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HIF306020

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, D.C.

The subcommittee met, pursuant to call, at 10:15 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.

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.

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, a/k/a 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 accident 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.

The Chairman. 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 government 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.

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. Each of the witnesses today has responded -- 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 --

Mr. Griffith. Yes, ma'am.

Ms. DeGette. -- 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.

[The information follows:]

**********COMMITTEE INSERT 1**********

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

STATEMENT 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:]

**********INSERT 2*********

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:]

**********INSERT 3*********

Mr. Griffith. Thank you so much.

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

STATEMENT OF DR. 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:]

**********INSERT 4**********

572 Mr. Griffith. Thank you very much and I will now recognize
573 myself for 5 minutes to start the committee questioning.
574 Dr. Denigan-Macauley, GAO found that the Select Agent
575 Program does not have a joint mission statement. Do CDC and APHIS
576 have the same missions stating what the program seeks to achieve;
577 yes or no?
578 Ms. Denigan-Macauley. No.
579 Mr. Griffith. Thank you. The Government Performance and
580 Results Act of 1993 requires agencies to develop strategic plans
581 that include documents and planning tools, such as mission
582 statements, strategic goals, and objectives and performance
583 measures. Is that correct; yes, or no?
584 Ms. Denigan-Macauley. Yes.
585 Mr. Griffith. Thank you. Although not binding to the
586 Federal Select Agent Program, these requirements have been found
587 by the GAO to serve as leading practices for individual programs.
588 Is that also correct; yes or no?
589 Ms. Denigan-Macauley. Yes.
590 Mr. Griffith. Both CDC and APHIS have performance measures
591 for their activities and select programs. Isn't that correct?
592 Ms. Denigan-Macauley. Yes.
593 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. Okay 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. Okay, 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. Okay. 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. Okay, 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. Okay 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. Okay, 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 inspectors 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. So you don't -- excuse me. 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 mitigate the -- 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. -- 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, I mean 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. Okay. 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 feasible, 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 it is 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. Very quickly, 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. Okay, 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. Okay 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. I mean 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 expertise 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 I mean 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. I mean 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

1100 often fake or hoax anthrax packets, including my own office at
1101 that time.
1102 And Dr. Edwin, as I have learned in preparation for today,
1103 prior to your role with the Select Agent Program, you served from
1104 2008 to 2016 as the responsible official and Biological Surety
1105 Officer for the Select Agent Program at the U.S. Army Medical
1106 Research Institute of Infectious Diseases. And it was from that
1107 place, in July of 2008 that a biodefense researcher from your
1108 institution, Bruce Ivins, died from an apparent suicide after
1109 learning that the FBI was going to file criminal charges against
1110 him for the 2001 anthrax attacks.
1111 In August of 2008, the FBI and Department of Justice
1112 announced that Dr. Ivins was likely solely responsible for the
1113 five deaths and the injuries caused by the anthrax mailings but
1114 in May of 2011, a panel of the National Academy of Sciences, at
1115 the request of the FBI, reviewed the scientific work and concluded
1116 the FBI might have overstated the genetic analysis linking the
1117 mailed anthrax to a flax of anthrax kept by Ivins.
1118 So my question, Dr. Edwin, is, on July 10th of 2008, when
1119 Dr. Ivins lost his security -- he lost his security clearance,
1120 as I understand. And as you were the responsible official for
1121 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. Well but what I am concerned about is -- that is incredibly important but 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 you know 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. Okay. 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. Okay, 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. Okay. 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. Okay.

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. Okay. Okay, 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. Okay.

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. Okay. 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 kind so 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 -- you know 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 is differences, to be able to get that. And some of them actually need approval you know 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.]