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CONCERNS OVER FEDERAL SELECT AGENT PROGRAM OVERSIGHT OF DANGEROUS PATHOGENS

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED FIFTEENTH CONGRESS

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CONCERNS OVER FEDERAL SELECT AGENT PROGRAM OVERSIGHT OF DANGEROUS PATHOGENS

THURSDAY, NOVEMBER 2, 2017

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:45 a.m., in room 2322 Rayburn House Office Building, Hon. Morgan Griffith (vice chairman of the subcommittee) presiding.

Members present: Representatives Griffith, Burgess, Brooks, Collins, Barton, Walberg, Walters, Costello, Carter, Walden (ex officio), DeGette, Tonko, and Ruiz.

Staff present: Jennifer Barblan, Chief Counsel, Oversight & Investigations; Kelly Collins, Staff Assistant; Zachary Dareshori, Staff Assistant; Ali Fulling, Legislative Clerk, Oversight & Investigations, Digital Commerce and Consumer Protection; Brighton Haslett, Counsel, Oversight & Investigations; Katie McKeogh, Press Assistant; Jennifer Sherman, Press Secretary; Alan Slobodin, Chief Investigative Counsel, Oversight & Investigations; Hamlin Wade, Special Advisor, External Affairs; Everett Winnick, Director of Information Technology; Christina Calce, Minority Counsel; Chris Knauer, Minority Oversight Staff Director; and Miles Lichtman, Minority Policy Analyst.

OPENING STATEMENT OF HON. H. MORGAN GRIFFITH, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF VIRGINIA

Mr. GRIFFITH. Good morning. I call the meeting of the Oversight Subcommittee to order.

Today the subcommittee examines the concerns over federal oversights of labs working with dangerous viruses and bacteria for research needed to protect public health and national security.

The Federal Select Agent Program under the joint management of the CDC and the USDA's Animal and Plant Health Inspection Services was established by legislation enacted in 2002, shortly after the 9/11 attacks and the anthrax mailings. These events supported Congress to conclude that certain dangerous pathogens, such as anthrax, smallpox, and plagues called select agents and toxins required regulation of its possession, use, and transfer.

The program oversees 276 registered laboratories and almost 4,000 individuals involved with vital research in the diagnostics,

vaccines, and medical countermeasures that save lives, protect American agriculture, and help protect the safety and security of the American people. In 2016, the program conducted 181 inspections of registered laboratories, and was notified of 177 separate incidents involving potential exposures with 998 lab workers monitored but, fortunately, with no illnesses developed.

Because of the importance of this work and its potential dangers, this subcommittee has convened hearings in recent years on safety lapses in federal high-containment laboratories: the anthrax incident at CDC that potentially exposed more than 80 CDC workers; a mistaken CDC shipment of deadly bird flu to a USDA lab; a U.S. Army lab's mistaken shipments of live anthrax samples for a decade to almost 200 different locations in the United States and around the world; and the FDA's discovery of decades-old, undeclared, and unregistered smallpox vials in a storage room the FDA had been renting from NIH and was missed by annual NIH safety inspections.

The pattern has been: incident involving handling of select agents, news stories, committee hearings, outrage, reaction, and short-term reform. Wash, rinse, repeat. The question before the subcommittee this morning is how do we break this pattern and instill a systematic approach toward oversight of federal select agents that improves safety and enhances the public's confidence.

The GAO's latest report adds urgency to this question. The GAO found that the program did not fully meet all key elements of effective oversight. That is troubling. Select agents are dangerous materials, posing a severe threat to human and animal health. One would have assumed that the oversight program for select agents would meet at least some of the effective oversight elements found at other government oversight programs for dangerous research, such as work involving radioactive materials and nuclear weapons. That is not the case.

For example, the GAO concluded that the program is not independent. Both CDC and APHIS, the joint managers of the program, have high-containment laboratories registered with the program. As a result, experts advise the GAO that the program cannot be entirely independent, as oversight of their own laboratories may represent a conflict of interest. One wonders whether or how this has impacted the program's oversight. Two years ago, the HHS Office of Inspector General reported to the committee was the CDC was the entity with the most referrals to the program—for program violations.

The GAO also found that experts and laboratory representatives raised concerns that the program's reviews did not target the highest-risk activities, such as anthrax inactivation, in part because it has not formally assessed which activities pose the highest risk. Thus, lab representatives told the GAO that the program focused on inventory controls and conducted time-consuming reviews so that nicknames such as Rob matched with registered names such as Robert.

On the other hand, as the subcommittee learned at its hearing in September of 2016, the incomplete inactivation of select agents, particularly anthrax, was a recurring problem in recent high-profile lab incidents. Unfortunately, the program has not focused on

the need for more specific reporting and investigation of incomplete inactivation of anthrax.

Technical expertise is another concern. Even with the recent extra hires, workforce and training gaps remain. The GAO has also noted the program did not have joint strategic planning documents to guide its oversight. It is perplexing how the CDC and APHIS operated for nearly 15 years without a joint strategic plan.

Finally, the GAO reviewed effective oversight approaches in selected foreign countries and regulatory sectors. For example, in Great Britain, oversight of laboratories that work with pathogens is under an independent government agency focused on health and safety. Under this structure, the agency has direct access to a department head with control over defining its own budget and staffing need without organizational conflict of interest.

The subcommittee will examine whether administrative responses are sufficient to help the program meet the key elements of effective oversight. However, it is also fair to ask whether Congress has a legislative role. This Program, at its inception, was created in a fragmented state, a marriage of two divisions from two sub-Cabinet agencies in different Cabinet departments. The program was created with a security emphasis of guards/guns/gates in response to terrorist attacks. Fifteen years later, does this regulatory model for bioresearch laboratories make the most sense with more concern about biosafety and the growing public health threat of emerging infectious diseases?

I welcome and thank our witnesses for appearing here today. I look forward to their testimony.

And with that, I yield back and now recognize the ranking member of the subcommittee, Ms. DeGette of Colorado.

[The prepared statement of Mr. Griffith follows:]

PREPARED STATEMENT OF HON. H. MORGAN GRIFFITH

Today, the subcommittee examines the concerns over federal oversight of labs working with dangerous viruses and bacteria for research needed to protect public health and national security.

The Federal Select Agent Program ("Program") under the joint management of the CDC and the USDA's Animal and Plant Health Inspection Service was established by legislation enacted in 2002, shortly after the 9/11 attacks and the anthrax mailings. These events spurred Congress to conclude that certain dangerous pathogens such as anthrax, smallpox and plague—called select agents and toxins—required regulation of its possession, use and transfer.

The Program oversees 276 registered laboratories and almost 4,000 individuals involved with vital research into diagnostics, vaccines, and medical countermeasures that saves lives, protects American agriculture, and helps protect the safety and security of the American people. In 2016, the Program conducted 181 inspections of registered laboratories, and was notified of 177 separate incidents involving potential exposures with 998 lab workers monitored but fortunately with no illnesses developed.

Because of the importance of this work and its potential dangers, this Subcommittee has convened hearings in recent years on safety lapses in federal high-containment laboratories:

- the anthrax incident at CDC that potentially exposed more than 80 CDC workers;
- a mistaken CDC shipment of deadly bird flu to a USDA lab;
- a U.S. Army lab's mistaken shipments of live anthrax samples for a decade to almost 200 different locations in the U.S. and around the world; and
- the FDA's discovery of decades-old, undeclared and unregistered smallpox vials in a storage room that FDA had been renting from NIH and was missed by annual NIH safety inspections.

The pattern has been: incident involving handling of select agents, news stories, committee hearing, outrage, reaction, and short-term reform. Wash, rinse, repeat. The question before the subcommittee this morning is how do we break this pattern, and instill a systematic approach toward oversight of federal select agents that improves safety and enhances public confidence.

The GAO's latest report adds urgency to this question. The GAO found that the Program did not fully meet all key elements of effective oversight. That is troubling. Select agents are dangerous materials, posing a severe threat to human or animal health. One would have assumed that the oversight program for select agents would meet at least some of the effective oversight elements found at other government oversight programs for dangerous research, such as work involving radioactive materials and nuclear weapons. That is not the case. For example, the GAO concluded that the Program is not independent. Both CDC and APHIS, the joint managers of the Program, have high-containment laboratories registered with the Program. As a result, experts advised the GAO that the Program cannot be entirely independent as oversight of their own laboratories may represent a conflict of interest. One wonders whether or how this has impacted the Program's oversight. Two years ago, the HHS Office of Inspector General reported to the committee that the CDC was the entity with the most referrals for Program violations.

The GAO also found that experts and laboratory representatives raised concerns that the Program's reviews did not target the highest-risk activities such as anthrax inactivation, in part because it has not formally assessed which activities pose the highest risk. Thus, lab representatives told the GAO that the Program focused on inventory controls and conducted time-consuming reviews so that nicknames such as "Rob" matched with registered names such as "Robert." On the other hand, as the subcommittee learned at its hearing in September 2016, the incomplete inactivation of select agents (particularly anthrax) was a recurring problem in recent high-profile lab incidents. Unfortunately, the Program had not focused on the need for more specific reporting and investigation of incomplete inactivation of anthrax.

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The GAO also noted the Program did not have joint strategic planning documents to guide its oversight. It is perplexing how the CDC and APHIS operated for nearly 15 years without a joint strategic plan.

Finally, the GAO reviewed effective oversight approaches in selected foreign countries and regulatory sectors. For example, in Great Britain, oversight of laboratories that work with pathogens is under an independent government agency focused on health and safety. Under this structure, the agency has direct access to a department head, with control over defining its own budget and staffing needs without organizational conflict of interest.

The subcommittee will examine whether administrative responses are sufficient to help the Program meet the key elements of effective oversight. However, it is also fair to ask whether Congress has a legislative role. This Program at its inception was created in a fragmented state—a marriage of two divisions from two subcabinet agencies in different Cabinet departments. The Program was created with a security emphasis of guards/guns/gates in response to terrorist attacks. Fifteen years later, does this regulatory model for bio-research laboratories make the most sense with more concern about biosafety and the growing public health threat of emerging infectious diseases?

I welcome and thank our witnesses for appearing here today. I look forward to the testimony.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you, Mr. Chairman.

Well, I can't really agree with you more that we need to look at this. You talk about when these protocols were put into place 15 years ago. I was on this subcommittee 15 years ago when we started having these hearings. And we have had quite a number of these hearings. Over the years, I have had quite a number of visits to the CDC in Atlanta. I was regaling Democratic committee staff last night with my stories of when I went to the former CDC lab up in Fort Collins, which deals with vector-borne diseases and

where they had these vector-borne diseases, aka West Nile, stored in modular units behind the building. And the units had grass growing up through the boards of the trailers and there were flies flying around in the trailers.

I am pleased to say that the Congressman from that area at that time, Bob Schaffer, and I were able to secure funding for a beautiful new facility up there in Fort Collins and they do have the vector-borne agents stored appropriately now.

But this just goes on and on and it is something that this subcommittee has to revisit over and over again. We have had so many near misses, as the chairman said, with pathogens like live anthrax, Ebola, most recently last November, the toxic form of ricin that was sent to a FEMA training center multiple times between 2011 and 2016.

At some point, something very bad is going to happen unless the CDC acts. And if that means that Congress has to assist in streamlining and improving the way that we handle these agents, then this committee and, I am sure—I see the chairman of the full committee here. I am sure the full committee would be eager to help because we can't just keep stumbling along like this from year to year.

The Select Agent Program has the vital task of ensuring that critical biodefense research proceeds without any danger to the health and safety of American citizens. And the Centers of Disease Control and the Animal and Plant Inspection Service, which jointly oversee the program, have to make sure that there is adequate oversight. But as the chairman just said, we are left today with the question of whether oversight of the Select Agent Program by both of these agencies is sufficient to guarantee that, on a consistent and long-term level, these high-containment labs are safely managing pathogens.

We have to remind ourselves that these pathogens have to be handled every time with utmost safety and security. We don't have room for error. We don't have room for accidental shipment of ricin here, hither, and yon. If these pathogens fall into the wrong hands or if infection occurs in the general public, it literally will be very difficult to put that genie back in the bottle. And so any amount of uncertainty in this area is just unacceptable.

I am glad that the GAO is here again today to discuss the most recent report on the Select Agent Program's oversight of dangerous pathogens. Like all of us, I am concerned about some of the findings of this report, particularly GAO's observation that the Select Agent Program may still not be applying the most effective approach to oversight at the laboratories that handle these programs.

For example, GAO concluded in the report, "The Program's reviews may not target the highest-risk activities, in part, because it has not formally assessed which activities pose the highest risk."

According to the report, the Select Agent Program inspectors may focus on concerns at laboratories, such as measures to deter theft, to the exclusion of biosafety concerns like how to handle or transfer pathogens. Both safety and security are essential concerns and both of these things are things that we have to work on together.

Now, I also want assurances that certain components of the CDC and APHIS are adequately staffed to oversee the Select Agent Program. For example, according to the GAO report, there has been a shortage of inspectors which has delayed the issuance of a number of post-inspection reports. If that is true, then some laboratories are allowing poor practices to continue for a longer period than necessary.

There are a number of other issues that are identified in the GAO's report that I am eager to hear the agency's response to. And in conclusion, I am pleased that they have continued their report on behalf of this committee to examine safety and oversight issues.

I am looking forward to hearing from everybody so that we don't have to come back here again next year or the year after, so that our constituents can rest easy and take this off of their ever-growing list of things that keep them up at night.

And with that, I yield back.

Mr. GRIFFITH. I thank the gentlelady.

I now recognize the chairman of the full committee, Mr. Walden of Oregon.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Mr. Vice Chairman, for holding this hearing on a really important issue involving how we can improve federal oversight of high-containment laboratories working with dangerous pathogens such as anthrax.

Our Federal Government needs to conduct critical research on diagnostic tests or vaccines to protect us from diseases, while safeguarding national security against bioterrorism. These are twin goals that are very important. To ensure the safety of lab scientists and the public, while also building confidence and support for this research, oversight of federal select agents is a matter that we need to make sure that we all get right.

In recent years, this subcommittee has held hearings on several safety lapses at federal labs that potentially exposed federal personnel and other individuals to hazardous biological agents. While the executive branch has taken several steps to improve lab safety since these lapses were first detected, the GAO's report on the Federal Select Agents Program oversight of dangerous pathogens shows that there are fundamental problems that have not been addressed by reactive short-term responses.

After nearly 15 years of existence, the program does not meet key elements of effective oversight and the co-managers of the program, the Centers for Disease Control and the USDA's Animal and Plant Health Inspection Service, lack a joint strategic document. The GAO's past work has found that such strategic planning is an essential tool to help agencies align their workforces with their missions and develop long-term strategies for recruiting, training, and retaining staff.

The GAO's report also provides potential solutions for improving select agent oversight. The Government Accountability Office reviewed alternative effective oversight approaches from the selected foreign countries. For example in Great Britain, oversight of the labs that work with pathogens is under an independent govern-

ment agency. Both Great Britain and Canada focus their oversight on biological safety, as opposed to the emphasis on biosecurity in the Federal Select Agent Program. Other regulatory sectors, such as the regulation of nuclear reactors, also offer potential solutions for improvement.

Finally, the GAO findings also suggest that it may be time for Congress to reexamine the structure and operations of the Federal Select Agent Program. Currently, the program is run by two different sub-Cabinet agencies from two different departments. Both agencies have high-containment labs registered with the Select Agent Program, an organizational conflict of interest because the overseers are not structurally distinct and separate from all the labs they oversee. So to address these concerns, the subcommittee needs to consider whether a legislative restructuring of the program is in order.

This program was also created in the immediate aftermath of 9/11 and those attacks and the attacks through anthrax mailings, with an understandable emphasis on biosecurity and close scrutiny of those who possess and transfer select agents and how the agents are secured. I was here when all that happened and, in fact, excluded from my own office because the anthrax had made its way into the Longworth Building.

However, nearly 15 years later, incidents at the high-containment labs have shown that primary risk lies with maintaining safety in the handling of these dangerous pathogens. And at a time of increased risk of emerging infectious diseases and the advent of gene editing, does an overhaul of the Federal Select Agent Program require legislation?

That is why we are here today, is to learn more from those of you involved. And I certainly appreciate the great work of the GAO so I want to thank you all for your participation and look forward to working in a bipartisan way to improve the Federal Select Agent Program.

With that, Mr. Vice Chair, I yield back the balance of my time.

[Prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Mr. Vice Chairman, for holding this hearing on the very important issue of improving federal oversight of high-containment laboratories working with dangerous pathogens such as anthrax.

Our federal government needs to conduct critical research on diagnostic tests or vaccines to protect us from diseases while safeguarding national security against bioterrorism. To ensure the safety of lab scientists and the public, while also building confidence and support for this research, oversight of federal select agents is a matter we need to get right.

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After nearly 15 years of existence, the program does not meet key elements of effective oversight, and the co-managers of the program—the Centers for Disease Control and the USDA's Animal and Plant Health Inspection Service—lack a joint strategic document. The GAO's past work has found that such strategic planning is an essential tool to help agencies align their workforces with their missions and develop long-term strategies for recruiting, training, and retaining staff.

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However, nearly 15 years later, incidents at the high-containment labs have shown that the primary risk lies with maintaining safety in the handling of these dangerous pathogens. At a time of increasing risks of emerging infectious diseases and the advent of gene-editing, does an overhaul of the Federal Select Agent Program require legislation?

I thank the witnesses for their participation, and look forward to working in a bipartisan way to improve the Federal Select Agent Program.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. I appreciate that.

I would ask unanimous consent that members' written opening statements may be made part of the record. Without objection, they will be entered into the record.

I would now like to introduce our panel of witnesses for today's hearing. First we have Dr. Mary Denigan-Macauley, the Acting Director for Health Care at the Government Accountability Office. Next, is Dr. Samuel Edwin, who serves as the Director of the Division of Select Agents and Toxins at the Centers for Disease Control and Prevention. And finally, we have Dr. Freeda Isaac, who is the Director of Agriculture Select Agent Services at the Animal and Plant Health Inspection Service.

Thank you all for being here today and providing testimony. We look forward to the opportunity to discuss concerns, and hopefully solutions, over the Federal Select Agent Program. As you are aware, the committee is holding an investigative hearing and when doing so, we have the practice of taking testimony under oath. Do any of you have objection to testifying under oath?

Seeing no objection, the Chair then advises you that you are under the rules of the House and the rules of the committee. You are entitled to be accompanied by counsel. Do any of you desire to be accompanied by counsel during your testimony today?

Again, seeing a negative response that they do not wish to have counsel, I would then, in that case, ask you if you would please rise and raise your right hand.

[Witnesses sworn.]

Mr. GRIFFITH. All right, thank you very much. I am putting this down for the record that each of the witnesses has responded in the affirmative.

You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute summary of your written statement.

Ms. DEGETTE. Mr. Chairman?

Mr. GRIFFITH. Yes.

Ms. DEGETTE. Before we start with the statements, can I ask unanimous consent to put Mr. Pallone's opening statement in the record?

Mr. GRIFFITH. Absolutely. Without objection, Mr. Pallone's opening statement is placed into the record.

All right, we are going to start with Dr. Denigan-Macauley. If you would, give your 5-minute opening statement.

STATEMENTS OF MARY DENIGAN-MACAULEY, ACTING DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE; SAMUEL EDWIN, DIRECTOR, DIVISION OF SELECT AGENTS AND TOXINS, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND DR. FREEDA ISAAC, DIRECTOR, AGRICULTURE SELECT AGENT SERVICES, ANIMAL AND PLANT HEALTH INSPECTION SERVICE

STATEMENT OF MARY DENIGAN-MACAULEY

Ms. DENIGAN-MACAULEY. Good morning, Vice Chairman Griffith, Ranking Member DeGette, and other subcommittee members. Thank you for the opportunity to testify today on the federal oversight of the Select Agent Program.

GAO has, for many years, identified challenges and recommended ways for improving the oversight of high-containment labs. These labs work with the most dangerous pathogens, such as the Ebola virus, requiring the highest safeguards. Agencies have made progress implementing our recommendation. However, my main point today is that oversight of these pathogens is not as strong as it should be, potentially allowing for grave consequences.

In our most recent review, we found that the Federal Select Agent Program does not meet criteria for effective oversight. These criteria have been used to assess oversight of other areas with low probability adverse events that can have significant consequences. An example of such an event is the Fukushima Daiichi nuclear accident in Japan in 2011.

Of the five criteria, I would like to highlight two this morning: independence and the ability to perform reviews.

First, according to our criteria, the organization conducting oversight should be structurally distinct and separate from the entities it oversees. The Select Agent Program is not. Both CDC and APHIS have labs registered with the program. CDC and APHIS have taken steps to reduce conflicts of interest. For example, in 2012, the agencies developed an MOU under which APHIS leads inspections of CDC labs. However, there was no reciprocal agreement for CDC to lead inspections of APHIS labs until 3 years later and we found that the agreement was not always followed.

Second, according to our criteria, the organization conducting oversight should have the ability to perform reviews. The Select Agent Program performs several types of reviews, including inspections. There is concern, however, that inspections do not target the highest risk activities. The program, in its current form, was borne from the horrific incidents of 9/11. Therefore, it is focused on security and inspectors spend considerable time assessing compliance

with inventory controls and reviewing records. While this can be helpful to know what is stored in the lab, it does little to reduce the risk of theft.

Very small amounts of material can be removed from vials and replicated without being detected. Moreover, recent high-profile incidents have been related to biosafety rather than security and no thefts have been reported in well over a decade.

It's interesting to note that other countries and regulatory sectors we reviewed approach oversight differently. For example in Great Britain, an independent government agency oversees labs and they apply a risk-based approach to inspections, targeting those with a history of performance issues or those conducting higher risk activities. They also focus on biosafety rather than biosecurity.

Besides not meeting the criteria, the program also does not have joint planning documents to guide its oversight efforts. Notably, it does not have a joint workforce plan to help it manage workforce challenges that we found. For example, CDC and APHIS have faced challenges hiring and retaining sufficient staff with the necessary expertise. Inspectors have a large workload and intensive travel schedule that has led to delays in issuing inspection reports.

In 2016, CDC took up to 224 days to issue some of its inspection reports, far exceeding the program's 30-day target and delaying fixes to any identified problems. Workload issues have also sometimes resulted in staff from APHIS being assigned responsibilities outside their area of expertise.

In conclusion, CDC and APHIS share a critical role ensuring that important work with select agents can be conducted in a safe and secure manner. The bottom line is that oversight needs to be strengthened.

Moving forward, the Federal Select Agent Program needs to take several steps, including assessing the potential risks posed by placing the program within APHIS and CDC, identifying and aligning efforts with activities that carry the highest risks, and developing a joint workforce plan. As these steps are taken, consideration could also be given to alternate oversight approaches.

Vice Chairman Griffith, Ranking Member DeGette, and other subcommittee members, this concludes my statement. I look forward to your questions.

[The prepared statement of Ms. Denigan-Macauley follows:]

United States Government Accountability Office

Testimony

Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

For Release on Delivery
Expected at 10:15 a.m. ET
Thursday, November 2, 2017

HIGH-CONTAINMENT LABORATORIES

Coordinated Efforts Needed to Further Strengthen Oversight of Select Agents

Statement of Mary Denigan-Macauley, Ph.D.
Acting Director, Health Care

GAO-18-197T

Vice Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee:

I am pleased to be here today to discuss our recent work on the oversight of select agents in high-containment laboratories in the United States.[1] Safety lapses have occurred at laboratories in the United States that conduct research on hazardous pathogens and toxins (known as select agents) that may pose a serious threat to humans, animals, or plants.[2] These lapses raise concerns about whether federal oversight of these laboratories is effective. For example, in November 2016, the Department of Homeland Security discovered that a private laboratory had inadvertently sent a toxic form of ricin (a potentially lethal poison) to one of its training centers multiple times since 2011, potentially putting training participants at risk. In May 2015, the Department of Defense (DOD) discovered that a DOD laboratory had inadvertently shipped live anthrax bacteria to nearly 200 other laboratories worldwide over the course of 12 years. And in July 2014, the National Institutes of Health discovered decades-old vials of smallpox in a storage room of a Food and Drug Administration laboratory on its campus.[3]

We have, for many years, identified challenges and areas for improvement related to the safety, security, and oversight of high-containment laboratories. In 2009, for example, we found a proliferation of high-containment laboratories across the United States, with the number of such laboratories in the government, academic, and private sectors

[1]GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145 (Washington, D.C.: Oct. 19, 2017). Laboratories that conduct research on pathogens fall into one of four biological safety levels (BSL), with those at BSL-3 and -4 referred to as high-containment laboratories for the purpose of this statement. Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular agents. BSL-3 laboratories work with indigenous or exotic agents with known potential for airborne transmission or pathogens that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic agents that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available.

[2]As of March 2017, 66 agents and toxins have been designated as "select agents and toxins"—that is, as needing specific types of safeguards and oversight. For the purpose of this statement, we use the term "select agents" to encompass both designated agents and toxins.

[3]According to agency documents, none of these three incidents resulted in human infection, severe illness, or death.

increasing since 2001.[4] In addition, we found that there was no single entity overseeing this proliferation, and that no federal agency knew how many such laboratories existed in the United States or the aggregate risks associated with the proliferation. We also found in 2009 and 2014 that, for the subset of these laboratories subject to federal oversight, the oversight was duplicative, fragmented, and dependent on self-policing.[5] More recently, we found in 2016 that stronger oversight mechanisms for federal high-containment laboratories were needed at the individual federal department and component agency levels.[6] We have made numerous recommendations over the years, including that a single entity be identified to determine the number of high-containment laboratories needed to meet national goals, the aggregate risks associated with the proliferation of laboratories, and the type of oversight needed.[7] Federal departments have made some progress in implementing recommendations from our past reports, including addressing issues we identified regarding duplicative oversight. However, the United States still has not identified a single entity to perform the functions we recommended.

All high-containment laboratories in the United States that register to work with select agents are regulated by the Federal Select Agent Program (which this statement subsequently refers to as the Select Agent Program),[8] through which two agencies share oversight responsibility.

[4]GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

[5]GAO, *Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program*, GAO-13-154 (Washington, D.C.: Jan. 31, 2014) and GAO-09-574. According to our past work, fragmentation refers to those circumstances in which more than one federal agency (or more than one organization within an agency) is involved in the same broad area of national need and opportunities exist to improve service delivery. GAO, *2017 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-17-491SP (Washington, D.C.: Apr. 26, 2017).

[6]GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305 (Washington, D.C.: Mar. 21, 2016).

[7]GAO-09-574.

[8]Entities that register with the Select Agent Program may include a single laboratory or multiple laboratories under one registration. For the purpose of this statement, we refer to all entities registered with the program as "laboratories." Some BSL-2 laboratories are registered with the Select Agent Program, but most registered entities are BSL-3 and -4 high-containment laboratories. For our October 2017 report, we focused on oversight of select agents in high-containment laboratories.

Specifically, oversight is shared by the Division of Select Agents and Toxins within the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and the Agriculture Select Agent Services within the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). The program was established to regulate the possession, use, and transfer of select agents in response to security concerns following bioterrorism attacks in the 1990s and early 2000s.

Other countries also regulate and oversee hazardous pathogens handled in high-containment laboratories, and they sometimes take approaches that differ from that of the United States. Moreover, other high-risk sectors in the United States, such as the nuclear industry, sometimes take different approaches to oversight. Notwithstanding such differences, our past work reviewing some of these sectors has identified five key elements of effective oversight in areas where low-probability adverse events can have significant and far-reaching effects.[9] These elements are as follows:

- **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.

My remarks today are based on our October 2017 report on the oversight of select agents in high-containment laboratories. Our report

[9]In particular, we have used these elements for reviews related to oversight of nuclear safety and oil and gas management. See GAO, *Nuclear Safety: Department of Energy Needs to Strengthen Its Independent Oversight of Nuclear Facilities and Operations*, GAO-09-61 (Washington, D.C.: Oct. 23, 2008) and *Oil and Gas Management: Key Elements to Consider for Providing Assurance of Effective Independent Oversight*, GAO-10-852T (Washington, D.C.: June 17, 2010).

(1) examined the extent to which the Select Agent Program has the elements of effective oversight and has strategic planning documents to guide its oversight efforts, and (2) described approaches that selected countries and regulatory sectors have used to promote effective oversight. Today, I will discuss key findings and recommendations from that report.

For our report, we discussed the five key elements of effective oversight above with agency officials, experts, and representatives from nongovernmental organizations to ensure their applicability to the oversight of select agents. We reviewed laws, regulations, and documents related to the Select Agent Program to determine the extent to which the program met the key elements. We also interviewed officials from CDC and APHIS and registered laboratories to discuss the program's inspections and other oversight responsibilities and other issues related to the five key elements. To obtain expert views on the effectiveness of the approaches the Select Agent Program and other selected countries and regulatory sectors have used to promote effective oversight, we worked with the National Academy of Sciences to convene a 2-day meeting with 18 experts. We also reviewed relevant documentation and interviewed regulatory officials from selected countries—including the United Kingdom and Canada—and other sectors such as nuclear energy. More detailed information on the scope and methodology of our work can be found in the October report. The work upon which this statement is based was conducted in accordance with generally accepted government auditing standards.

In summary, we found that the Select Agent Program does not fully meet all key elements of effective oversight. For example, the program is not structurally distinct and separate from all laboratories it oversees and, therefore, does not meet the key element of independence. Regarding another key element—the ability to perform reviews—some experts and laboratory representatives raised concerns that the program's reviews may not target the highest-risk activities, in part because it has not formally assessed which activities pose the highest risk. Moreover, the program does not have joint strategic planning documents, including a joint workforce plan, to guide its shared oversight efforts. We made 11 recommendations to address these issues. HHS and USDA agreed with our recommendations and outlined actions they are taking, or plan to take, to address them.

Select Agent Program Does Not Fully Meet Key Elements of Effective Oversight or Have Joint Strategic Planning Documents to Guide Its Efforts

The Select Agent Program does not fully meet key elements of effective oversight. In particular, the program has oversight shortcomings related to each of our five key elements: independence, performing reviews, technical expertise, transparency, and enforcement. In addition, the program does not have joint strategic planning documents to guide its oversight efforts, such as a joint strategic plan and workforce plan. It did, however, begin taking steps to develop a joint strategic plan during the summer of 2017.

First, regarding independence, the Select Agent Program is not structurally distinct and separate from all of the laboratories it oversees because the two components of the Select Agent Program are located in CDC and APHIS, both of which also have high-containment laboratories registered with the program. Many experts at our meeting raised concerns that the Select Agent Program cannot be entirely independent in its oversight of CDC and APHIS laboratories because the Select Agent Program is composed of divisions of those agencies. To help reduce conflicts of interest, the program has taken steps such as having APHIS lead inspections of CDC laboratories. However, it has generally done so in response to concerns raised by others. The program itself has not formally assessed all potential risks posed by its current structure and the effectiveness of its mechanisms to address those risks. The Office of Management and Budget's Circular A-123 requires federal agencies to integrate risk management activities into their program management to help ensure they are effectively managing risks that could affect the achievement of agency objectives.[10] In addition, federal internal control standards state that management should identify, analyze, and respond to risks related to achieving defined objectives.[11] Without (1) regularly assessing the potential risks posed by the program's current structure and the effectiveness of its mechanisms to address them and (2) taking actions as necessary to ensure any identified risks are addressed, the

[10]Office of Management and Budget, *Management's Responsibility for Enterprise Risk Management and Internal Control* (Washington, D.C.: July 15, 2016).

[11]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999), and *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). GAO/AIMD-00-21.3.1 was effective through the end of fiscal year 2015 (Sept. 30, 2015). GAO-14-704G is the 2014 revision of GAO/AIMD-00-21.3.1 and became effective the first day of fiscal year 2016 (Oct. 1, 2015).

program may not be aware of or effectively mitigate impairments to its independence that could affect its ability to achieve its objectives.

Second, regarding the ability to perform reviews, we found that the Select Agent Program performs several types of reviews to ensure compliance with regulatory and program requirements. However, the program may not target the highest-risk activities in its inspections, in part because it has not formally assessed which activities pose the highest risk to biological safety and security.[12] For example, many experts at our meeting and laboratory representatives we interviewed raised concerns about the amount of time inspectors spend assessing compliance with inventory controls (e.g., by counting and examining vials containing select agents) and reviewing inventory records during the inspection process, which takes time away from inspecting other aspects of biological safety and security. Experts at our meeting said that these activities do little to reduce the risk of theft of select agents (a security concern) because samples could be clandestinely removed from vials and replicated without being detected by the inventory controls currently in place. Further, other laboratory representatives told us that activities to assess compliance with certain program requirements, such as time-consuming reviews of records, did little to reduce risk and were unnecessarily burdensome to both researchers and inspectors. These inspection activities are generally intended to address biological security concerns; however, recent high-profile incidents at registered laboratories have concerned biological safety rather than security.

To improve the inspection process and identify trends and associations between inspection findings and risk, a 2015 internal review of the CDC component of the Select Agent Program recommended that the CDC and APHIS components of the program work together to analyze inspection and investigation data. According to program officials, they have not yet addressed the recommendation because they do not currently have adequate tools to do so, but the program is transitioning to a new database that will enhance their ability to identify trends and associations and thereby guide improvements to the inspection process. However, the program did not provide a plan for when or how the program will carry out

[12]We found in our past work that, according to experts and CDC officials, there is a baseline risk associated with any high-containment laboratory and that the risks from accidental exposure or release can never be completely eliminated. GAO, *High-Containment Laboratories: Recent Incidents of Biosafety Lapses*, GAO-14-785T (Washington, D.C.: July 16, 2014).

these analyses to improve the inspection process. Federal internal control standards state that management should identify, analyze, and respond to risks related to achieving defined objectives.[13] Without developing and implementing a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities, the Select Agent Program will not have assurance that it is effectively balancing the potential safety and security gains from its oversight efforts against the use of program resources and the effect on laboratories' research.

We also found that the Select Agent Program did not fully meet the other three key elements of effective oversight: technical expertise, transparency, and enforcement. For example, although the program has taken steps to hire additional staff and enhance the technical expertise of its staff, workforce and training gaps remain. In addition, although the program has increased transparency about registered laboratories and violations of the select agent regulations to the public and registered laboratories since 2016, the information it shares is limited and there is no consensus about what additional information could be shared, given security concerns. Lastly, although the program has authority to enforce compliance with program requirements, it is still working to address past concerns about the need for greater consistency and clarity in actions it takes in exercising this authority.

In addition to not fully meeting the five key elements of effective oversight, we found that the Select Agent Program does not have joint strategic planning documents to guide its shared oversight efforts across CDC and APHIS. For example, the program does not have a joint mission statement to collectively define what the program seeks to accomplish through its oversight. It also does not yet have a strategic plan. Agencies can use strategic plans to set goals and identify performance measures for gauging progress towards those goals. Strategic plans can also outline how agencies plan to collaborate with each other to help achieve goals and objectives. The program began taking steps to develop a joint strategic plan during the course of our review and, in August 2017, began soliciting bids from contractors for the plan's development. The statement of work for the contract stipulates that the contractor shall develop guiding principles for the Select Agent Program along with a mission statement

[13]GAO/AIMD-00-21.3.1 and GAO-14-704G.

and strategic goals and objectives, among other requirements. However, it does not have any requirements related to development of a joint workforce plan. We have found in the past that agencies' strategic workforce planning should be clearly linked to the agency's mission and long-term goals developed during the strategic planning process.[14] Developing a joint workforce plan that assesses workforce and training needs for the program as a whole would help the program to better manage fragmentation by improving how it leverages resources to ensure all workforce and training needs are met. Leveraging resources is especially important given fiscal constraints.

In our report, we recommended that CDC and APHIS take several steps to address these findings. First, we made five recommendations to improve independence, including that CDC and APHIS regularly assess the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks, and take actions as necessary to ensure any identified risks are addressed so that impairments to independence do not affect its ability to achieve its objectives. Second, to improve the ability to perform reviews, we recommended that the directors of the Select Agent Program work together to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities. We also made several other recommendations, including recommending that the directors of the Select Agent Program develop a joint workforce plan that assesses workforce and training needs for the program as a whole.

Selected Countries and Regulatory Sectors Employ Other Approaches to Promote Effective Oversight

Selected countries and regulatory sectors employ approaches to promote effective oversight that sometimes differ from those of the Select Agent Program by, for example, having regulatory bodies that are structurally independent from the entities they oversee or taking a risk-based approach to performing reviews. To illustrate, with regard to independence, Great Britain's Health and Safety Executive, whose mission is to protect worker and public health and safety and which oversees laboratories that work with pathogens, is an independent government agency. According to officials from the Health and Safety

[14]GAO, *Human Capital: Key Principles for Effective Strategic Workforce Planning*, GAO-04-39 (Washington, D.C.: Dec. 11, 2003).

Executive and laboratory representatives, one strength of this approach is that it avoids potential organizational conflicts of interest because none of the laboratories it oversees are part of the same agency. Some other regulatory sectors in the United States, including the Nuclear Regulatory Commission (NRC), are also structurally independent from regulated facilities as a mechanism to ensure independence. Prior to the creation of NRC in 1974, the U.S. Atomic Energy Commission was responsible for both promotion and oversight of the nuclear industry. The Energy Reorganization Act of 1974 established NRC as a separate, independent entity. According to a Senate committee report, this was a response to growing criticism that there was a basic conflict between the U.S. Atomic Energy Commission's regulation of the nuclear power industry and its development and promotion of new technology for the industry.[15]

Related to the ability to perform reviews, regulators in Great Britain and Canada apply a risk-based approach by targeting laboratories with a documented history of performance issues or those conducting higher-risk activities. In both Great Britain and Canada, the organizations that oversee laboratories generally focus their oversight on (1) biological safety, and (2) regulation of all potentially hazardous pathogens in laboratories. In contrast, the Select Agent Program originated from security-related concerns and regulates only those pathogens identified on the U.S. select agent list and no other pathogens that may be handled in high-containment but are not select agents, such as West Nile virus.

Other differences we found in approaches include relying on scientists and other laboratory personnel to have requisite technical expertise on the pathogens and activities in their laboratories, sharing incident information on their public websites, and having prosecutorial authority when incidents occur.

In conclusion, CDC and APHIS share a critical role in ensuring that important research on select agents can be conducted in high-containment laboratories in a safe and secure manner. The Select Agent Program has made a number of improvements over the past few years, such as hiring additional staff and improving training to enhance expertise. Nevertheless, the program does not fully meet all key elements of effective oversight and more is needed to develop joint strategic plans

[15]S. Rep. No. 93-980 at 2 (1974).

to collectively guide its shared oversight efforts. In our prior work, we have found that existing federal oversight of high-containment laboratories is fragmented and largely self-policing, among other things. Our October 2017 report, in combination with these past findings, continues to raise questions about whether the current government framework and oversight are adequate.

Vice Chairman Griffith, Ranking Member DeGette, and Members of the Subcommittee, this concludes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

GAO Contacts and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact Mary Denigan-Macauley, Ph.D., Acting Director, Health Care, at (202) 512-7114 or deniganmacauleym@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Individuals who made key contributions to this statement include Sushil Sharma, Ph.D., Dr.PH (Assistant Director); Amy Bowser; Caitlin Dardenne, Ph.D.; John Neumann; Cynthia Norris; Timothy M. Persons, Ph.D.; and Lesley Rinner. Staff who made key contributions to the report(s) cited in the statement are identified in the source products.

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Mr. GRIFFITH. I thank the gentlelady for yielding back.

I now recognize Dr. Edwin for a 5-minute opening statement.

STATEMENT OF SAMUEL EDWIN

Mr. EDWIN. Thank you, Mr. Chairman, Ranking Member DeGette, and members of the subcommittee. I am Dr. Sam Edwin, Director of the Division of Select Agent and Toxins, which resides within the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention. I, along with my counterpart, Dr. Freeda Isaac, direct the Federal Select Agent Program.

I have held this position for just over 1 year and welcome this opportunity to testify before you. I appreciate the subcommittee's continued interest in improving oversight of laboratories that work with select agents and toxins.

Laboratory research on select agents and toxins plays a critical role in saving lives and protecting Americans. It is also an important part of our nation's contribution to support preparedness and defense against naturally-occurring diseases and potential bioterrorism events. Maximizing safety and security through our oversight is a complex and unending endeavor, not something that can be checked off a list.

I would like to acknowledge the important contributions that GAO's continued engagement and recommendations have made in our work to improve the program. We accept and will implement each of the five recommendations for CDC in the current GAO report. This morning, I will highlight actions that we have already taken in several of the areas addressed in the report.

First, our program has taken a number of steps to identify highest risk activities conducted at the registered laboratories and ensure that these activities are targeted during inspections. We determined risk based on the type of work being done by a particular entity and modify the frequency and focus of the inspections based on the findings at each inspection. When our program identifies what appears to be a commonly used processes that present a high risk, we target inspection to reduce that risk across all of the registered entities.

We are in the process of transitioning to a new electronic information system which will provide real-time access to each registered entity's key program information and documents. After it is fully implemented, we will have the ability to monitor and analyze the data in real-time to identify potential risks, improve the inspection process, and continually enhance overall biosafety and security oversight.

Second, in the area of enforcement authority, we are taking steps to assess risk from violations at individual facilities, as well as identify and address recurring violations. We recently finalized an effort to evaluate categories of noncompliance with select agent regulations, group them according to the level of severity, and enforcement options. We used this information to ensure consistency between inspections.

Third, regarding the technical expertise, our program has inspectors who have the necessary practical experience and advanced professional degrees. That said, continued training of inspection staff

is a key priority that we continually refine to address training needs.

In addition, we are in the early stages of developing a joint strategic plan for the Federal Select Agent Program. This includes assessment of workforce and training needs for staff across the program.

Fourth, we have taken a number of steps to increase transparency and collaboration with the regulated community, including developing a process where we respond to requests for clarification regarding the select agent regulations. We also share draft policies and guidance documents for their input prior to finalizing, and we also implemented a process for dispute of inspection findings, and analyzing and reporting of the aggregate program data annually. The most recent report was just published last week.

We are committed to further strengthening oversight of laboratories that handle select agents and toxins and appreciate the involvement of GAO and others that have provided recommendations toward that end. We value of the subcommittee's input as we continue to improve our oversight and enhance the safety and security of this work.

Thank you for the opportunity to testify. I would be glad to answer any questions that you may have.

[The prepared statement of Mr. Edwin follows:]

Written Testimony
House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations

Oversight of Hazardous Pathogens under the Federal Select Agent Program

Statement of

Samuel S. Edwin, PhD

Director, Division of Select Agents and Toxins
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
Department of Health and Human Services

For Release upon Delivery
Expected at 10:15 a.m.
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Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Samuel S. Edwin, Director of the Division of Select Agents and Toxins (DSAT), which resides within the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention (CDC). I -- along with my counterpart at the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service/Agriculture Select Agent Services (AgSAS), Dr. Freeda Isaac -- direct the Federal Select Agent Program (FSAP or program). I have held this position for just over one year, and welcome this opportunity to testify before you. I appreciate the Subcommittee's continued interest in improving oversight of laboratories that work with select agents and toxins to ensure that this important work is done in as safe and secure a manner as possible.

Laboratory research on biological select agents and toxins plays a critical role in saving lives and protecting Americans. It is also an important part of our nation's contribution to support preparedness and defense against naturally occurring diseases and potential bioterrorism events. However, the nature of scientific laboratory work with these materials means that some risk is always present. Our goal is to reduce risk to the maximum extent possible.

I will provide a brief background of our program and CDC's role and responsibilities implementing the FSAP, followed by a discussion of steps taken to strengthen the FSAP and enhance the safety and security of high-containment laboratories regulated under this program.

Background on the Federal Select Agent Program

The regulation of select agents and toxins is a shared federal responsibility involving the Department of Health and Human Services (HHS), Department of Agriculture, and Department of Justice (DOJ). The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) authorizes HHS to regulate the possession, use, and

transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The Secretary of HHS delegated this authority to CDC. USDA was given similar authority to regulate select agents and toxins that have the potential to pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting security risk assessments of entities and individuals prior to their possession, use, or transfer of select agents or toxins. DOJ delegated this authority to the Federal Bureau of Investigation (FBI). This oversight helps prevent access to these pathogens and toxins by terrorists or others who may wish to misuse them.

The FSAP promotes laboratory biosafety and security through: (1) promulgating, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR 331); (2) providing guidance to the regulated community; and (3) inspecting facilities that work with select agents and toxins to verify that the laboratories meet safety, security and record-keeping requirements. Under these regulations, entities must undergo a rigorous registration process and obtain approval before they can possess and work with select agents and toxins. At the end of 2016, 276 entities -- including academic, non-federal government, federal government, and private laboratories -- were registered with the FSAP to possess select agents and toxins. The program currently regulates 66 select agents and toxins. The list of biological select agents and toxins is reviewed at least once every two years to determine if agents or toxins need to be added to or deleted from the list.

Key functions and activities of the FSAP include:

- Maintaining a national database of entities and individuals authorized to work with select agents and toxins. This database serves several functions, including: allowing the program to proactively reach out to entities in advance of and following natural disasters

or other events to ensure all select agents and toxins are properly secured; and enabling the federal government to quickly identify those authorized to have access to particular agents, when needed, in connection with an investigation;

- Establishing requirements to prevent unauthorized access to, or theft, loss, or release of, select agents and toxins, and assessing compliance of registered entities with these requirements;
- Receiving reports of theft, loss, or release, following up with each entity to ensure appropriate actions are taken to prevent similar incidents from happening in the future, and notifying appropriate authorities;
- Taking appropriate enforcement action when deficiencies in biosafety or security measures are identified, including referring a matter to the HHS Inspector General (HHS IG) or the FBI, to address the risk and increase compliance with regulations in the future; and
- Serving as a resource on the regulations by providing guidance to those working with select agents and toxins, interpreting the regulations to help entities follow the requirements, and conducting training and outreach to increase knowledge of and compliance with the regulations.

Strengthening Oversight under the FSAP Program

Maximizing safety and security through oversight at the FSAP-regulated laboratories is an unending endeavor, not something that can be checked off a list. I would like to acknowledge the important contribution that the Government Accountability Office's (GAO) continued engagement and recommendations for FSAP have made in our work to improve the program.

DSAT accepts and will implement all of GAO's recommendations in its current report. Below I will highlight some steps that DSAT, in partnership with USDA, has taken to strengthen oversight of facilities registered to work with select agents and toxins. And you have my commitment to continue efforts to improve the system for oversight of these facilities.

Independence:

To ensure our independence in regard to our role in regulating laboratories, DSAT entered into a Memorandum of Understanding (MOU) with AgSAS in 2012, under which AgSAS leads all select agent inspections of CDC laboratories. AgSAS and DSAT recently modified the MOU by strengthening procedures to delineate roles and responsibilities to ensure each component of the FSAP carries out its inspection responsibilities as outlined in the MOU. The MOU supplements structural safeguards that have been in place since 2003: DSAT is located within the Office of Public Health Preparedness and Response (OPHPR), a part of CDC that does not include any laboratories and has a separate reporting line to the CDC Director. We believe that the MOU designating AgSAS as the lead inspector for CDC laboratories, and the organizational separation between DSAT and CDC's regulated laboratories, provide strong protections against any actual or perceived conflict of interest.

Ability to Perform Reviews: Risk-Based Oversight:

The FSAP has taken a number of steps to identify the highest risk activities conducted at registered entities and ensure that these activities are targeted in inspections.

As part of the initial inspection to determine whether to approve an entity's application for FSAP registration, which authorizes the entity to conduct specified work with select agents and toxins, the FSAP establishes a baseline that identifies the biological safety and security risk of the work to be done with each select agent or toxin the entity will possess. The program can

then, based on findings in the course of follow-up inspections, reassess the baseline risk, the mitigation factors in place to reduce the risk, and the residual risk such as any identified departures from the biosafety and security requirements of the select agent regulations. FSAP can determine the frequency of verification inspections at an entity based on the initial risk assessment, in conjunction with any findings or assessments from subsequent inspections or reassessments, incidents or compliance matters. In addition, FSAP identifies inspection findings as having a low, moderate, or high severity, based on the risk they pose. This contributes to the assessment of risk at an individual facility and enhances our ability to identify and address across the regulated community recurring violations that pose the greatest risk.

Also at a programmatic level, when FSAP identifies processes that present a high risk, the FSAP works to reduce that risk across registered entities, as applicable. Such was the case in response to incidents in 2014 – 2015 involving incomplete inactivation of *Bacillus anthracis* spores that are produced by the bacteria that causes anthrax. FSAP requested that registered entities observe a voluntary moratorium on the transfer and use of anthrax samples that had undergone inactivation, and subsequently amended the select agent regulations to specifically address inactivation. On January 19, 2017, FSAP published the Final Rule "Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements" that included additional biosafety requirements and specific provisions for the inactivation of select agents. In conjunction with publication of the new regulatory provisions, FSAP published a guidance document on the inactivation or removal of select agents and toxins for future use.

In addition, FSAP is in the process of transitioning to a new electronic information system, eFSAP. This system will allow the regulated community to interact with the program more

efficiently and allow for better and faster reporting of issues of potential public health concern. After eFSAP is implemented, FSAP will have greater real-time access to programmatic data such as registration amendments to change the number of select agents used at a facility, changes in personnel authorized to work with select agents and toxins, transfers of select agents to other facilities, and inspection reports. This access will expedite and enhance the ability of FSAP to monitor and analyze the data and identify potential risk, and thereby continually enhance oversight of biosafety and security.

Technical Expertise:

FSAP inspectors have the practical experience and advanced professional degrees (e.g., microbiology and veterinary medicine) necessary to perform reviews of select agent laboratories. That said, continued training of inspection staff is a key priority for the FSAP, and we have a robust training program for inspectors that we continually refine to address unmet training needs. FSAP training initiatives include sending staff to a multi-day in-person training course on biosafety level -3 (BSL-3) safety training and expanded opportunities for intensive BSL-4 training. In addition, FSAP holds regularly scheduled inspector training opportunities, occurring monthly or more frequently depending on the topic covered. Topics for these sessions include natural disaster response, facility reviews, facility security, and biosafety issues of interest. FSAP also organizes annual inspector trainings for both DSAT and AgSAS inspectors. The annual FSAP inspector training for 2017 is scheduled for this week (November 1-3, 2017). In addition, the FSAP is in the early stages of developing a joint DSAT (public health) and AgSAS (agriculture) strategic plan that includes assessment of workforce and training needs for staff across the program.

Transparency:

The FSAP has taken a number of steps to increase transparency and collaboration with the regulated community, including:

- Developing a formal process to publicly respond to requests for clarification regarding the select agent regulations (i.e., provide regulatory interpretations).
- As appropriate, sharing draft regulatory policies and interpretations, guidance documents, and intended actions with the regulated community before these efforts are finalized. This builds credibility and allows our stakeholders to provide valuable input into those issues that will affect their work.
- Implementing a formal dispute resolution process, which allows registered entities to dispute specific inspection findings.
- Hosting a three-day, in-person Responsible Officials training workshop in December 2016, which included the opportunity for peer-to-peer engagement of the regulated community with the FSAP, as well as networking between colleagues. The FSAP will host another Responsible Official workshop at the end of this month (November 2017).
- Establishing an independent forum, through the American Biological Safety Association (ABSA) International, to encourage routine peer-to-peer sharing regarding best practices among those working with select agents and toxins. ABSA International has supported online discussions, an in-person workshop, and webinars, thereby allowing the regulated community to share information and best practices with each other independent of the FSAP.

- Developing a post-inspection survey that allows registered entities the opportunity to provide feedback on their inspection experience.
- Continuing to create other opportunities to engage stakeholders through analysis and reporting of our program's findings, such as the reporting of aggregate program data via the *FSAP Annual Report* and the annual analysis of data related to the timeliness of inspection report processing via publication of the *DSAT Inspection Report Processing Annual Summaries*.

We also are exploring avenues for disseminating further information regarding common deficiencies identified during inspections, and an analysis of data related to potential occupational exposures to select agents and toxins, from which we are able to identify common causes and provide recommendations for prevention.

Enforcement Authority:

FSAP recently finalized the *Severity Spectrum of Inspection Departures and Enforcement Actions,* which outlines categories of noncompliance with regulations related to biosafety and security, grouped according to the level of severity, as well as related enforcement options that may be applied. The document provides awareness of how FSAP considers the severity of inspection findings. As I mentioned earlier, regulatory violations (departures) are now grouped into a three-tier risk scoring system in the categories of low, moderate, and serious severity levels. We provided the regulated community an opportunity for input and feedback during the development process, and posted the final version on the FSAP website. FSAP is also using this information to help ensure consistency between inspections. For example, analysis of this data informed training initiatives to reduce variability between inspectors. The training will be completed at our joint inspection training November 1-3, 2017.

Conclusion

FSAP is committed to further strengthening oversight of laboratories that handle select agents and toxins, and appreciates the input of GAO and other entities that have provided recommendations toward that end. We have and will continue to work diligently, thoughtfully, and collaboratively with our federal partners and others who share in our commitment to protect Americans from biological threats. We value the Subcommittee's input as we continue to improve our oversight and enhance the safety and security of laboratories working with select agents and toxins.

Thank you for the opportunity to testify. I would be glad to answer to any questions you may have.

Mr. GRIFFITH. Thank you so much.

I now recognize Dr. Isaac for a 5-minute opening statement.

STATEMENT OF DR. FREEDA ISAAC

Dr. ISAAC. Mr. Chairman and members of the subcommittee, I appreciate the opportunity to testify at today's important hearing. I am Dr. Freeda Isaac. I am the Director of USDA Animal and Plant Health Inspection Service, Agriculture Select Agent Services.

AGSAS, along with our counterparts at the Centers for Disease Control and Prevention oversee the Federal Select Agent Program. Together, our two agencies oversee the possession, use, and transfer of biological select agents and toxins. These select agents and toxins have the potential to pose a severe threat to public, animal, or plant health, or to animal and plant products. I can assure you that this is a mission we take very seriously. Our goal is the same as yours. We want to have a program that allows our nation's scientists and researchers to safely and securely conduct important work and development with select agents and toxins.

Over the last few years, we have worked hard to strengthen our oversight of this program. Aside from our own efforts, we have received recommendations from outside experts, such as from GAO and the Federal experts Security Advisory Panel. We take these recommendations very seriously and we have used them to improve oversight of our program. I can confidently say that biosecurity and biosafety are stronger today than they were when I started.

I do appreciate this latest GAO report on our select agent program. We cooperated fully with the audit, and agree with its recommendations, and we have already taken steps towards implementing them.

We agree with the report that the independence of the Select Agent Program is important and that we must minimize potential conflicts of interest. We had taken steps in the past to reduce potential conflicts of interest. Notably, APHIS inspects CDC laboratories that use select agents and toxins and CDC inspects ours.

We also agree with the recommendation to develop a plan to identify the types of laboratory activities that pose the most safety and security risks and to align inspection and assessment activities in line with those risks. However, I will note that our current inspection process does include some efforts to evaluate and analyze risk. For example, we analyze safety and security risks based upon the type of laboratory and agents it works with and we changed the frequency of inspections, based upon a facility's compliance history.

Another recommendation urges us to improve transparency with the regulated community. This has been a priority for us. We want these labs to clearly know what is expected of them and to understand how to properly secure select agents.

We helped establish an independent forum to foster industry collaboration. We have set up new processes that allow stakeholders to review and provide input on program documents and policies. This extra communication and transparency helps them to understand their role and helps create a culture of safety in these facilities.

APHIS and CDC are committed to having the strongest possible Select Agent Program. We take these GAO recommendations seriously and we will use them, as we have all those previous reviews, to make this program stronger.

This concludes my testimony. I would be happy to answer any questions you or the members of the subcommittee may have.

[The prepared statement of Dr. Isaac follows:]

Testimony of

Dr. Freeda Isaac
Director, Agriculture Select Agent Services
Animal and Plant Health Inspection Service
U.S Department of Agriculture

Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
November 2, 2017

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify today about the role of the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) and its operation of the Federal Select Agent Program (FSAP). APHIS, through its Agriculture Select Agent Services (AgSAS), and the Centers for Disease Control and Prevention (CDC) Division of Select Agents and Toxins jointly oversee the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products.

As director of the program, I can assure you that this is a mission that we take very seriously. We all recognize the importance of ensuring the safety, security, and proper use of these potentially dangerous agents. Every day, I and our employees, are working directly with laboratories and researchers to ensure they understand our select agent regulations and that they are following all proper protocols. Aside from developing and enforcing the select agent regulations, we provide guidance and clarification to laboratories about best practices and regulatory compliance. We want to make sure that the facilities we regulate are doing things right and that they can safely use and adequately secure these potentially deadly agents.

Over the last few years, we have received a number of recommendations from organizations that have evaluated the efficacy of our biosecurity and biosafety programs, and we have diligently worked to implement as many of those recommendations as we can. Whether it was the Federal Experts Security Advisory Panel (FESAP), the Fast Track Action Committee on the Select Agent Regulations (FTAC-SAR) or any of the recent Government Accountability Office (GAO) reviews, we have taken these recommendations seriously and used them to make the FSAP stronger and more accountable. I can confidently say that biosecurity and biosafety are stronger today than they were when I started.

Current Activities

We appreciate continued support from Congress for the Federal Select Agent Program. An increase in funding in FY 2017 allowed APHIS to strengthen the program's scientific and

technical capabilities. This funding has allowed APHIS to hire eight additional expert personnel who will increase the scientific and technical capabilities of AgSAS. One benefit is that more scientific and technical personnel will be involved in complex inspections, improving both the inspections' efficiency and the technical knowledge and knowledge transfer among our personnel. The additional staff will also allow us to improve our timeliness for registrations and renewals for new and existing facilities and individuals.

With the additional funding, we will also continue working to update and modernize the National Select Agent Registry (NSAR) database – APHIS/CDC's joint FSAP database. The two agencies are creating a new, more efficient and user-friendly platform that allows stakeholders to safely and more securely submit entity information directly. An improved database will also give us better and more real-time data to analyze for any potential risks, allowing us to fix potential problems before issues arise. The database and our other efforts will move us toward the goal of having aligning APHIS and CDC processes so that there is consistency across FSAP.

On the stakeholder front, we now have dedicated staff focused on improving our communication and training with registered entities to ensure that those we regulate fully understand their obligations under the select agent regulations.

The November GAO Audit on High-Containment Laboratories

We appreciate this latest GAO report on our select agent program. This is the most recent in a series of evaluations GAO has conducted of our program, and their past recommendations have helped to make this program stronger. We cooperated fully with this audit, agree with its recommendations, and have already taken steps toward implementing them.

Broadly, the audit determined that APHIS and CDC need to improve our coordination and ensure the independence of our programs within our Departments. We will continue work in carrying out these recommendations in the coming weeks and months.

Specifically, here is an update on what we will do in response to those recommendations for APHIS:

We agree that the independence of the select agent program is important, and think that minimizing any potential conflicts of interest with USDA laboratories is essential. In practice, I regularly meet with the APHIS Administrator's office to provide updates on the select agent program major activities, enforcement actions, and overall administration of the program. We are developing a document that will formally outline this relationship.

We also agree with the recommendation to work with CDC to establish control activities to help ensure each component of the program carries out its inspection responsibilities as outlined in the program's memorandum of understanding. While we have made great strides in aligning our two programs and improving consistency of inspections and operation, updating our joint formal standard operation procedure will greatly improve our ability to meet this goal.

We agree that we should regularly assess, such as through an external review, the potential risks posed by the program's structure and the effectiveness of its mechanisms to address those risks and take actions as necessary. We have a track record of both evaluating our own program and working with experts to develop recommendations for strengthening our program. We are considering various options with CDC to review the current structure.

We will work to carry out the recommendation to work with CDC to develop and implement a plan to identify which laboratory activities carry the highest biological safety and security risks and to respond to those risks by aligning inspections and other oversight efforts to target those activities. However, I think it is important to note that the current inspection process does include some risk assessment and analysis activities. This includes establishing a baseline assessment that identifies the safety and security risk based on the work being performed and for which select agents and toxins the entity uses. We also determine the frequency of inspections dependent upon the risks of that facility combined with any incidents or compliance issues we have previously identified.

We have already worked very hard on the recommendation to improve transparency and increased our communications with stakeholders so they better understand the program and how to properly secure and use select agents and toxins.

Our efforts include our work to establish an independent forum to foster peer-to-peer sharing at workshops and webinars on best practices; the development of a formal process to respond to questions and provide guidance and interpretation about the select agent regulations; and the sharing of draft policies, interpretations and guidance documents with industry for feedback and clarification.

Lastly, to improve technical expertise and overcome fragmentation, we have already hired a contractor to help us prepare a joint strategic plan that will incorporate these recommendations, and have held several initial meetings with them.

Conclusion

APHIS and CDC are committed to having the strongest possible FSAP. We will take these GAO recommendations very seriously, as we have previous GAO recommendations and those of the other panels that have reviewed this program.

Our goal is the same as theirs: We want a program that allows our nation's scientists and researchers to be able to safely and securely conduct important work and development with select agent and toxins to advance human, animal, and plant safety.

I appreciate the opportunity to testify. I would be happy to answer any questions you or the members of this subcommittee may have.

Mr. GRIFFITH. Thank you very much and I will now recognize myself for 5 minutes to start the committee questioning.

Dr. Denigan-Macauley, GAO found that the Select Agent Program does not have a joint mission statement. Do CDC and APHIS have the same missions stating what the program seeks to achieve; yes or no?

Ms. DENIGAN-MACAULEY. No.

Mr. GRIFFITH. Thank you. The Government Performance and Results Act of 1993 requires agencies to develop strategic plans that include documents and planning tools, such as mission statements, strategic goals, and objectives and performance measures. Is that correct; yes, or no?

Ms. DENIGAN-MACAULEY. Yes.

Mr. GRIFFITH. Thank you. Although not binding to the Federal Select Agent Program, these requirements have been found by the GAO to serve as leading practices for individual programs. Is that also correct; yes or no?

Ms. DENIGAN-MACAULEY. Yes.

Mr. GRIFFITH. Both CDC and APHIS have performance measures for their activities and select programs. Isn't that correct?

Ms. DENIGAN-MACAULEY. Yes.

Mr. GRIFFITH. Are their performance measures the same?

Ms. DENIGAN-MACAULEY. No.

Mr. GRIFFITH. Is there any overlap of the performance measures each agency uses?

Ms. DENIGAN-MACAULEY. No.

Mr. GRIFFITH. So CDC and APHIS are using different metrics to measure their own performance in the Select Agent Program. Is that correct?

Ms. DENIGAN-MACAULEY. Yes.

Mr. GRIFFITH. How about collectivity? Does the Federal Select Agent Program have performance measures to track its progress?

Ms. DENIGAN-MACAULEY. No.

Mr. GRIFFITH. Dr. Edwin, the GAO found that the Federal Select Agent Program does not have a joint strategic plan. Is the program taking steps to develop a joint strategic plan; yes or no?

Mr. EDWIN. Yes.

Mr. GRIFFITH. Good. Did the program take these steps before the GAO raised the issue with CDC and APHIS?

Mr. EDWIN. We have individual strategic plans but not a joint one and we are working on a joint strategic plan.

Mr. GRIFFITH. But you didn't take that action before you got the GAO report.

Mr. EDWIN. That is correct.

Mr. GRIFFITH. And I am glad you are following some of those suggestions and both agencies have agreed that the suggestions make sense. So I appreciate that.

Would such a step, including hiring an outside contractor to develop the joint strategic plan—would such a step include hiring an outside contract to help to develop the joint strategic plan; yes or no?

Mr. EDWIN. Yes.

Mr. GRIFFITH. And has such an outside contractor been hired yet?

Mr. EDWIN. Yes.

Mr. GRIFFITH. Good. Has the outside contractor prepared a joint strategic plan?

Mr. EDWIN. He is working towards preparing that, been in place for a month or so.

Mr. GRIFFITH. OK but we don't have a plan yet. When do you expect one?

Mr. EDWIN. We are having, actually, meetings with the leadership, and the staff, and their coordinator. And they are in the process of developing one, probably within the next few weeks.

Mr. GRIFFITH. OK, will you let the committee know when that has happened?

Mr. EDWIN. Yes.

Mr. GRIFFITH. Thank you.

To avoid a conflict of interest with inspecting CDC labs, the CDC signed a memorandum of understanding with APHIS in 2012 so that APHIS would take the lead on select agent inspections of CDC labs. Isn't that correct?

Mr. EDWIN. That is correct.

Mr. GRIFFITH. And so for most of the decade, the CDC was inspecting its own labs. Is that correct, 2003 to 2012?

Mr. EDWIN. Yes.

Mr. GRIFFITH. OK. And isn't it true that the CDC signed a memorandum of understanding to avoid the conflict after the press and this committee raised concerns about CDC inspecting itself?

Mr. EDWIN. That is correct. After receiving guidance, we have taken that step.

Mr. GRIFFITH. OK, I appreciate that.

Dr. Isaac, APHIS signed an MOU with CDC in 2012 so that APHIS would take the lead on select agent inspections of CDC labs, however, it was not until 2015 that you all signed a reciprocal MOU with CDC so that CDC would take the lead on select agent inspections of your labs. Isn't that correct?

Dr. ISAAC. Yes, that is correct.

Mr. GRIFFITH. Thank you. At the briefing with the committee staff last week, you could not explain the 3-year delay on the MOU for the APHIS lab inspections. Isn't that correct?

Dr. ISAAC. That is correct.

Mr. GRIFFITH. And now that you have had time to research it and think about it, are you in a position today to explain the 3-year delay?

Dr. ISAAC. Yes. At that time, after discussing it with my staff, we did have some concerns regarding the authority of CDC to oversee some of the APHIS laboratories because those laboratories contained USDA-only agents and the CDC laboratories that APHIS takes the lead on have either overlap or USDA-only agents. So the authority is clear that APHIS has that authority.

After we discussed that, I think the reason that we have changed the MOU is that administratively, consulting with our counsel, we determined that we could administratively have CDC oversee the inspections and sign the reports, as long it is done jointly with APHIS.

Mr. GRIFFITH. OK and so I have only got a few seconds left and I appreciated your statement that things are safer now that you

are there. I appreciate that. I think that is right. We want to get it even better but I do find it curious that we had an MOU in place for over a decade with one of the agencies and your legal staff took about 10 years to come up with the opinion you now have. Oh, 3 years. OK, excuse me, 3 years to come up with the plan you now have. They seemed to have drug their feet a little bit with that.

I have to yield back and now recognize the ranking member, Ms. DeGette, for 5 minutes of questioning.

Ms. DEGETTE. Thank you, Mr. Chairman.

Dr. Denigan-Macauley, the laboratories we are talking about hold high-risk biological agents. If improperly handled, these could result in serious or lethal infection of lab workers or even the general public. Is that correct?

Ms. DENIGAN-MACAULEY. Yes.

Ms. DEGETTE. And in other words, if we don't operate these programs with precision, with pretty much zero room for error, theoretically, we could have risk to both public health and national security. Is that correct?

Ms. DENIGAN-MACAULEY. Yes, it is.

Ms. DEGETTE. Now in your most recent audit, you found there were still problems with the Select Agent Program. In particular, you found that the program may not be sufficiently independent from the Centers for Disease Control and Prevention and the U.S. Department of Agriculture that it may not have enough inspectors and the inspectors it does have may not be targeting the most high-risk activities when they examine laboratories. Is that an accurate summary of your conclusions?

Ms. DENIGAN-MACAULEY. Yes, it is.

Ms. DEGETTE. And as you heard in my opening statement, I have been on this committee a long time, this is not the first time we have had these hearings. What do you think are the primary or root cause reasons we keep seeing this happen over and over again with respect to this program?

Ms. DENIGAN-MACAULEY. Yes, thank you for the question. There will never be zero risk, unfortunately. There will always be some risk that has to be taken but we do believe strongly that the oversight needs to be strengthened to prevent these safety lapses from happening. And we do also believe, as our report states, that they really need to look at the highest risk activities and make that formal determination. While some steps have been taken, it has not been a full formal assessment to best understand what those activities are.

Ms. DEGETTE. And I know you made a number of recommendations regarding the Federal Select Agent Program. The CDC and USDA have taken steps to implement the recommendations but your report shows that there is still work to be done. So my question is, Can you prioritize the recommendations that you have made? Which ones are the highest priority to make this a safer program with the greatest expediency and why?

Ms. DENIGAN-MACAULEY. Generally, GAO does not prioritize our recommendations. However, today I highlighted two that we feel very strongly about. The fact that they are not independent, that both entities are inspecting their own labs, they have to have in-

spectors there, according to the agencies because of the necessary expertise. So we definitely raised that as a concern.

And we also raised the concern about not knowing what the highest risk activities are.

Ms. DEGETTE. Dr. Ewin, what is your agency's response to those two particular issues?

Mr. EDWIN. So we are actually looking at risk. Our assessment of risk——

Ms. DEGETTE. Well, number one, about having independent inspectors. What is your agency's response to that?

Mr. EDWIN. So in order to do the inspections, we really do need the expertise of the agents that we—you know the public health agents are agents that are involving animal and plant health. And we are structurally separate from the main CDC and we work closely, almost on a weekly basis, on compliance and other issues with the——

Ms. DEGETTE. You don't think you can have independent inspectors because of the level of—I don't understand your answer to my question.

Dr. Denigan-Macauley, the GAO, said number one, independent inspectors. And what you are saying is well, the inspectors have to have, obviously, the level of training. Does that mean you can't have independent inspectors?

Mr. EDWIN. Oh, I am not saying that at all.

Ms. DEGETTE. Then what are you saying? I have got 50 seconds left.

Mr. EDWIN. I think you know our inspectors are professionals, no matter if you are looking at CDC——

Ms. DEGETTE. All right, can you have independent inspectors, as the GAO is requiring?

Mr. EDWIN. Yes.

Ms. DEGETTE. Thank you.

Now, the second recommendation was that we focus on the most high-risk activities. Are you implementing that recommendation?

Mr. EDWIN. We are focused and look at all the high-risk activities, including the type of the agent.

Ms. DEGETTE. So are you implementing that?

Mr. EDWIN. Yes.

Ms. DEGETTE. Thank you.

Mr. EDWIN. Yes.

Ms. DEGETTE. What about you, Dr. Isaac, your agency? What is your agency's response to her first highest priority, the independence issue?

Dr. ISAAC. Yes, we already currently have two things in place, which is our reporting structure within APHIS, where the program reports directly to the APHIS administrator. We also have CDC inspect APHIS laboratories.

We also are, as the recommendation is, we are pursuing an option to have an external review of our program to identify the risks of how we are structured and to develop options to be able to take care of that risk.

Ms. DEGETTE. And quickly, with respect to her second most important recommendation that we look at the most high-risk activities, is your agency also beginning to work on that?

Dr. ISAAC. Yes, we are.

Ms. DEGETTE. Thank you. That will work.

I yield back.

Mr. GRIFFITH. I thank the gentlelady.

I now recognize the vice chairman of the full committee, Mr. Barton of Texas.

Mr. BARTON. Thank you, Chairman and thank you and Ms. DeGette for organizing and holding this hearing.

We have kind of been here before. It looks like every 2 or 3 years we get a GAO report and the subcommittee has a hearing and you all come and say the appropriate things. And then we wait another 2 or 3 years and we have another hearing. Maybe this time it is different. You know I can't speak for anybody else but I am ready to, if necessary, legislate to change the law and actually put in the statute some of the recommendations of the GAO.

My first question is just a generic question. In one of the footnotes it says that we think we have 276 laboratories in the United States that handle these toxins. Why do we need 276 laboratories to handle, or study, or whatever something that is so dangerous? Does anybody want to answer that?

Mr. EDWIN. The number of laboratories that are registered with the Select Agent Program have been decreasing but we, our authority doesn't dictate the number of laboratories.

And when you talk about the laboratory, when we talk about the laboratory numbers, there are only a few laboratories that work with these highly pathogenic——

Mr. BARTON. Well 276 is more than a few.

Mr. EDWIN. Yes.

Mr. BARTON. Do you dispute that number?

Mr. EDWIN. No, I do not dispute the number but not all of them work with all of the agents that we regulate. Some are just working with——

Mr. BARTON. Can anybody start one of these laboratories? Do one of your agencies have to issue a license? I mean if Diana DeGette and I decided to quit Congress and go into business and create one of these laboratories——

Ms. DEGETTE. A very highly unlike scenario.

Mr. BARTON [continuing]. What would we have to do? Could we just start it up or do we have to go to CDC or the Ag Department?

Mr. EDWIN. So depending on the agents that you are applying to work with, there is an initial registration process that involves a very comprehensive——

Mr. BARTON. Registration with who?

Mr. EDWIN. If you are working with agents of public health concern, with CDC. And if it is a USDA agent——

Mr. BARTON. Can you reject the application?

Mr. EDWIN. If the measures that are not in place to safely and securely handle these agents, yes.

Mr. BARTON. But if they appear to be willing to comply, there is no limit on how many people can set up these laboratories, if they, on paper, agree to comply with your requirements. Is that correct?

Mr. EDWIN. So on paper and also the physical inspection of the facilities to have all of these measures in place.

Mr. BARTON. Well, I guess to get to the bottom line, should we put a limit on the number of these laboratories that handle these highly dangerous materials?

Mr. EDWIN. I think that is a bigger question that involves multiple parties in biodefense and the scientific community to make——

Mr. BARTON. I don't have any frame of reference but it would appear to me, when you see the potential danger and you see the way some of these agents have been accidently transported and handled, I would think it might be advisable to put some sort of a limit or to go in and really, really look at the existing facilities with the potential to literally close some of them.

Because I was stunned. I thought we had maybe 10 or 15 and that they were all highly classified and under control with the Department of Defense or some really, really high security areas. And apparently, anybody that wants to, any pharmaceutical company, any agriculture company, if they are willing to put the money up and at least pay lip service, can set up one of these laboratories.

Mr. EDWIN. When the program first started, I think the number was close to 400. And because of all the requirements, the number has actually gradually been coming down.

Mr. BARTON. Do either of your agencies have the ability to absolutely close one of these facilities? If you feel they are totally in noncompliance, can you shut it down permanently?

Mr. EDWIN. We can suspend and revoke their registration to work with select agents and toxins.

Mr. BARTON. You can suspend their registration?

Mr. EDWIN. Yes.

Mr. BARTON. OK. Last question and my time is about to expire.

And Ms. DeGette and I think Mr. Griffith both alluded to this. GAO says there needs to be independence. Why couldn't we just create a separate agency that all it does is inspect these, take both of your inspection groups and combine them to a totally independent group? What would be wrong with that idea?

Dr. ISAAC. So——

Mr. BARTON. I might even let GAO answer that.

Ms. DENIGAN-MACAULEY. Yes, we offer many oversight alternative approaches. We review the program in its current form but that was one of the reasons our methodology included going out. For example, the Nuclear Regulatory Commission is an independent and it was decided years ago that that needed to be made. And several laboratories in other countries such as Great Britain are in that——

Mr. BARTON. So that is a feasible alternative?

Ms. DENIGAN-MACAULEY. It is a feasible alternative but not something that we looked at in detail to know the cost associated with that.

Mr. BARTON. Do either of you want to comment on that before I yield back?

Dr. ISAAC. So if I could just offer a comment is that because of the extreme scientific technical nature of the work that we do, and part of our oversight is to understand the research and the type of work that is being done with these agents, and understanding the proper use of the agent, where we are situated within HHS and

USDA, we are able to share resources within those departments for that technical expertise, as well as administrative and emergency response activities. We are able to tap into experts to implement regulations very quickly that require immediate implementation.

Mr. BARTON. Well that begs the question an independent agency could do the same thing.

I yield back.

Mr. GRIFFITH. I thank the gentleman for yielding back.

I would make a point of clarification. Dr. Denigan-Macauley, we have been talking about 276 labs but so that people who may watch this now or later will know, 276 labs are actually entities and those entities may have multiple labs. So we could actually be talking about 1200 or more labs. Is that correct?

Ms. DENIGAN-MACAULEY. That is correct.

Mr. BARTON. I appreciate that. Thank you.

And now we will yield or recognize Mr. Tonko, the gentleman from New York, for 5 minutes of questioning.

Mr. TONKO. Thank you, Mr. Chair.

Five of GAO's eleven recommendations concern the need to improve the independence of the Federal Select Agent Program. As we know, the Federal Select Agent Program is not an independent agency but a program managed jointly by the Centers for Disease Control and Prevention and an agency under the United States Department of Agriculture called the Animal and Plant Health Inspection Service or APHIS.

GAO's report states that while CDC and APHIS have taken steps to reduce conflicts of interest potentially posed by this structure, more can be done in this area. So, GAO, let's start with you.

Dr. Denigan-Macauley, can you please explain why GAO believes independence is important for an entity like the Federal Select Agent Program?

Ms. DENIGAN-MACAULEY. Sure. We have previously used these criteria to look at adverse events with low probability and can have high consequence. So for example, the foot and mouth disease outbreak that happened over in the United Kingdom was a very tragic event, a low probability that it would occur. The Fukushima Diiachi nuclear reactor incident in 2011 is another example.

While much research is conducted in this country very safely and securely, the probability is horrific if something were to happen. So, therefore, the criteria fit. And we also vetted the criteria with numerous folks that are experts within this field.

Mr. TONKO. Thank you. I would like to learn more about what CDC and APHIS have already done to enhance the independence of the Select Agent Program.

So, Dr. Edwin, what actions have you taken to reduce conflicts of interest between FSAP and CDC?

Mr. EDWIN. So the Division of Select Agents and Toxins is located in the Office of Public Health and Preparedness. And the reporting lines to the CDC chief is a separate thing for us.

And also, being in that particular office, they do not have any laboratories that we regulate. Being in that office, it helps us to pivot because the Emergency Operations is also under the same office. If there is a national incident, then we can immediately pivot and the entire structure is there to support such an activity.

So I see that as a very huge advantage that we have and I have direct access to the CDC Director, if there is anything that I need to engage with her on.

Mr. TONKO. OK, thank you.

And Dr. Isaac, the same question. What have you done to reduce conflicts of interest between FSAP and APHIS?

Dr. ISAAC. Yes, operationally, the Agriculture Select Agent Program, we report directly to the APHIS administrator. We have a face-to-face briefing with the administrator every month, where we update him on the program activities and other incidents and enforcement issues that occur with all USDA laboratories.

And even though under the administrator, there is other laboratories because of the chain of command of those laboratories is separate from our chain of command. So with that direct link, it highlights how important the program is to APHIS.

The other aspect that we do is we utilize CDC as part of any concerns we have with USDA laboratories. They accompany us on those inspections and they will assist us in enforcement actions or they may actually take the enforcement action themselves.

Mr. TONKO. OK and turning back to GAO, in terms of the independence here, Dr. Denigan-Macauley, can you broadly discuss GAO's recommendations to increasing the independence of the Select Agent Program? And how would those ideas benefit the program?

Ms. DENIGAN-MACAULEY. Sure. Dr. Isaac is correct that they do report directly to their director. However, this was not on paper. It is not known if it was actually being done. So that is one of our recommendations is to ensure that this is documented formally that this is done.

One of the concerns that we have about not being independent is that this is a small community and they are there on each other's inspections. They say that the expertise is needed. We understand that this is a very technical field, however, there are other options for, that we talk about in the report, reaching out. Other sectors have come up with other options such as advisory panels to be able to bring in that expertise so that they can focus on the regulations and the expertise can be brought in.

Mr. TONKO. Thank you very much.

I yield back, Mr. Chair.

Mr. GRIFFITH. Thank you very much.

I now recognize Dr. Burgess of Texas for 5 minutes of questions.

Mr. BURGESS. Thank you, Mr. Chairman and thanks to our witnesses for being here today.

Dr. Denigan, if I could just continue on Mr. Tonko's line of questioning for a moment. So the independent inspectors would, of necessity, come from other laboratories or entities and people would cross-check each other?

Ms. DENIGAN-MACAULEY. My apologies. Could you repeat the question?

Mr. BURGESS. Well, just where are the independent inspectors, where are we to get them?

Ms. DENIGAN-MACAULEY. There are some advisory committees here, even in the United States, that could be expanded to provide that level of expertise. We are not prescriptive in how that exper-

tise would be obtained. Rather, we ask them to look at approaches using other regulatory sectors and other countries to determine how they gather that expertise.

For example, some folks also put more emphasis on the actual labs to provide their own level of expertise and they require certification of the biosafety officers.

So there are many different approaches that are out there. This is not the only one.

Mr. BURGESS. It seems to me, and I don't know that I am sure about this, but for it to truly be an independent inspector, it probably couldn't be within the agency itself. That is one part of HHS'—or one part of CDC inspect another part. Is that a concern?

Ms. DENIGAN-MACAULEY. Yes, it is and that is something that we noted in our report because the budget still comes from CDC and it still comes from APHIS. And so the decisionmaking process is coming from the CDC and APHIS. And this is one small program, amongst all the other activities that they have to consider.

So yes, our criteria is that they must be structurally independent and separate.

Mr. BURGESS. Thank you for that.

Dr. Edwin, let me just ask you. It may be a little bit off topic but you talked in your written statement, on page 4, receiving reports of theft, loss, or release, and the bottom of the paragraph, notifying appropriate authorities.

I was not in Congress when the anthrax event happened. I came the subsequent year after that but I remember reading about it in the newspapers and how horrific it was because anthrax, the early symptoms, are the symptoms of common cold, flu. And the ER doctor, one of the ER doctors, of the story that is seared into my memory, the ER doctor had seen a lot of cases of flu that day and this was another case of flu, until it turned out to be something much, much worse.

So is there any method of notification, be on the lookout for, when—not for perhaps that situation but if you have got a breach, if someone finds that ricin has been shipped around the country, is there a dissemination of this knowledge to first responders and medical experts in emergency rooms so that perhaps the unusual symptoms they are seeing is something that must need to be considered?

Mr. EDWIN. So this is one example where you know we have pivoted to our emergency operations that was providing exactly that information and connecting them to not only the subject matter expertise within the CDC, and other departments but also that the public health officials, and stuff and exactly providing that information on those types of incidents.

On small ones that occur that we have reported in this, we make sure that if they need assistance from one of our SMEs on the list on that particular potential exposure, we try to connect them. And they, in turn, make sure that a person is taken care of the way he should.

So because the local physicians that may be treating won't have that particular expertise, we make sure that we connect the SMEs with the treating physicians.

Mr. BURGESS. At that time, in fact it was the Thanksgiving holiday of that year, and I was in labor and delivery. And the emergency room brought up a pregnant woman who was 28 weeks and for all the world looked like she had viral gastroenteritis. So I did the normal treatment and was fixing to sign her out and release her and she said, "Is it important that I tell you that my grandfather is a member of President Bush's Cabinet?" And I thought for a minute and I thought it may be.

So in short order, I was able to call some people and get some idea about whether or not these GI symptoms could be related to the same concern that was going in the Nation's Capital.

But it certainly brought home to me had she not mentioned that casual reference, I wouldn't have known to look. Now, as it turned out, it was unimportant. It didn't impact her clinical course but it could have is the point. And then I would have been just the same as that poor ER doctor that I read about who attended the unfortunate postal worker. He has got to live with that for the rest of his life that he missed that diagnosis. If there is anything we can do to help people come to the right conclusion more quickly, I think we should.

Thank you, Mr. Chairman. I will yield back.

Mr. GRIFFITH. Thank you very much, Dr. Burgess. That was compelling testimony of why this is so important, all of this.

With that, I recognize the gentlelady from Indiana, Ms. Brooks, for 5 minutes of questions.

Mrs. BROOKS. Thank you, Mr. Chairman, and thanks so much to our witnesses for sharing with us this important testimony.

Going back, actually, to that time frame, I happened to be a U.S. Attorney in Southern District of Indiana during the anthrax attacks. And so government offices all across the country were, rightfully, really alarmed and concerned and, in fact, received often fake or hoax anthrax packets, including my own office at that time.

And Dr. Edwin, as I have learned in preparation for today, prior to your role with the Select Agent Program, you served from 2008 to 2016 as the responsible official and Biological Surety Officer for the Select Agent Program at the U.S. Army Medical Research Institute of Infectious Diseases. And it was from that place in July of 2008 that a biodefense researcher from your institution, Bruce Ivins, died from an apparent suicide after learning that the FBI was going to file criminal charges against him for the 2001 anthrax attacks.

In August of 2008, the FBI and Department of Justice announced that Dr. Ivins was likely solely responsible for the five deaths and the injuries caused by the anthrax mailings but in May of 2011, a panel of the National Academy of Sciences, at the request of the FBI, reviewed the scientific work and concluded the FBI might have overstated the genetic analysis linking the mailed anthrax to a flax of anthrax kept by Ivins.

So my question, Dr. Edwin, is, on July 10th of 2008, when Dr. Ivins lost his security—he lost his security clearance, as I understand. And as you were the responsible official for the Select Agent Program at that time, were you aware of any concerns about Dr. Ivins prior to that date and why he lost his security clearance on that date?

Mr. EDWIN. So, I was the alternate responsible official and there was a military officer that was the responsible official at that time. And it was also just you know I started in January and this is the suitability assessments that the Army does. Every individual that accesses select agents in the containment labs have personnel reliability program. So that is a certifying official that Dr. Ivins was under decertified him from entering the laboratory.

Mrs. BROOKS. Thank you. And I would like to talk a little bit about this issue because it involves insider threats in the information. Is there enough information sharing with the Select Agent Program about potential or actual insider threats?

Mr. EDWIN. So we require insider threat awareness training for all the entities and this is one place where agent accountability plays a very important role. You know we make sure that the agents that they have recorded and what they are working with. Not only does it help with the insider threat, it also gives safety priority, biosafety because we know where the agents are and the people inside the lab that are working are also aware where they are.

Mrs. BROOKS. But what I am concerned about that is incredibly important I am concerned about the focus on the personnel that have access to these agents.

And so have there been improvements made in reviewing the suitability of the personnel who are registered to work with the select agents? Is there baseline psychological testing? Are there two rules in the biocontainment suite? Are there reassessments of their security clearances?

Mr. EDWIN. Yes, all of those are true and continuous monitoring is also in place for people that are working with the highest threat or tier 1 agents that we call it.

Mrs. BROOKS. And since I have learned that there are so many different places where these labs exist, is this happening? And are you all confident, including the GAO, with respect to the amount of oversight there is of what Dr. Edwin just stated is happening? Is this happening in all of the labs?

Dr. ISAAC. Yes, in 2012 we did publish a new regulation which required for all tier 1 pathogens, which are the highest risk pathogens, that every entity has a suitability program. And that is what is part of our inspection process, that we ensure that they have a robust review of their personnel suitability and take action.

It is also a requirement in the regulations that if they remove access for any reason, that that is reported to the Federal Select Agent Program and that the reason for a person's removal is reported to us.

Mrs. BROOKS. Thank you.

Doctor?

Ms. DENIGAN-MACAULEY. Yes, thank you. In 2009, GAO reported that we did not have a single entity overseeing all of these labs. It is important to note today that what we are discussing is the Federal Select Agent Program. There are other pathogens, other diseases, viruses, bacteria, toxins that do not fall into the Select Agent Program, such as tuberculosis.

So I do not have confidence that we have a good understanding of this robust program being implemented in all of the labs.

Mrs. BROOKS. Thank you. And thank you all for your work. It is critically important for the country.

I yield.

Mr. GRIFFITH. The gentlelady yields back.

I now recognize Mr. Walberg of Michigan for 5 minutes.

Mr. WALBERG. Thank you, Mr. Chairman. Thanks to the panel for being here.

According to GAO's report, both witness agencies have faced challenges in hiring and retaining a sufficient number of staff with appropriate expertise. The report outlined some of the negative consequences of insufficient staffing, including inability to meet deadlines and lack of expertise.

But Dr. Denigan-Macauley, could you explain in greater detail the downfalls your team saw as a result of these staffing challenges?

Ms. DENIGAN-MACAULEY. Sure. I should mention, again, that these are very challenging jobs that do require a high level of expertise and, in general, the program is working to ensure that they have that level of expertise. However, we did find that not all folks had the same level of expertise and sometimes, because of staffing issues, we are pushed out of their area where they had that level of expertise.

So these are real. On paper it looks like an FTE but these are real problems that put people in a difficult situation. And not having these labs, this program sufficient staffed is very challenging.

Mr. WALBERG. I understand both the CDC and APHIS have taken steps to hire more staff in the past few years and, specifically, have begun to fill vacancies at their respective agencies since this report was completed.

I see from the report that the CDC developed a formal workforce plan for its component of the program in 2016 and was working to fill those positions. Dr. Edwin, would you tell us a little more about the workforce plan, and the hiring that you have done since that plan was developed, and the full size of your program staff?

Mr. EDWIN. So in the last 14 months, we filled 17 positions, including my position. And we also have started with Dr. Isaac and their staff, the Strategic Workforce Plan that includes both training and workforce of the entire Federal Select Agent Program.

Mr. WALBERG. With regards to the number of FTEs, are all of those individuals inspectors?

Mr. EDWIN. We have 51 inspector positions and the others are support staff that look at different security requirements and other associated tasks within the division.

So when I started with CDC they already had identified this deficiency and we were given the 16 some positions to fill, which we successfully filled.

And I also want to say that most of our inspectors have come from the laboratories, select agent laboratories, and over 50 percent, about 65 percent or so have Ph.Ds. and the others have master's degrees. So you know we do have that intellectual capital in the inspectors.

Mr. WALBERG. So more specifically then, based upon that with the academic qualifications they have, the experience they have, what steps is the agency taking to address workload issues?

Mr. EDWIN. So you know with the addition of the inspectors, the estimated amount of time for travel and inspections outside has decreased by about 20 percent. It used to be about 45 and with the estimate, with the current inspection staff, there is about 25 percent the last time I spoke to our operations chief, which was a couple days ago.

And in addition, with the new information system that we are developing, it is capturing a lot of efficiencies and it is going to provide the time, additional time for inspectors to be able to expediently do the inspection reports and increase efficiency on the performance of our program.

Mr. WALBERG. So going in a positive direction.

Mr. EDWIN. Yes.

Mr. WALBERG. Thank you.

Similarly, APHIS developed a 5-year business plan, which included a plan to hire additional staff. Dr. Isaac, would you tell us about the 5-year plan and the hiring you have done since the plan was developed and the full size of your program staff?

Dr. ISAAC. Yes. In 2015 we developed a 5-year plan, which highlighted, essentially, the goals of the program, and where we wanted to be, and the type of staffing that we would need to be able to fully meet all of our goals.

As a result of that, we were able to, and we are very thankful to Congress, we were able to get additional funds this year that allowed us to hire eight additional technical staff. So with that technical staff, we were able to create several new positions, including a science officer position that deals with a lot of the in-depth technical scientific questions, as well as a dedicated facility specialist who has expertise in that area, additional security specialist, training specialist, and policy analyst. And we are very grateful for that and we believe that that is going to help us fulfill and meet all of our goals for effective oversight.

Mr. WALBERG. Thank you. I yield back.

Mr. GRIFFITH. I thank the gentleman for yielding back.

I now recognize Mr. Carter of Georgia for 5 minutes of questioning.

Mr. CARTER. Thank you, Mr. Chairman, and thank each of you for being here.

Dr. Denigan-Macauley, just a second ago I believe that Representative Brooks asked you about the—or you made the comment about the pathogens that are covered under the Special Agent Program—the Select Agent Program. Who makes that decision on what is covered and what is not covered?

Ms. DENIGAN-MACAULEY. So CDC and APHIS are probably better in a position to answer that. However, collectively, they review what goes in, I believe it is every 2 years or so. But it is a Board of folks that make that decision.

Mr. CARTER. A Board of folks?

Ms. DENIGAN-MACAULEY. Experts in the field, APHIS and CDC collectively.

Mr. CARTER. Dr. Edwin, do you want to expand on that?

Mr. EDWIN. Are we talking about the review of the——

Mr. CARTER. No, I am talking about the Board that makes that decision on what is in the Select Agent Program and what is not in it.

Mr. EDWIN. Oh, so the biennial review. We call that process the biennial review.

Mr. CARTER. Right.

Mr. EDWIN. It is a group of individuals from various government agencies.

Mr. CARTER. I am sorry.

Mr. EDWIN. It is a group of individuals from various government agencies that look at this you know every 2 years and give us the guidance to make the changes that are necessary.

Mr. CARTER. OK. In your opinion, is there anything in there that should be in there or anything that shouldn't be in there?

Mr. EDWIN. So you know we look at this every 2 years.

Mr. CARTER. I understand you look at it but I am talking about now, today.

Mr. EDWIN. I think that there are some agents that probably we need to relook at but we are approaching that with the committees.

Mr. CARTER. When is the next time it will be up?

Mr. EDWIN. It will be in a year and a half.

Mr. CARTER. OK, Dr. Isaac——

Mr. EDWIN. We do a lot of preparation before we get to that.

Mr. CARTER. All right. Anything that you think that probably ought to be in there that is not?

Dr. ISAAC. We published a regulation this year and we will start a review process on the select agent list. We did receive some recommendations from our scientists, scientific experts who assess the list of select agents and make recommendations for removal or addition.

And in this last published, we elected not to remove any agents based on some concerns regarding security and policy issues. So we will, this coming year, we will be doing that assessment again and working through not only our subject matter panel experts, scientific experts that we work with, but also interagency experts.

Mr. CARTER. OK. Anything, Doctor, that you think?

Ms. DENIGAN-MACAULEY. No, I think that the point the GAO has made in the past is that our oversight of pathogens in general, pathogens and toxins——

Mr. CARTER. Right.

Ms. DENIGAN-MACAULEY. Is not comprehensive.

Mr. CARTER. OK.

Ms. DENIGAN-MACAULEY. And that is not the same with other countries.

Mr. CARTER. All right, I want to go to something real quick and that is the incident reporting forms. From what I understand, between 2003 and 2015 there is a little bit of controversy as to exactly how many incidents we had. I think it was reported we had 10 and then they identified 11 more. And then I believe that GAO made the recommendation that we improve the incident reporting forms. And I am just wondering, have we done that? How is that progressing? How are we doing?

Mr. EDWIN. So we have made the changes. One of the significant changes is now if there is an inactivation failure, at least it can be formally reported to the program, which was not part of that form.

It is just 2 weeks ago I was approved by the OMB and we have that in place.

Mr. CARTER. So you have it in place and it is working now.

Just out of curiosity, because there was a little bit of confusion as to how many incidents actually took place between that time frame between 2003 and 2015, it was either 10 or 21, which there is a big difference between those. You believe it was 21.

Since that time, how many have we had, do you have any idea? Since 2015, how many incidents have we had?

Ms. DENIGAN-MACAULEY. GAO reported that we had 21 incidents of inactivation and it is the Form 3. We have not done work to understand how many more may have occurred since then.

Mr. CARTER. Since that time you came up with the 21?

Ms. DENIGAN-MACAULEY. Correct.

Mr. CARTER. OK. OK, Dr. Denigan-Macauley, just last month I believe you came out with a report about the way that other countries are doing this, going about this process. It seems to me like the one thing that we are lacking here in America is that we don't have a national strategy.

Did we learn anything from other countries? I believe you looked at Great Britain and maybe Canada. Are they doing things that we need to be doing?

Ms. DENIGAN-MACAULEY. Yes, we did, actually. We looked at a variety of different countries and they have very different approaches that are outlined in our report.

And for example, as I mentioned, Great Britain has a separate entity that oversees it. It is similar to an OSHA but with much more teeth and they oversee the safety and security of a variety of different fields.

So yes, we do outline many options.

Mr. CARTER. Are you going to make those recommendations that we need to be following?

Ms. DENIGAN-MACAULEY. We made the recommendation that these other oversight approaches should be taken into consideration as they move forward.

Mr. CARTER. OK.

Ms. DENIGAN-MACAULEY. We did not make a specific recommendation on a specific change. That is the dialogue that we believe needs to happen now.

Mr. CARTER. OK. All right, thank you very much.

Mr. Chairman, I yield back.

Mr. GRIFFITH. I thank the gentleman very much.

Ms. DeGette and I have agreed that I can ask a couple of oddball science questions. So if you all will bear with me, I am trying to educate myself.

So you all have all of these pathogens—and I am asking both Dr. Isaac and Dr. Edwin—and I assume that many of them are live or living organisms. Is that correct?

Mr. EDWIN. That is correct.

Dr. ISAAC. Yes.

Mr. GRIFFITH. And when your inspectors are going in, are they looking for any mutations or to make sure that there is no possibility of, for lack of a better term, I am going to say cross-pollination?

And the reason for this is I have just read this fascinating read called Inheritors of the Earth by Chris Thomas, a British scientist, who is talking about all kinds of things. And in there, he talks about a plant that comes over from Sicily, creates a hybrid, which becomes a separate species in Great Britain. It took about 300 years. But then, once the railroads came to town, they have discovered it created another hybrid in York in a matter of just maybe a few decades.

And so I am worried that we have got all these dangerous things. Are we making sure there are no mutations or that there isn't something else going on? Because, apparently, organisms, as complicated, these are all ragworts and groundsel species. Well, they are a lot more complicated than some of the microorganisms. Are we making sure? Is that part of the inspection, that we are making sure we don't have mutations or hybridization going on within our own labs?

Mr. EDWIN. So we have a process to capture what you are describing, a strain within an organism and variants. You know there is that opportunity for them to—our database captures that information. And as we inspect and look at the inventories, we also pay attention to that.

It is an ongoing process and we encourage, anytime that there are differences, to be able to get that. And some of them actually need approval if they are making an antibiotic-resistant strain. So it needs to go through the Institutional Biosafety Committees that have experts locally at the entity and then the process comes here. And we have an expert panel of experts from various agencies. We call these sometimes and they provide us the guidance as well as we look at it internally as well.

So we are paying attention to those, especially since science is evolving rapidly.

Mr. GRIFFITH. I appreciate that because the concern has a little bit different look to it and all of a sudden, we have accidently created something even worse than the original.

Dr. Isaac, are you all doing similar things?

Dr. ISAAC. Yes, we are doing similar things. We require that individual strains be registered and that if there are variations within their research protocol as to the type of virus that they are working or creating, and the type of species, animal species that they are working with, that they also report that to us. And we review those research protocols.

And that is the same for animal pathogens and plant pathogens.

Mr. GRIFFITH. All right. With that, I yield back.

Any additional questions, Ms. DeGette?

Ms. DEGETTE. No, thank you.

Mr. GRIFFITH. All right. Well, that concludes this hearing. It was, hopefully, not too painful but we do want to make sure we keep the American public protected and we appreciate the work of the GAO in helping us with that and your cooperation with them.

In conclusion, I thank all of you. And the members who participated in today's hearing. I remind members they have 10 business days to submit questions for the record and I ask that the witnesses all agree to respond promptly to the questions.

And with that, this hearing is adjourned.

[Whereupon, at 12:05 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

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.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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December 5, 2017

Dr. Mary Denigan-Macauley
Acting Director
Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Dr. Denigan-Macauley:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, November 2, 2017, to testify at the hearing entitled "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, December 15, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

December 15, 2017

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
House of Representatives

Subject: Select Agent Oversight – GAO Responses to Questions for the Record

This letter notifies you of our enclosed responses to questions for the record following the November 2, 2017 hearing titled "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens." I am pleased to be able to provide you with the requested information. If you or your staff have any questions about our responses, please contact me at (202) 512-7114 or deniganmacauleym@gao.gov.

Sincerely yours,

Mary Denigan-Macauley

Mary Denigan-Macauley, Ph.D.
Acting Director, Health Care

Enclosure

The Honorable Morgan Griffith

1. **In addition to facing challenges in hiring staff, GAO's report noted that some staff lack technical expertise. Specifically, one of the problems arising from the small workforce was that staff were sometimes assigned tasks outside of their area of expertise. One example noted in the report was a security specialist being assigned to inspect ventilation systems.**
    a. **How often does this happen – an employee being assigned work that he or she is not qualified for, or at the very least, for which he or she lacks expertise?**
    b. **Can you provide any other examples?**

Analysis of the frequency and extent of staff being assigned work for which they are unqualified was beyond the scope of our review. However, during the course of our review, in the fall of 2016, a number of APHIS officials were performing multiple roles to help the APHIS component of the Federal Select Agent Program carry out its duties with its available staff, according to officials we interviewed. For example, a manager within the program was taking on the role of the training specialist, and the role of the scientific officer was being carried out by another manager. APHIS is aware of these gaps and, as we reported, added several new positions in 2017, including a scientific officer, a security manager, and a training specialist.[1] We are not aware of similar examples within the CDC component of the program.

2. **Both agencies reported to GAO that additional training opportunities were needed for their staff. According to the report, both agencies are in the process of improving training for program staff, including by hiring additional training specialists.**
    a. **Have those training specialists begun employment yet?**
    b. **What will the role of those specialists be? How specifically will they help staff find training opportunities or gain technical expertise?**

As of December 2017, CDC was in the process of hiring an additional training specialist and was using two detailees from CDC's Office of Public Health Preparedness and Response to assist with training until it selects someone, according to officials. Once hired, the training specialist will be responsible for leading and coordinating the design and development of instructional activities to address the training needs of Federal Select Agent Program staff, according to an agency document. In addition, in September 2017, CDC awarded a contract to further assist the program with training. According to the contract's performance work statement, the contractor is responsible for assessing training needs and gaps and developing a custom training program for both new and experienced inspectors.

APHIS hired its first training specialist for its component of the Federal Select Agent Program in November 2017, according to APHIS officials. The new training specialist is responsible for developing and coordinating training activities to increase the technical abilities of program staff and help ensure APHIS inspectors' training needs are met, according to an agency document and officials. As we noted in our October 2017 report, APHIS's animal inspection training needs have not been explicitly addressed in the past when CDC has taken the lead on training. However, both agencies agreed with our recommendation to develop a joint workforce plan that

[1]GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145 (Washington, D.C.: Oct. 19, 2017).

assesses workforce and training needs for the program as a whole and are planning to assess training needs as part of their joint strategic planning efforts.

3. **GAO's report noted that one way CDC and APHIS work to mitigate the organizational conflicts of interest issue is to allow the agency partner to take the lead in inspecting their own laboratories. So CDC would take the lead in overseeing APHIS's labs in select agent inspections and vice versa.**
    a. **Please explain in greater detail what it means to allow the partner agency to "take the lead" in those inspections.**
    b. **How could those inspections be truly effective, if CDC's area of expertise is overseeing federal select agents that pose a severe threat to human health, while APHIS's area is federal select agents that pose a severe threat to animal health? How could each of the agencies be qualified to inspect labs handling select agents that are not in their area of expertise?**

When one of the agencies from the Federal Select Agent Program takes the lead on an inspection, that agency is responsible for coordinating all inspection activities and writing the inspection report. For example, the lead agency is responsible for organizing the inspection before it takes place, such as determining the number of inspectors needed and notifying the laboratory of the inspection. During the inspection, the lead agency leads the opening and closing meetings with the inspected laboratory while the joint inspection team, composed of both CDC and APHIS inspectors, works together to conduct the inspection. Following the inspection, the lead agency drafts the inspection report and is the point of contact for the laboratory to submit any responses related to the report. Regardless of the lead agency, CDC generally conducts the legal reviews of joint inspection reports because of staffing constraints at APHIS, according to program officials.

To ensure the Federal Select Agent Program has the appropriate expertise to conduct effective inspections, CDC inspectors participate in inspections of CDC-owned laboratories to provide expertise in human pathogens, and APHIS inspectors participate in inspections of APHIS-owned laboratories to provide expertise in animal and plant pathogens. In addition, CDC and APHIS conduct many joint inspections of laboratories that work with select agents that affect both humans and animals, thus facilitating collaboration and enhancing expertise. However, as we reported, the Federal Select Agent Program has not formally assessed all potential risks posed by its current structure, including potential conflicts of interest arising from the need to draw on the expertise of inspectors from the agencies that own the laboratories. Nor has it assessed the effectiveness of mechanisms it uses to address those risks, including having APHIS lead inspections of CDC-owned laboratories and CDC lead inspections of APHIS-owned laboratories. We recommended that CDC and APHIS regularly assess such risks and the effectiveness of its mechanisms to address them and take actions as necessary to ensure any identified risks are addressed. Both agencies agreed with our recommendation and are exploring options to ensure potential risks are assessed and addressed.

GREG WALDEN, OREGON
CHAIRMAN

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RANKING MEMBER

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COMMITTEE ON ENERGY AND COMMERCE

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December 5, 2017

Dr. Samuel S. Edwin
Director
Division of Select Agents and Toxins
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Edwin:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, November 2, 2017, to testify at the hearing entitled "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

Responses to Questions for the Record
Dr. Samuel Edwin, Centers for Disease Control and Prevention
Energy and Commerce Committee's Subcommittee on Oversight and Investigations hearing entitled "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens"
(November 2, 2017)

The Honorable Morgan Griffith

1. **How does the CDC Division of Select Agents and Toxins (DSAT) determine whether the Select Agent Program inspections DSAT conducts are effective in improving biosecurity and biosafety at high-containment laboratories?**

DSAT co-directs the Federal Select Agent Program (FSAP) along with its colleagues at the Agriculture Select Agent Services located within U.S. Department of Agriculture (USDA). FSAP is charged with administering the FSAP, including inspecting entities' compliance with select agent regulations to ensure they have appropriate measures in place to deter the unauthorized access, theft, loss, or release of biological select agents and toxins (BSAT).

FSAP is committed to maximizing the effectiveness of the inspection process in improving biosafety and biosecurity at high-containment laboratories that handle select agents and toxins. Toward that end, the program is engaged in ongoing efforts to further strengthen the inspection process, including:

- Regularly scheduled inspector training opportunities, occurring monthly or more frequently depending on the topic covered. Topics for these sessions include natural disaster response, facility reviews, facility security, and biosafety issues of interest. FSAP also organizes annual inspector trainings for both DSAT and AgSAS inspectors
- Sending staff to a multi-day in-person training course on Biosafety Level (BSL) -3 safety training and expanded opportunities for intensive BSL-4 training.
- Development of a joint DSAT (public health) and AgSAS (agriculture) strategic plan that includes assessment of workforce and training needs for staff across the program.
- Implementing practices to emphasize activities and conditions likely to pose the greatest risk.

FSAP has developed program measures to track and evaluate aspects of our effectiveness regarding oversight, including:

- Frequency of inspections (e.g., making sure we conduct inspections on time, according to program goals, such as conducting a renewal inspection every three years)
- Timeliness of inspection reports (e.g., evaluating how quickly we are able to provide important inspection findings back to the entities so that they can take any key actions needed)

Departures from the regulations identified during inspections are used to correct practices and procedures at the entity to ensure that the safety and security is commensurate with the risk of the work being conducted with select agents and toxins at the facility, the adequacy of mitigation measures in place, and the frequency and type of future inspections at an entity.

Additionally, we work to ensure expedited completion of any necessary follow-up or actions needed to mitigate the situation, for entities engaged in high-risk activities or any incident involving a select agent or toxin.

To further improve the effectiveness of the inspection process, FSAP recently developed a new information management system that, over time, will allow FSAP staff to perform data analytics and trend analysis on inspection findings. This, along with the implementation of a departure severity matrix, will allow tracking over time of both the number and seriousness of deficiencies for individual entities and across the regulated community. We will be examining trends and associations between inspection findings and risk in order to better understand and anticipate actions most strongly and most often associated with poor outcomes; ultimately we will use this information to improve biosafety and biosecurity practices across regulated entities and improve the inspection process.

Facility inspections are just one aspect of FSAP oversight of laboratories. The program provides consistent and ongoing engagement with regulated entities before, during, and after inspections. FSAP works with laboratories on multiple fronts (e.g., through the entity registration process, and providing technical assistance and guidance to registered entities to promote laboratory safety and security), including quickly addressing and responding to emerging issues. Another aspect of FSAP's oversight role is to authorize individuals to work with select agents and toxins following a security risk assessment performed by the Federal Bureau of Investigation. The assessment is to determine whether an entity or an individual who wishes to register to possess, use or transfer a select agent or toxin, or an individual who has been identified by a registered entity as having a legitimate need to access a select agent or toxin, meets one of the statutory restrictors which would either prohibit registration or restrict access, respectively. FSAP shares many of its activities and measures regularly with the public (such as through the publication of the 2016 DSAT Inspection Report Processing Annual Summary and the 2016 Annual Report of the Federal Select Agent Program). FSAP Directors also regularly attend and present at various meetings and interact with laboratory leadership.

2. Should theft-loss-release reports be used to measure the performance of the Federal Select Agent Program?

No, we suggest that the theft, loss, and release reports not be used to measure FSAP's performance. Use of theft-loss-release reports to measure performance of the FSAP program could undercut one of the primary uses of these reports. We encourage laboratories working with select agents and toxins to report all incidents involving select agents and toxins – even ones that may not meet the legal criteria to require reporting – to increase the amount of information available for analysis, which in turn will improve our ability to take or recommend actions to protect laboratory personnel, staff and the community. Anything that discourages entities from submitting reports – such as using them as performance measures in ways that could penalize the entities making them – will hamper our ability to analyze potentially hazardous situations and recommend improvements. Laboratory research on biological select agents and toxins is an important part of our nation's contribution to support preparedness and defense against naturally occurring diseases and potential bioterrorism events. However, the nature of scientific laboratory work with these materials means that some risk is always present. Our goal is to reduce risk to the maximum extent possible.

FSAP views reports on releases and losses as a good oversight tool. These reports assist us with gauging what is occurring at the entity, identifying common causes of safety and security lapses, and providing recommendations to entities to minimize risk and keep these situations from happening in the future.

However, the theft, loss, and release reports are not a good measure of the performance of the FSAP as a whole. Many reports of losses and releases are due to human error rather than

institutional or system failure, which no amount of regulation or oversight can totally prevent. FSAP's role is to ensure that if such an event happens, the entity has plans and training in place to mitigate the impact of the event (e.g., minimize harm to lab workers and prevent the spread of the agent or toxin outside the facility), and to eliminate or reduce the likelihood of recurrence.

3. **The Select Agent Program has a mandate to protect biosecurity (i.e., prevent bad actors from possessing or accessing select agents). Should the Select Agent Program also have a mandate to protect biosafety (i.e., protect the safety of the research scientist in the lab)?**

   We believe that the Federal Select Agent Program does have such a mandate. Section 351A of the Public Health Service Act provides that the HHS Secretary shall by regulation provide for the establishment and enforcement of safety procedures for the possession, use, and transfer of select agents and toxins, including measures to ensure the proper training and appropriate skills to handle such agents and toxins, and the proper laboratory facilities to contain and dispose of such agents and toxins. The Secretary of Agriculture has a parallel mandate in the *Agricultural Bioterrorism Protection Act of 2002.*

   The select agents and toxins biosafety regulations for the Department of Health and Human Services can be found in section 73.12 of Title 42, Code of Federal Regulations, and those for the Department of Agriculture can be found in section 331.12 of Title 7 and section 121.12 of Title 9, Code of Federal Regulations. These provisions require that a biosafety plan be written that is commensurate with the risk of the select agent or toxin, given its intended use. These provisions emphasize safe work practices, appropriate containment equipment, well-designed facilities, and administrative controls based on the work with BSAT to minimize risks of unintentional infection of laboratory workers and to prevent possible release of select agents or toxins to the outside environment.

   Both biosafety and security are absolutely critical, requiring dedicated attention on the part of both inspectors and those working with these materials to ensure that this work remains as safe and secure as possible.

4. **Both CDC and APHIS have noted the benefits to the Select Agent Program's current structure, including access to experts and other support from your respective divisions. For example, according to the GAO report (p.15) select agent program inspectors sometimes obtain technical assistance from experts in CDC and APHIS, such as in cases where the inspectors are not familiar with certain techniques or equipment being used in a registered laboratory. Are any of these experts registered with the select agent program, or are they otherwise subject to select agent program regulation and oversight?**

   Yes. Some of the subject matter experts (SMEs) that provide technical assistance on specific agents are employed by an entity registered with FSAP and are subject to select agent regulations and oversight. When SMEs from the regulated entities are consulted, FSAP obtains assistance regarding technical issues associated with the select agents or toxins themselves or the systems and procedures used to work with them, not guidance on the regulatory treatment or oversight of these agents or toxins. In terms of regulatory compliance, FSAP inspectors have the practical experience and advanced professional degrees (e.g., microbiology and veterinary medicine) necessary to perform reviews of select agent laboratories. FSAP training includes all aspects to assess the entity's compliance with the select agent regulations (e.g., security and biosafety training). FSAP training initiatives also include sending staff to a multi-day in-person training

course on Biosafety Level (BSL) -3 safety training and expanded opportunities for intensive BSL-4 training.

However, given the complexity and high risk inherent in this work and the evolving scientific research and expertise that is required, FSAP must sometimes rely on technical scientific information provided by subject matter experts outside of the regulatory program, including from researchers that are themselves doing some of the leading work in the area of select agents and/or toxins. FSAP also consults with outside subject matter experts when needed, through venues such as the CDC's Intragovernmental Select Agents and Toxins Technical Advisory Committee. This advisory committee provides recommendations and guidance to FSAP, although any recommendations to change to the regulations are made by the FSAP Directors, and must be approved by the Secretary of Health and Human Services or the Administrator of USDA's Animal and Plant Health Inspection Service, as appropriate.

The Honorable Buddy Carter

1. **In January and March 2017, HHS and USDA issued updated select agent regulations and guidance that included clear definitions of inactivation and a validated inactivation procedure that are consistent across the Federal Select Agent Program. Moreover, NIH and CDC stated that it plans to include a new appendix in the revised Biosafety in Microbiological and Biomedical Laboratories manual that specifically addresses the development, validation, and implementation of inactivation protocols, which they anticipate releasing in 2 to 3 years.**

    a. **Why is it going to take you three years to issue the revised Biosafety in Microbiological and Biomedical Laboratories manual?**

    Since 1984, CDC and the National Institutes of Health (NIH) have partnered to co-author the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), a comprehensive guide on biosafety practices and policies for laboratories working with pathogens. The BMBL provides the foundational guidance used in laboratories across the U.S. Currently in its fifth edition, CDC and NIH are revising the more than 400 page guide with up-to-date information on current best practices and the newest technologies for biosafety.

    Given the wider laboratory community's reliance on the BMBL and the level of detail provided by the guide, preparing a new edition of the BMBL is a major undertaking. The 5th edition was issued in December 2009, more than 10 years after the 4th edition (April 1999). For the fifth edition, CDC and NIH reached out to more than 200 scientific and biosafety experts to ensure that the BMBL captures the best available guidance and evidence, and the agencies are engaged in a similarly comprehensive and exhaustive process for the sixth edition. The process of gathering this input, reviewing available evidence, and developing reliable new guidance is time consuming. CDC and NIH are deep into the process for writing the sixth edition and expect to publish the updated guidance in 2019.

    b. **Can you guarantee this committee that the guidance and training you have today is sufficient to prevent any future failed deactivations of pathogens?**

    On January 19, 2017, FSAP published the Final Rule "Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and

Enhanced Biosafety Requirements" that added specific regulatory requirements that must be followed for the inactivation of select agents. In conjunction with the publication of the Final Rule, FSAP also published guidance to help entities implement these provisions, the "Guidance on the Inactivation or Removal of Select Agents and Toxins for Future Use." The guidance is available at https://www.selectagents.gov/irg-changes.html. In addition, FSAP has provided guidance through its outreach to the regulated community including the most recent training workshop for Responsible Officials held during the week November 27. While this work does not come without risk, the efforts of FSAP continue to focus on helping to minimize this risk, and therefore ensure that this important research can be conducted in a way that is as safe and secure as possible.

GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
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ONE HUNDRED FIFTEENTH CONGRESS

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December 5, 2017

Dr. Freeda E. Isaac
Director
Agriculture Select Agent Services
Animal and Plant Health Inspection Service
14700 River Road
Riverdale, MD 20737

Dear Dr. Isaac:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Thursday, November 2, 2017, to testify at the hearing entitled "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Friday, December 15, 2017. Your responses should be mailed to Ali Fulling, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Ali.Fulling@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Greg Walden
Chairman

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations

Attachment

USDA APHIS Questions for the Record
House Committee on Energy and Commerce
Hearing on "Concerns Over Federal Select Agent Program Oversight of Dangerous Pathogens"
November 2, 2017
Dr. Freeda Isaac

The Honorable Morgan Griffith

1. How does the USDA Animal and Plant Health Inspection Service determine whether the Select Agent Program inspections APHIS conducts are improving biosecurity and biosafety at high-containment laboratories.

The inspections that APHIS conducts as part of the select agent program are intended to improve biosecurity and biosafety of high-containment laboratories by focusing on the highest risk activities and mitigations, and through inspections tailored to the baseline risk assessments for each registered entity. APHIS is confident that these inspection procedures ensure that regulated entities are properly securing and using these potentially damaging agents and toxins.

Nevertheless, APHIS is constantly looking for improvements, and the Agency believes that its new select agent database will yield additional data and information that it can use to improve its oversight of select agents and toxins to strengthen biosecurity and biosafety.

2. Should theft-loss-release reports be used to measure the performance of the Federal Select Agent Program?

No, APHIS does not believe that these reports are an appropriate metric for the program. The joint APHIS/CDC forms, Report of Theft, Loss or Release of Select Agents and Toxins, are submitted to APHIS or CDC by both registered and non-registered entities upon discovery of a theft (unauthorized removal of select agent or toxin), loss (failure to account for select agent or toxin), or release (occupational exposure or release of an agent or toxin outside of the primary barriers of the biocontainment area) of a select agent or toxin. These reports are an essential oversight tool that provides important information about what registered entities are doing and to help the program identify any potential weaknesses. If these reports were used as a direct performance metric, it could disincentive self-reporting by regulated entities and give the program less information.

3. The Select Agent Program has a mandate to protect biosecurity (i.e., prevent bad actors from possessing or accessing select agents). Should the Select Agent Program also have a mandate to protect biosafety (i.e., protect the safety of the research scientists in the lab)?

Biosafety has always been a key component of the select agent program. *The Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (P.L. 107-188) includes a mandate for biosafety. The select agent regulations have incorporated biosafety since the program was created, and FSAP adds biosafety regulations (including most recently in 2017) when necessary to further protect laboratory workers and researchers.

4. Both CDC and APHIS have noted the benefits to the Select Agent Program's current structure, including access to experts and other support from your respective divisions. For example, according to the GAO report (p. 15) select agent program inspectors sometimes obtain technical assistance from experts in CDC and APHIS, such as in cases where the inspectors are not familiar with certain techniques or equipment being used in a registered laboratory. Are any of those experts registered with the select agent program, or are they otherwise subject to select agent program regulation and oversight?

The technical experts on which the select agent program relies are not necessarily registered with the program. The select agent program selects technical experts based on their academic expertise, training, or previous experience working with select agents and toxins; only those who are actively possessing, using, or transferring select agents or toxins are subject to our regulations. In instances where the program requests the technical assistance of experts regulated by the program, the program uses venues such as the Intra-governmental Select Agents and Toxins Technical Advisory Committee to manage the input and provide a comprehensive recommendation, which alleviates individual conflicts of interest between the regulatory authority and regulated personnel.

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