in 2009[15] 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."[16]

CDC and NIH have established four main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.[17] 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.

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.[18] The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.[19] And since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.[20] 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.[21]

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[13] 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 and somewhat plateaued. In the latest report, GAO stated that there are 276 entities registered.
[14] 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.
[15] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.
[16] 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.
[17] 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/bmbl5/.
[18] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.
[19] *Id.*
[20] *Id.*
[21] *Id.*

c. GAO Report on the Federal Select Agent Program

In response to the Committee's request, GAO reviewed the effectiveness of current oversight procedures within the Federal Select Agent Program and oversight procedures from other countries and regulatory sectors. GAO also examined strategic planning documents at both the CDC and APHIS.

GAO found that the oversight procedures in the FSAP did not meet the criteria for effective oversight as determined by GAO. That is, the program is lacking in each of the five elements identified by GAO as critical to effective oversight:[22]

- Independence: The organization conducting oversight should be structurally distinct and separate from the entities it oversees.

- Ability to perform reviews: The organization should have the access and working knowledge necessary to review compliance with requirements.

- Technical expertise: The organization should have sufficient staff with the expertise to perform sound safety and security assessments.

- Transparency: The organization should provide access to key information, as applicable, to those most affected by operations.

- Enforcement authority: The organization should have clear and sufficient authority to require that entities achieve compliance with requirements.

GAO determined that the FSAP is not independent from the entities it oversees. To be considered independent, the agencies cannot regulate themselves, but both the CDC and the USDA's Animal and Plant Health Inspection Service (APHIS) oversee laboratories within their agencies.[23] However, the GAO cited some benefits to the current structure of the FSAP, including the program officials' ability to access experts within the CDC and APHIS.[24] The FSAP has taken some steps to reduce potential conflicts of interest, but those steps are not sufficient to ensure independence. For example, both CDC and APHIS have made structural changes to increase independence, such as relocating a program component to an office that does not have a laboratory, and APHIS has made organizational changes, such as realigning supervisory responsibilities such that the FSAP does not report to a division director whose office included a laboratory.[25] Further, both CDC and APHIS signed a memorandum of

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[22] GAO, "High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens," GAO-18-145 (October 2017). https://www.gao.gov/assets/690/687868.pdf.
[23] *Id*. at 15.
[24] *Id*..
[25] *Id*. at 15-16.

understanding in 2012 to reduce organizational conflicts of interest at the CDC.[26] However, in practice, neither CDC nor APHIS always follow this memorandum.[27] Finally, while the FSAP has taken steps to reduce conflicts of interest, those steps are generally taken in response to a concern raised by others; the program itself has not proactively assessed potential risks that could arise due to the lack of independence.[28]

GAO also found that while the Select Agent Program performs several types of reviews to ensure compliance with regulatory and program requirements, those reviews are not tailored to target the highest-risk activities in the program.[29] The failure to use a targeted review process was partly due to the fact that the FSAP has not formally assessed which activities are high risk.[30] Additionally, inspections sometimes focused on verifying information that had little to do with reducing risk, such as reviewing records to match nicknames with full names and counting vials without verifying that the contents of the vials were uncompromised.[31] Further, GAO found that FSAP reviews were generally more focused on security concerns, like preventing theft, than on biological safety, like reducing the risk of researcher exposure to select agents, despite the fact that biological safety incidents may be more likely to occur.[32] A 2015 report recommended that CDC and APHIS collaborate to identify high risk areas in order to improve the inspection process, but that recommendation has not yet been addressed.[33]

GAO further found that the CDC and APHIS lack a workforce of sufficient size and training. While both agencies have increased the number of full time inspectors since 2016, the FSAP still may not have adequate staff to complete work in a timely fashion. The lack of staff results in high workloads, which creates additional problems, including low staff retention rates, staff being assigned work outside of their areas of expertise, and delays in issuing inspection reports.[34] Roughly 27 percent of reports exceeded the 30 day target.[35] This delay in issuing reports in turn delays the implementation of corrective safety measures.[36] GAO also determined that inspectors from both agencies lacked sufficient knowledge about their regulatory responsibilities, but that training opportunities were not always readily available to those inspectors.[37] Gaps in training could be attributed in part to the inspectors' inability to devote time to training due to high workloads.[38] Both agencies are in the process of improving training for program staff, including by hiring additional training specialists.[39]

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[26] APHIS would provide the lead inspector for all inspections of registered laboratories owned by CDC. In March 2015, the memorandum was amended to state that CC would lead inspections of all USDA-owned laboratories. *Id*. at 19-20.
[27] *Id*.
[28] *Id*. at 20-21.
[29] *Id*. at 23.
[30] *Id*. at 24.
[31] *Id*. at 24-25.
[32] *Id*. at 25.
[33] *Id*. at 26.
[34] *Id*. at 28.
[35] *Id*. at 27.
[36] *Id*. at 28.
[37] *Id*. at 30.
[38] *Id*. at 31.
[39] *Id*.

GAO found that the Select Agent Program shares limited information with the public, primarily due to security concerns. While the FSAP has recently increased its transparency, including by issuing its first public report on the program in 2016, GAO found that in order to increase public trust, there should be more transparency to the public about activities conducted at laboratory.[40] In addition, GAO found that more transparency for laboratories, including by sharing information between laboratories about research and incidents, would allow laboratories to learn from each other and improve their operations and biological safety and security.[41]

In response to a program violation, the Select Agent Program may take administrative action such as suspending or revoking a laboratory's registration, refer the violation to HHS Office of Inspector General or APHIS's Investigative and Enforcement Services, or refer violations to the Federal Bureau of Investigations.[42] The program has taken enforcement actions in the past, but has done so inconsistently and without a set of criteria.[43] In 2016, GAO recommended that the FSAP develop and implement criteria.[44] The CDC finalized and implemented such criteria in June of 2017, and in September 2017, the program finalized guidance on when to refer laboratories for violations and enforcement.[45]

GAO also found that the Select Agent Program lacks joint strategic planning documents to guide its oversight efforts. While each component has some form of strategic planning documents, they are fragmented in their goals and performance measures.[46] Strategic planning documents could improve oversight by enabling the program to set goals, measure progress, and collaborate across agencies. The FSAP is in the process of developing a joint strategic plan, and began soliciting bids for the plans development in August 2017.[47]

GAO also examined the oversight procedures at regulatory bodies in other countries and the other regulatory sectors in the United States. GAO found that in some regulatory sectors in both Great Britain and the United States, regulatory bodies benefit from structural independence from the entities they oversee. GAO examined Great Britain's Health and Safety Executive and the U.S. Atomic Energy Commission, and found that independence promoted objectivity and reduced potential conflicts of interest.[48]

GAO found that other countries, such as Great Britain and Canada target their reviews based on a history of laboratory incidents or to laboratories conducting high-risk activities.[49]

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[40] *Id*. at 33.
[41] *Id*. at 34.
[42] *Id*. at 35.
[43] *Id*. at 36.
[44] *Id*.
[45] *Id*. at 37.
[46] *Id*. at 38.
[47] *Id*. at 39.
[48] *Id*. at 41-42.
[49] *Id*. at 43-44.

Similarly, the Nuclear Regulatory Commission focuses its oversight on facilities that handle the most high-risk materials.[50]

To ensure that regulatory staff have appropriate expertise, regulatory bodies in Great Britain, France, and Germany rely on expert advisory committees that serve as a resource to staff.[51] In Canada and the Netherlands, laboratory personnel are primarily responsible for understanding and addressing the risks associated with the laboratory work.[52]

With respect to transparency, most countries and regulatory bodies tried to balance safety concerns with public trust. Great Britain's Health and Safety Executive, the Nuclear Regulatory Commission, and the Federal Aviation Administration share certain information about registered facilities, investigations and incidents, and safety data to inform the public, while still protecting information that could be misused.[53] The Netherlands also shares such information with the public, as well as making it available upon request.[54] Switzerland primarily makes such information available only by request.[55]

Regarding enforcement actions, GAO found that in the countries they reviewed, each had the ability to suspend or close laboratories for violations, and pursue criminal prosecution for serious violations.[56] In Canada, laboratory staff are sometimes given immunity from prosecution if they voluntarily report certain incidents.[57]

GAO made 11 recommendations to both agencies involved in overseeing the Select Agent Program. With respect to APHIS, GAO recommended:

- To improve independence, the Administrator of APHIS should formally document the reporting structure for the APHIS component of the Select Agent Program from the APHIS director of the program to the Administrator of APHIS.

With respect to both APHIS and CDC, GAO recommended that:

- To improve independence, the two agencies should work together to establish control activities to help ensure that each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding.

- To improve independence, the two agencies should work together to assess regularly the potential risks posed by the FSAP's structure and the effectiveness of its mechanisms to

[50] *Id*. at 46.
[51] *Id*. at 48.
[52] *Id*. at 49.
[53] *Id*. at 50-51.
[54] *Id*. at 50.
[55] *Id*.
[56] *Id*. at 51.
[57] *Id*. at 52.

address those risks, and take actions as necessary to ensure that any identified risks are addressed.

- To improve the ability to perform reviews, the two agencies should work together to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks by aligning oversight efforts to target those activities.

- To improve transparency, the two agencies should work together to determine what additional information about laboratories' use of select agents, incidents, and violations of the select agent regulations is appropriate for the program to share with registered laboratories.

- To improve technical expertise and overcome fragmentation, in conjunction with development of the strategic plan, the two agencies should work together to develop a joint workforce plan that assesses workforce and training needs for the program as a whole.

III. ISSUES

The following issues may be examined at the hearing:

- How do CDC and APHIS determine whether the federal select agent inspections they conduct are effective in improving biosecurity and biosafety at high-containment laboratories?

- Does the Federal Select Agent Program place too much emphasis in its inspections on biosecurity at the expense of biosafety?

- Is the organizational conflict-of-interest in the Federal Select Agent Program an acceptable cost for the access to technical expertise?

- Is legislation needed to help the Federal Select Agent Program meet the key elements of effective oversight?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin or Brighton Haslett at (202) 225-2927.