

BIORESEARCH LABS AND INACTIVATION OF DANGEROUS PATHOGENS

HEARING BEFORE THE SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS SECOND SESSION

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BIORESEARCH LABS AND INACTIVATION OF DANGEROUS PATHOGENS

TUESDAY, SEPTEMBER 27, 2016

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

The subcommittee met, pursuant to call, at 2:02 p.m., in Room 2322 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, Blackburn, Flores, Brooks, Hudson, Collins, DeGette, Schakowsky, Castor, Yarmuth, Kennedy, Green, and Welch.

Staff present: Elena Brennan, Staff Assistant; Rebecca Card, Assistant Press Secretary; Ryan Coble, Detailee, Oversight and Investigations; Charles Ingebretson, Chief Counsel, Oversight and Investigations; David Schaub, Detailee, Oversight and Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Deputy Chief Counsel, Oversight; Gregory Watson, Legislative Clerk, Communications and Technology; Jeff Carroll, Democratic Staff Director; Ryan Gottschall, Democratic GAO Detailee; Christopher Knauer, Democratic Oversight Staff Director; Elizabeth Letter, Democratic Professional Staff Member; and Miles Lichtman, Democratic Professional Staff Member.

Mr. MURPHY. While I know they just called votes, we are going to try and do opening statements, and then we will break for a little bit for some quick votes and come back. This is what happens on the Hill. I apologize.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

All right. Well, today this subcommittee will continue our examination of bioresearch labs and handling of dangerous pathogens, including the 66 pathogens classified as Federal Select Agents. Specifically, we will focus on the inactivation of bacteria and viruses, or making dangerous organisms harmless and incapable of spreading disease while retaining characteristics for future use including crucial biodefense research.

This research allows for the development of diagnostic tests to detect emerging infectious diseases as well as discovering vaccines and other medical countermeasures to protect us from epidemics. First, I would like to thank the GAO for their hard work and pivotal report as well as their participation in today's hearing. I would

also like to thank CDC, FDA, NIH, and the Department of the Army for their participation today. Thank you for being here.

Disastrously, recent incidents at Federal bioresearch labs have revealed lackadaisical methods used to inactivate anthrax, a deadly select agent. Such negligence continues to put human lives at risk. In 2015, the Army's Dugway Proving Ground shipped live anthrax, thought to have been successfully killed, to contractors, subcontractors and private labs in all 50 States and nine foreign countries for more than a decade.

The dangers presented by such a careless mistake are unacceptable, and thankfully no one was harmed so the Army dodged a catastrophe in this matter. However, without major overhaul, how deadly agents like anthrax are handled and how research is conducted, the risk of repeating this mistake remains viable.

In 2014, this subcommittee held a hearing on the shipment of live anthrax thought to have been activated. The anthrax was shipped from a high containment lab at CDC to another lab at CDC with a lower level of biosafety. And the transfer of live anthrax potentially exposed over 80 CDC employees.

An internal CDC review and USDA inspection found multiple failures. Unapproved inactivation techniques were used; a virulent strain of anthrax was unnecessarily used in the research; lab staff lacked training and knowledge required to inactivate anthrax; lack of standard operating procedures for inactivation; inability to find anthrax samples; and disinfectant used for decontamination was expired.

These kinds of incidents drove direct action from the White House—a Federal laboratory stand-down was ordered in the summer of 2014. However, and disappointingly, even with consciousness raised about the lab safety, bioresearch labs persist in questionable inactivation practices today.

Recently, we learned that the CDC in Ft. Collins, Colorado sent a shipment of Zika, dengue, and chikungunya virus to CDC Atlanta. The viruses were used in control panels for a triplex diagnostic test under emergency use authority. Despite CDC Ft. Collins' knowledge that the inactivation had not been confirmed, the shipment was sent. Let me restate that. Dangerous, live viruses including Zika were handled and shipped across the country. CDC Ft. Collins told CDC Atlanta don't open the package until inactivation was confirmed, and ultimately, thankfully, the package was not opened.

This continued problem of mistakenly shipping live anthrax and other pathogens led the committee to make a bipartisan request to the GAO to evaluate issues relevant to inactivation. By coincidence, the request was made 2 weeks before the discovery of the massive anthrax inactivation problems at Dugway.

Today, the GAO will present its finding and recommendations on the inactivation of dangerous pathogens. Failed inactivation has been long overlooked by regulators and the research community. The GAO brings us several important findings. First, the GAO found that the Federal Select Agent Program operated by both the Departments of Health and Human Services and Agriculture does not require laboratories to identify incidents involving failed inac-

tivation in its reporting, resulting in inconsistent and incomplete reports.

From 2003 until 2015, the Select Agent Program reported ten incidents, but GAO documented an additional 11 situations in which select agents were not effectively inactivated. Since the Select Agent Program lacks standard practices for identifying such incidents, we simply don't know how often they occur or why. This is extremely disturbing.

In their report, the GAO noted the need for better and more consistent follow-up when problems with inactivation are discovered. The GAO found that the Federal Select Agent regulators were inconsistent in both their referrals for further investigation and in their enforcement approach. As one example, two incidents at CDC under investigation by the USDA in 2014 were not referred for further investigation. The lack of consistency by select agent regulators, CDC, and the USDA leaves this subcommittee and the public with zero confidence in regulators' ability to protect the safety of the American public.

But the GAO's most alarming discovery is the fact that today we still don't know what it takes to effectively and reliably inactivate certain select agent pathogens. In some cases, the chemical or radiological dosing is not actually effective; in other cases, the process for verifying the inactivation is not reliable. It is extremely troubling that after 15 years of efforts, we still lack competency in ensuring the safety of the public from dangerous and sometimes fatal bacteria and viruses.

This needs to be among our highest priorities for reforming the Select Agent Program. To reiterate, it has been 15 years since we became aware of the need for a Select Agent Program and clearly there is a lot of work to do.

I do want to commend the Army for its response to the shocking shipments of anthrax from the Dugway laboratory, and I want to acknowledge the cooperation we have received from both the NIH and the FDA. Both have worked to identify improvements needed and to implement those changes, including creating new offices and committing additional resources.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

Today this subcommittee will continue our examination of bioresearch labs and the handling of dangerous pathogens, including the 66 pathogens classified as Federal "select agents." Specifically, we will focus on the inactivation of bacteria and viruses, or making dangerous organisms harmless and incapable of spreading disease while retaining characteristics for future use—including crucial biodefense research. This research allows for the development of diagnostic tests to detect emerging infectious diseases, as well as discovering vaccines and other medical countermeasures to protect us from epidemics.

First, I would like to thank the GAO for their hard work and pivotal report, as well as their participation in today's hearing. I'd like to also thank CDC, FDA, NIH and the Department of the Army for their participation today.

Disastrously, recent incidents at Federal bioresearch labs have revealed lackadaisical methods used to inactivate anthrax, a deadly select agent. Such negligence continues to put human lives at risk. In 2015, the Army's Dugway Proving Ground shipped live anthrax—thought to have been successfully killed—to contractors, subcontractors and private labs in all 50 States and nine foreign countries for more than a decade. The dangers presented by such a careless mistake are unacceptable. Thankfully, no one was harmed, so the Army dodged a catastrophe in this matter.

However, without major overhaul of how deadly agents, like anthrax, are handled and how research is conducted, the risk of repeating this mistake is remains viable.

In 2014, this subcommittee held a hearing on live anthrax that was shipped out—once again—thought to have been inactivated. The anthrax was shipped from a high-containment lab at CDC to another lab at CDC with a lower level of biosafety. The transfer of live anthrax potentially exposed over 80 CDC employees. An internal CDC review and USDA inspection found multiple failures: unapproved inactivation techniques were used; a virulent strain of anthrax was unnecessarily used in the research; lab staff lacked training and knowledge required to inactivate anthrax; lack of standard operating procedures for inactivation; inability to find anthrax samples; and disinfectant used for decontamination was expired. These kinds of incidents drove direct action from the White House—a stand-down was ordered in the summer of 2014.

However, and disappointingly, even with consciousness raised about lab safety, bioresearch labs persist in questionable inactivation practices today. Recently we learned that the CDC in Fort Collins, Colorado sent a shipment of Zika, Dengue, and chikungunya viruses to CDC Atlanta. The viruses were used in control panels for a triplex diagnostic test under emergency use authority. Despite CDC Ft. Collins' knowledge that the inactivation had not been confirmed, the shipment was sent. Live viruses—including Zika—were handled and shipped across the country. CDC Ft. Collins told CDC Atlanta not to open the package until inactivation was confirmed. Ultimately, the package was not opened.

This continued problem of mistakenly shipping live anthrax and other pathogens led the committee to make a bipartisan request to the GAO to evaluate issues related to inactivation. By coincidence, the request was made two weeks before the discovery of the massive anthrax inactivation problem at Dugway. Today, the GAO will present its findings and recommendations on the inactivation of dangerous pathogens. Failed inactivation has been long overlooked by regulators and the research community. GAO brings us several important findings. First, the GAO found that the Federal Select Agent Program, operated by both the Departments of Health and Human Services and Agriculture, does not require laboratories to identify incidents involving failed inactivation in its reporting resulting in inconsistent and incomplete reports. From 2003 until 2015, the Select Agent Program reported 10 incidents, but GAO documented an additional 11 situations in which select agents were not effectively inactivated. Since the Select Agent Program lacks standard practices for identifying such incidents, we don't know how often they occur, or why.

The GAO also noted the need for better and more consistent follow-up when problems with inactivation are discovered. According to GAO's report, the Federal select agent regulators were inconsistent in both their referrals for further investigation and in their enforcement approach. As one example, two incidents at CDC under investigation by USDA in 2014 were not referred for further investigation. The lack of consistency by select agent regulators—CDC and USDA—leaves this subcommittee and the public with zero confidence in regulators' ability to protect the safety of the American public.

GAO'S most alarming discovery is the fact that today, we still don't know what it takes to effectively and reliably inactivate certain select agent pathogens. In some cases, the chemical or radiological "dosing" is not actually effective; in other cases, the process for verifying the inactivation is not reliable. It is extremely troubling that after 15 years of efforts, we still lack competency in ensuring the safety of the public from dangerous, and sometimes fatal, bacteria and viruses. This needs to be among our highest priorities for reforming the Select Agents Program.

To reiterate, it has been 15 years since we became aware of the need for an effective Select Agents Program. Clearly, there's still a lot of work to do.

I do want to commend the Army for its response to the shocking shipments of anthrax from the Dugway laboratory, and also I want to acknowledge the cooperation that we've received from both the NIH and the FDA; both have worked to identify improvements needed and to implement those changes, including creating new offices and committing additional resources.

Mr. MURPHY. I welcome and thank all the witnesses for testifying today, and I now recognize Ranking Member Ms. DeGette.

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

Ms. DEGETTE. Mr. Chairman, sadly, there are 6 minutes left on the vote on the floor, so I will consolidate my opening statement. I will ask unanimous consent to put the full statement in the record and also all the other statements of the other members. And I just want to register my displeasure with this process this morning not letting Members fully speak.

As the chairman said, we are continuing to examine the issue of inactivation and whether we have the proper scientific understanding and processes to ensure pathogens are inactivated by shipping or releasing them. Of course, this gained public attention following the Army's Dugway Proving Ground incident, where researchers for years had been shipping live anthrax to labs across the world inadvertently.

Researchers must inactivate pathogens for a variety of reasons. For example, Federal agencies, universities, and others inactivate disease-causing agents so that vaccine development and diagnostic testing can occur in lower safety labs. This work is critical for promoting medical advancements and bolstering public health preparedness. It is part of this committee's ongoing bipartisan efforts to accelerate the path of cures and medical breakthroughs.

But as valuable as this research may be, it can also be very dangerous. All of the agencies here today share the responsibility for making sure that harmful pathogens are being handled without posing a risk to the public. Now it is true we have all taken the inactivation events we are talking about today very seriously. I know all of the agencies here have been acting to try to implement reforms to ensure that past mistakes aren't repeated. I am eager to hear about those efforts, but I also want to know what more needs to be done to address the possible risk to public health.

The GAO is here to testify about their body of work, and what they have done is identify a number of issues around the reporting and referral of incidents regarding incomplete inactivation. For example, the number of incidents of incorrect inactivation is unknown. The GAO found that the Select Agent Program failed to identify at least 11 inactivation incidents in the last 12 years. How many more are there? We don't know.

I am really interested in hearing from the witnesses about their plans to implement the GAO's recommendations and how we can go further. I am also interested to hear about the scientific gaps that exist for the inactivation process for pathogens. High containment labs across the country still have not adopted a uniform approach to the inactivation of dangerous pathogens, which of course increases the risk that this may happen again.

This is something we just simply have to get right. And so I think research is really important to national security and the process of working with these pathogens must minimize all potential risk. I guess we are lucky that nobody has been injured or killed from exposure to these agents in the last few years, but just because we have had good luck doesn't mean that we should take this for granted. And I know nobody here does. I know nobody here does.

So I am looking forward to working with everybody here and I am looking forward to working with you and the other members of the committee, Mr. Chairman, to make sure that in fact we get this right. With that I will submit the rest of my statement for the record and the other opening statements of the other Democratic members.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Thank you, Mr. Chairman.

This hearing offers the subcommittee a valuable opportunity to check in on the progress that the Federal Select Agent Program has made in improving practices and procedures at high-containment laboratories. These places handle pathogens that have the potential to pose a severe threat to public health and safety.

Our specific today is whether we have the proper scientific understanding and processes to ensure that pathogens are inactivated before shipping or releasing them.

This issue gained public attention last year when it revealed that the Army's Dugway Proving Ground had been inadvertently shipping live anthrax to labs across the world for years.

Researchers must inactivate pathogens for a variety of reasons. For example, Federal agencies, universities, and others inactivate disease causing agents so that vaccine development and diagnostic testing can occur in lower safety-level labs. This work is crucial for promoting medical advancements and bolstering public health preparedness. It is a critical part of this committee's bipartisan efforts to accelerate the pace of cures and medical breakthroughs.

However, as valuable as this research may be, it can also be very dangerous. All of the agencies here today share the responsibility of making certain that harmful pathogens are being handled without posing undue risks to the public.

I know that we all have taken the inactivation events we are talking about today very seriously. All the agencies before us have been implementing reforms to ensure that past mistakes are not repeated. We're all eager to hear about those efforts.

But we also want to understand what more needs to be done to address this possible risk to public health.

We have a witness from the GAO with us today to testify about the oversight of high-containment laboratories. GAO's most recent report focuses on inactivation procedures at these labs.

GAO researchers have identified a number of issues related to the reporting and referral of incidents involving incomplete inactivation. For example, they found the total number of incidents of incorrect inactivation is unknown. They found that the Select Agent Program failed to identify at least 11 inactivation incidents in the last 12 years. They also found the Select Agent Program did not consistently refer inactivation incidents to HHS or USDA for further investigation and enforcement.

These findings underscore the need for further coordination, clarity, and guidance within the Select Agent Program. The report offers recommendations to the CDC, NIH, and APHIS, particularly regarding how to regulate the possession, use, and transfer of these pathogens.

I am particularly interested in hearing from each of our witnesses about their plans to implement the GAO's recommendations.

Mr. Chairman, I am also eager to learn about the scientific gaps that still exist regarding inactivation processes for pathogens. High-containment labs across the Government have still not adopted a uniform approach to inactivation of dangerous pathogens, which increases the risk that incomplete inactivation occurs.

We must get this right.

Research on select agents and other harmful pathogens is a critical national security endeavor. However, the process of working with these pathogens must minimize all possible risk. If something goes wrong in this program, there could be disastrous consequences.

We are fortunate that no one in the United States has been injured from exposure to select agents in the number of incidents in the past few years. However, our good fortune does not diminish the threat that the mishandling of these pathogens poses to the health and welfare of millions of Americans. At the end of the day, I need to be able to tell my constituents that the hundreds of laboratories around the country that handle these pathogens—including the CDC's facility in Fort Collins that sits just outside my district—are doing so safely and with care.

I know the agencies represented before us today understand what is at stake here. We have seen promising efforts to investigate incidents, conduct Government-wide reviews, and implement recommendations. And we know that institutional and cultural changes take time.

I look forward to working with all parties before us today to make this program safer, mishaps less common, and accountability more robust.

I thank the Chairman and I yield back.

Mr. MURPHY. And when we return, if the members still want to give theirs or the ranking member does.

Mrs. Blackburn, you can be recognized for 1 minute, and then we are going to have to run.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. That is exactly right, we are going to have to run to the floor. But I do want to welcome you all.

And as the chairman has said and the ranking member has said, we have been here before on this issue. July 16th, 2014, we had a hearing on this issue. I have visited the CDC to look at processes and procedures, and it is such a concern to us. Even in your own report you have found what is at the core of this problem. The lack of approval, the lack of written instructions, there is not a best practices process in place.

So the GAO, we are delighted to have you here and want to talk with you about three of your findings—the tracking, the gaps, scientific gaps that exist, and then the Federal Select Agent Program and the inconsistencies there. So we thank you so much for being here. Mr. Chairman, I thank you for your attention to the issue.

Mr. MURPHY. Thank you. And so the panelists, we are going to run down and vote. Half an hour or so, I guess, the voting; we will be back. So you get a slight reprieve and then we will be right back. Thank you.

[Recess.]

Mr. MURPHY. All right. OK, thank you. Then we will move on. So I ask unanimous consent that any other Members' written opening statements be introduced in the record, and without objection, the documents will be entered into the record.

Let me introduce the witnesses for today's hearing, then. Dr. Tim Persons will lead off our panel. Dr. Persons was appointed chief scientist of the U.S. Government Accountability Office in July 2008. As such, he is a member of the Senior Executive Service of the U.S. Federal Government; also serves as a director for GAO's Center for Science Technology and Engineering. We thank Dr. Persons for being with us today and look forward to his comments.

I would also like to welcome Dr. Daniel Sosin from the Centers for Disease Control and Prevention. With over 30 years of public health, analytical science, and emergency response and medical training experience at the CDC, Dr. Sosin now serves as deputy director and chief medical officer for the Office of Public Health Preparedness and Response. Thank you for being here, Dr. Sosin.

Next, we welcome Dr. Steve Monroe, associate director for Laboratory Science and Safety at the Centers for Disease Control and Prevention. With an extensive background in microbiology and in-

fectious disease, I look forward to hearing from Dr. Monroe on steps taken to improve lab safety policies at the Federal level.

And next up, I introduce Dr. Mark Davidson who is associate deputy administrator at the U.S. Department of Agriculture's Veterinary Service Program. In this role Dr. Davidson oversees the program's national import/export activities as well as all agricultural select agent services. We thank him for being with us today and look forward to his testimony.

Joining us today from the National Institutes of Health we have Mr. Jeff Potts. Mr. Potts serves as the biorisk manager of the NIH where he oversees the coordination of all high containment laboratories within the NIH intramural research program. We thank Mr. Potts for being here.

And finally, we will welcome Major General Barbara Holcomb, commanding general of Medical Research and Materiel Command at Fort Detrick and chief of the U.S. Army Nurse Corps. We thank Major General Holcomb for being here and providing her expertise on behalf of the biological select agents and toxins biosafety program at the Department of Defense.

Again I want to thank all of our witnesses for being here and I appreciate that. You are all aware that this committee is holding an investigative hearing, and when doing so we have the practice of taking testimony under oath. Do any of you have any objections to taking testimony under oath?

Seeing no objections, the Chair then advises all of you that under the rules of the House and the rules of the committee you are entitled to be advised by counsel. Do any of you desire to be advised by counsel? Seeing none then, in that case would you all be please rise and raise your right hand and I will swear you in.

[Witnesses sworn.]

Mr. MURPHY. Thank you. You are all now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. We will have you each give a 5-minute opening statement starting with Dr. Persons. Make sure the microphone is on. Pull it as close as you as possible and pay attention to the timing light if it is on.

Thank you, Dr. Persons.

STATEMENTS OF TIMOTHY PERSONS, PH.D., CHIEF SCIENTIST, GOVERNMENT ACCOUNTABILITY OFFICE; DANIEL M. SOSIN, M.D., DEPUTY DIRECTOR AND CHIEF MEDICAL OFFICER, OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEPHAN S. MONROE, PH.D., ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MARK DAVIDSON, D.V.M., ASSOCIATE DEPUTY ADMINISTRATOR, VETERINARY SERVICES, DEPARTMENT OF AGRICULTURE; JEFFREY POTTS, BIORISK MANAGER, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND MAJOR GENERAL BARBARA R. HOLCOMB, COMMANDING GENERAL, ARMY MEDICAL RESEARCH AND MATERIEL COMMAND

STATEMENT OF TIMOTHY PERSONS

Dr. PERSONS. Will do, sir. Thank you.

Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, I'm pleased to be here to discuss our findings in the report on inactivation issued last week. As you may know, inactivation is a process for destroying the hazardous effects of pathogens while retaining their characteristics for research as in developing vaccines. This delicate balance between eliminating a pathogen's destructive effects and preserving its attributes for study and research must be achieved with safety as a top priority.

The Federal Select Agent Program oversees many of our Nation's high containment labs jointly through the CDC and APHIS. In accordance with this committee's long-term strategic interest in the program's oversight, you asked us to begin our work before the May 2015 revelations concerning a DoD lab's unintended shipment over the course of 12 years of live *Bacillus anthracis*—that is, the bacterium that causes anthrax—to almost 200 laboratories worldwide. Although regulating these strategically important labs is and will remain a complex endeavor, the nature and extent of this specific challenge had not yet been anticipated when you made your request.

There are three findings from our report. As for the first, we found that the total number of incidents involving incomplete inactivation is both unknown and unknowable. While the program reported that ten incidents occurred from 2003 through 2015, GAO identified an additional 11 that the program did not initially identify. Taken together, these 21 incidents involved a variety of pathogens, labs and inactivation methods as shown in the figure before you. Because the program cannot easily identify these incidents, it does not know how often they occur or why they occur. This makes it difficult to develop guidance for mitigating future ones.

Lying behind this difficulty are, first, the fact that currently no clear and consistent definition of inactivation exists in the guidance or regulations the program and the NIH have promulgated; and second, the program's forms are currently not structured to specifically identify this type of incident. As a result, researchers regulated by the program cannot consistently identify and report these

incidents, which means in turn that regulators cannot provide an accurate number of them.

Our second key finding is the three critical challenges that affect the implementation of inactivation in high containment labs. The challenges we identified are, one, the gaps in scientific knowledge; two, the limited Federal guidance on how to develop and implement inactivation protocols; and three, the inconsistent use of safeguards.

With respect to gaps in knowledge we found that scant resources are dedicated to research and to the publication of research on inactivation methods. With respect to limited guidance, we found that while inactivation protocols are often developed throughout a lab sometimes they vary within the same department, potentially increasing biosafety and/or biosecurity risk. With respect to safeguards we found among other things a general lack of cultural emphasis on safety in several labs we visited. This lack increase is the risk of human error which in turn can result in exposure to dangerous pathogens.

Our third key finding is that CDC and APHIS neither referred violations consistently to their inspector general nor consistently enforced regulations related to these incidents. For example, we found that CDC and APHIS did not use the same set of criteria for referring violations for further investigation and did not clearly document the bases for referring or not referring violations.

We found that it was not clear why some incidents were referred and enforced and others were not. For example, the program required one private and two academic labs to develop corrective action plans following incidents, but never required Federal labs to develop corrective action plans on similar occasions until the Dugway revelations in 2015. Without consistent criteria and documentation of decisions for referring violations and enforcing regulations, the program cannot ensure that its regulatory approach to overseeing high containment labs is applied consistently.

Mr. Chairman, these findings in conjunction with our work over the past decade raise serious questions about the nature, extent, and consistency of the oversight that the program provides. We have identified problems and made recommendations concerning systemic issues, including among others the lack of a strategic understanding of the nature and extent of the national need for high containment labs, the duplicative, fragmented and self-policing oversight structure, and the need for updated policies and stronger oversight.

We have recommended among other things that a single oversight entity be identified to determine, one, the number, location and mission of the labs needed to meet national goals to counter biological security threats; two, the aggregate risks associated with their proliferation; and three, the type of oversight needed.

Although some of our recommendations have been implemented, a key recommendation regarding the need for a single entity has not been addressed even while biosafety and biosecurity lapses have continued, increasing the risk of exposure to workers and the general public. In this era of rapidly emerging infectious diseases and ongoing threats to national and homeland security, the time

for getting both biosafety and biosecurity right across our research enterprise is now.

Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, this concludes my prepared remarks. I am happy to respond to any questions you may have.

[The statement of Dr. Persons 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
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HIGH- CONTAINMENT LABORATORIES

Actions Needed to Mitigate Risk of Potential Exposure and Release of Dangerous Pathogens

Statement of Timothy Persons, Chief Scientist

John Neumann, Director
Natural Resources and Environment

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee:

We are pleased to be here today to discuss our work on high-containment laboratories, with a particular focus on the inactivation of pathogens, which is the removal of a pathogen's hazardous effects while retaining characteristics of interest for future use.¹ A number of concerns have been raised in recent years about the biological safety and security of pathogens in high-containment laboratories, and we have previously reported on these issues. For example, in 2009, we found that oversight of high-containment laboratories is duplicative and fragmented and relies on self-policing.² Agencies have made some progress in implementing many of our past recommendations, but the United States still does not have a single entity charged with overseeing the implementation of a national strategy to identify the aggregate risks associated with the expansion of the number of high-containment laboratories and the nature and extent of oversight needed.

Our testimony today summarizes our August 2016 report entitled *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*.³ In May 2015, the Department of Defense discovered that one of its laboratories had inadvertently sent live *Bacillus anthracis*, the bacterium that causes anthrax, to almost 200 laboratories worldwide over the course of 12 years. Several other incidents involving incomplete inactivation of pathogens have occurred in the United States in recent years, potentially exposing people to dangerous pathogens that can cause infectious diseases.⁴

¹Inactivation is a process used in laboratories to render pathogens unable to cause disease but still retaining characteristics of interest for future use, such as for vaccine development.

²GAO, *High-Containment Laboratories: National Strategy for Oversight Is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009).

³GAO, *High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk*, GAO-16-642 (Washington, D.C.: Aug. 30, 2016).

⁴Incidents involving incomplete inactivation include incidents in which researchers had intended to inactivate samples before removing them from containment but failed to do so because of an issue with the inactivation method, a mix-up of samples, or another unforeseen event.

Researchers in high-containment laboratories may perform inactivation for a variety of reasons, such as to develop vaccines or perform diagnostic testing, and may perform inactivation on a variety of pathogens, including pathogens classified as select agents. Select agents are pathogens, such as bacteria, viruses, and toxins, that have the potential to pose a severe threat to human, animal, or plant health and safety, or to animal or plant products.⁵ The Federal Select Agent Program (Select Agent Program) regulates the possession, use, and transfer of select agents and is comprised of the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention's (CDC) Division of Select Agents and Toxins and the Department of Agriculture's (USDA) Animal and Plant Health Inspection Service's (APHIS) Agriculture Select Agent Services. These agencies are responsible for providing oversight and ensuring that high-containment laboratories that work with select agents comply with relevant regulations.⁶ In addition, the National Institutes of Health (NIH) provides oversight and guidance for working with pathogens that contain recombinant or synthetic nucleic acid molecules.⁷

This testimony addresses (1) the extent to which incidents involving incomplete inactivation occurred from 2003 through 2015, (2) any challenges that may affect the implementation of inactivation in high-containment laboratories, and (3) the extent to which the Select Agent Program referred violations and enforced regulations related to incidents involving incomplete inactivation.

⁵As of August 2016, 65 select agents or toxins have been determined to have the potential to pose a severe threat to human, animal, or plant health, or to animal or plant products. In this testimony, the term "select agents" encompasses both select agents and toxins.

⁶42 C.F.R. Part 73 (CDC); 7 C.F.R. Part 331 (APHIS-plant); 9 C.F.R. Part 121 (APHIS-animal).

⁷Department of Health and Human Services, National Institutes of Health, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (Bethesda, Md.: April 2016). NIH defines recombinant or synthetic nucleic acid molecules as either (1) molecules that are constructed by joining nucleic acid molecules and can replicate in a living cell or (2) nucleic acid molecules that are synthesized chemically or by other means. Researchers routinely generate pathogens containing recombinant or synthetic nucleic acid molecules for a variety of purposes, including the creation of vaccines using recombinant material. For the purpose of this testimony, the term "recombinant pathogens" refers to pathogens that contain molecules that are constructed by joining different nucleic acid molecules together (recombinant) or completely new nucleic acid molecules (synthetic).

For our August 2016 report, we examined the implementation of inactivation at federal, academic, and private high-containment laboratories in the United States, including incidents involving incomplete inactivation. We convened, with the assistance of the National Academy of Sciences, a meeting with experts to discuss issues related to the inactivation of pathogens in high-containment laboratories. To evaluate the extent to which incidents involving incomplete inactivation occurred, we analyzed documentation on incidents reported to the Select Agent Program and NIH from 2003 through 2015 and interviewed agency officials. During interviews with agency officials and our expert meeting, we asked about challenges and safeguards associated with the implementation of inactivation in high-containment laboratories. We also reviewed Select Agent Program guidance and inspection documents and interviewed agency officials regarding the steps the program had taken to refer violations and enforce regulations related to incidents involving incomplete inactivation. Additional information on our scope and methodology is available in our report. The work upon which this testimony is based was performed in accordance with generally accepted government auditing standards.

The Total Number of Incidents Involving Incomplete Inactivation of Pathogens Is Unknown

The total number of incidents involving incomplete inactivation that occurred from 2003 through 2015 is unknown for three reasons: (1) the inability to easily identify incidents involving incomplete inactivation in incident databases; (2) the absence of reporting requirements for pathogens that are not select agents; and (3) the absence of a clear, consistent definition of inactivation.

First, we found that the Select Agent Program and NIH do not have the ability to easily identify incidents involving incomplete inactivation because their incident reporting forms are not structured to specifically identify this type of incident. As a result, neither the Select Agent Program nor NIH (for the oversight of recombinant pathogens) was able to provide us with an accurate number of all incidents involving incomplete inactivation that occurred from 2003 through 2015. We identified additional incidents that the Select Agent Program and NIH did not initially identify.

Second, we found that federal incident reporting, in general, is required only for (1) incidents that involve select agents, which are reportable to the Select Agent Program, and (2) incidents that involve recombinant pathogens, which are reportable to NIH. Thus, incidents involving incomplete inactivation of pathogens that are neither select agents nor recombinant pathogens, such as West Nile virus or the bacteria that

causes tuberculosis, are generally not required to be reported to any federal agency.⁸

Third, we found that there is currently no clear and consistent definition of inactivation in guidance or regulations issued by the Select Agent Program and NIH.⁹ As a result, researchers may not consistently define inactivation, which potentially affects how and when they report incidents involving incomplete inactivation. Moreover, experts at our meeting noted that this can make it difficult to understand when an incident occurs. These experts stated that there is a need for a clear, consistent definition of inactivation across key federal guidance documents, and our past work has also shown that the use of standardized definitions is key to ensuring that information is reported consistently.¹⁰

Without the ability to easily identify incidents involving incomplete inactivation on reporting forms, the Select Agent Program and NIH are unable to easily search their respective databases to determine the frequency and causes of incidents related to the pathogens they regulate. In addition, without a clear and consistent definition of inactivation across key federal guidance, researchers may not know when to include incomplete inactivation in an incident report, potentially affecting the number of incidents reported. We concluded that, collectively, these issues prevent the Select Agent Program and NIH from knowing the extent to which incomplete inactivation occurs and whether incidents are properly identified, analyzed, and addressed. Not knowing the magnitude of the problem may inhibit agencies' ability to achieve program missions

⁸As a way to address the issue of incident reporting in a broader scope, we previously recommended in a March 2016 report that federal high-containment laboratories report all incidents, whether they involve select agents or not, to senior agency officials. 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).

⁹These guidance documents do include some information on inactivation but do not include a definition of it.

¹⁰Our prior work has found that metrics should be reported in a consistent fashion, and that a key part of consistent reporting is ensuring that standardized definitions, methodologies, and procedures will be used. In addition, our prior work has found that inconsistent definitions limit the comparability of programs across agencies. See GAO, *Defense Inventory: Actions Underway to Implement Improvement Plan, but Steps Needed to Enhance Efforts*, GAO-12-493 (Washington, D.C.: May 3, 2012).

of investigating any incidents in which noncompliance may have occurred.

In our report, we recommended that the agencies develop clear definitions of inactivation for use within their respective guidance documents. We also recommended that they revise reporting forms to help identify when incidents involving incomplete inactivation occur and analyze the information reported to help identify the causes of incomplete inactivation to mitigate the risk of future incidents. HHS and USDA agreed with our recommendations and noted steps they were taking to address them. For example, CDC and APHIS are proposing revisions to the select agent regulations to include a definition of inactivation and are planning to update their reporting forms.

Gaps in Science and Limited Guidance Affect the Implementation of Inactivation in High-Containment Laboratories

Several challenges affect the implementation of inactivation in high-containment laboratories, including (1) limited scientific information for developing and implementing inactivation protocols,¹¹ (2) limited federal guidance for developing inactivation protocols, (3) inconsistent implementation of safeguards to help ensure inactivation is properly conducted, and (4) varied documentation requirements for shipping inactivated material. Experts in our meeting stated that such challenges may affect laboratories' ability to mitigate the risk of incomplete inactivation.

First, we found that insufficient scientific information exists for developing and implementing inactivation protocols. This could result in incomplete inactivation, according to peer-reviewed literature and our group of experts. Examples of insufficient scientific information include a lack of understanding about (1) mechanisms of inactivation, (2) the ability of some pathogens to repair themselves after inactivation, and (3) viability testing (a procedure to determine the extent to which viable pathogens remain in a sample after an inactivation process).

Second, we found that federal guidance for developing and validating inactivation protocols is limited. Major sources for technical guidance that researchers commonly use—such as NIH guidelines and Select Agent Program guidance—provide little detailed information on development

¹¹A protocol is a detailed plan for a scientific procedure.

and validation of inactivation protocols. In lieu of guidance, we found that researchers in laboratories we visited often developed inactivation protocols at a laboratory level and that protocols sometimes varied within the same department, agency, or laboratory, which may increase the risk of incomplete inactivation. We concluded that without more comprehensive and consistent federal guidance on the development and validation of inactivation protocols, protocols will vary in their scientific soundness and effectiveness, increasing the risk that inactivation may not be achieved.

Third, we found that the high-containment laboratories that we visited did not consistently apply safeguards when conducting inactivation, and there is limited federal guidance on doing so. Examples of safeguards that were inconsistently applied at these laboratories included conducting viability testing following inactivation procedures, implementing verification mechanisms to ensure inactivation protocols are followed, and sharing lessons learned.

Fourth, according to experts from our meeting, documenting the shipment of inactivated pathogens provides an important safeguard if the pathogen is determined to be still viable and needs to be destroyed to prevent potential exposures or release. However, we found through our review of agency documents and interviews with agency officials that laboratories vary in their documentation requirements for shipping inactivated pathogens. Without guidance for documenting the shipment of inactivated pathogens, laboratories are at risk of being unable to locate shipped pathogens in a timely manner, which is important if material thought to be inactivated is determined to still be viable.

In our report, we recommended that the agencies take several steps to address these findings. First, we recommended that the Secretaries of Health and Human Services and Agriculture coordinate research efforts and take actions to help close gaps in the science of inactivation and viability testing. Second, we recommended that the agencies create comprehensive and consistent guidance for the development, validation, and implementation of inactivation protocols, including the application of safeguards. Third, we recommended that guidance on documenting the shipment of inactivated material be developed. HHS and USDA agreed with these recommendations and described steps they are taking to address them. For example, HHS and USDA stated that they are developing a federally supported program to improve laboratory biological safety that will include examination of gaps related to inactivation. In addition, for the Select Agent Program the agencies said they plan to

develop guidance to assist with the development and implementation of inactivation protocols and viability testing.

The Select Agent Program Inconsistently Referred Violations and Enforced Regulations Related to Incidents Involving Incomplete Inactivation

The two agencies that comprise the Select Agent Program—CDC and APHIS—did not consistently refer incidents involving incomplete inactivation for further investigation and enforcement to the HHS Office of Inspector General or APHIS's Investigative and Enforcement Services. For example, the CDC component of the program referred a number of incidents involving incomplete inactivation that it investigated at high-containment laboratories between 2004 and 2015 to the Office of Inspector General. In contrast, the APHIS component of the program investigated two 2014 incidents at CDC laboratories involving incomplete inactivation that it did not refer to its Investigative and Enforcement Services.¹² We found that it was unclear why some incidents were referred and enforced and not others.

According to an interagency memorandum of understanding regarding the Select Agent Program, CDC and APHIS should maintain consistency in the application and enforcement of the select agent and toxin regulations. We found, however, that CDC and APHIS did not use the same set of criteria for referring violations for investigation by the HHS Office of Inspector General or APHIS's Investigative and Enforcement Services. Moreover, they did not clearly document the bases for referring or not referring violations. In addition, it was unclear why the Select Agent Program took certain administrative actions, such as revoking or suspending an entity's registration to possess select agents or requiring a corrective action plan, in response to some violations and not others. The Select Agent Program recently took some steps to increase consistency in the application and enforcement of the select agent regulations. However, the extent to which these steps will improve the understanding and transparency of the program's enforcement is not yet clear. Without consistent criteria and documentation of decisions for referring violations and enforcing regulations related to incidents involving incomplete inactivation, the Select Agent Program will not have reasonable assurance that its regulatory approach to overseeing high-containment laboratories is applied consistently.

¹²Beginning in October 2012, CDC and APHIS agreed that APHIS will lead inspections of CDC laboratories and CDC will lead inspections of APHIS laboratories.

In our report, we recommended that CDC and APHIS develop and implement consistent criteria and documentation requirements for referring violations to investigative entities and enforcing regulations related to incidents involving incomplete inactivation. HHS and USDA agreed with this recommendation and described steps they recently took, or are planning to take, to increase consistency in the application and enforcement of the select agent regulations. For example, they said that for the Select Agent Program they have developed a draft document that provides guidance on when to refer violations and options for enforcement actions but they did not provide a time frame for finalizing and implementing the draft document.

In conclusion, these inconsistencies, in conjunction with our past work, also raise larger questions about the potential limitations of the Select Agent Program as a whole to effectively and independently oversee high-containment laboratories, both within HHS and across other federal agencies. Select Agent Program officials and an expert from our group noted that the Select Agent Program is independent in its oversight of HHS labs since it organizationally exists in a separate part of the department from the HHS agencies that have high-containment laboratories. However, as we have noted in our prior work, existing federal oversight of high-containment laboratories is fragmented and largely self-policing, raising questions about whether the government framework and oversight are adequate.

Chairman Murphy, 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 Contact and Staff Acknowledgments

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Mr. MURPHY. Thank you, Doctor. Now Dr. Sosin, you are recognized for 5 minutes.

STATEMENT OF DANIEL M. SOSIN

Dr. SOSIN. Chairman Murphy, Ranking Member DeGette, distinguished members of the subcommittee, thank you for the opportunity to testify before you today regarding the contributions of the Centers for Disease Control and Prevention to the Federal Select Agent Program. I'm Dr. Daniel Sosin, deputy director and chief medical officer of the Office of Public Health Preparedness and Response at the CDC.

Much has changed since I testified before the subcommittee last year regarding our response to the inactivation failure involving *Bacillus anthracis* spores at Dugway Proving Ground. Since last November, I have been privileged to lead the Division of Select Agents and Toxins through significant change. Inspection reports are more timely, clear, risk-based, and consistent. The regulated community is stronger partner in achieving standards of biosafety and pathogen security. Incident response planning is more proactive and public awareness of select agent work and oversight is improving.

But our work is by no means done, and I am pleased to introduce Dr. Sam Edwin who joined the CDC 3 weeks ago as the new director of the Division of Select Agents and Toxins, and who will continue CDC's commitment to improving the Federal Select Agent Program.

I would like to recognize the important contributions that GAO has made to understanding challenges with the inactivation of pathogens, and proposing ways to improve laboratory practice and Government oversight. We concur with the recommendations related to the Federal Select Agent Program and have already initiated efforts to address them.

As recommended in GAO's new report, the Department of Health and Human Services is expecting to publish a final rule which will improve oversight of inactivation protocols. We are also developing guidance to be released concurrently that will assist the regulated community with implementation of the new requirements. We are improving incident reporting and data collection also recommended in the GAO report by updating the form used to report theft loss or release of select agents and toxins. We expect that incomplete inactivation as a potential cause of exposure to select agents will now be explicitly captured.

We are working to improve consistency in how we assess severity of inspection findings to focus attention where it is needed most. We are using this process to better standardize the application of enforcement actions, including referral to the Inspector General as was recommended by GAO. These steps will increase the consistency and transparency of oversight.

Research done on select agents and toxins saves lives by supporting the development of vaccines and drugs and the tools needed to identify these pathogens when disease can successfully be treated or prevented. We continually strive to balance our mission to advance safety and security with our commitment to science. The scientific methods and objectives of research with biological agents

are diverse and complex, and we must be careful not to overprescribe methods and interfere with medical advances.

We are increasing regulatory compliance through collaboration with the regulated community which shares a common interest in biosafety and pathogen security and also bears responsibility for assessing the risk of their work and applying appropriate safety measures. We also use the experience and judgment of our inspectors, over 60 percent of whom hold Ph.D.s in microbiology and most of the rest master's degrees, to provide guidance on risk assessment and risk management as well as review the work of the laboratory scientists during inspections.

When necessary we set specific method requirements through rule change as we are doing with the inactivation of select agents. For 70 years the scientists and staff at CDC have been on the front lines of public health tackling pandemics and threats to the health of the American people. The Division of Select Agents and Toxins is responsive in making improvements, including the GAO recommendations on inactivation.

Work with select agents saves lives and we are balancing the need for regulatory constraints with the benefits of scientific discovery. I assure you that we have and will continue to work diligently and thoughtfully to evolve this oversight program and protect Americans from biological threats. We welcome the subcommittee's input as we continue on this path. Happy to take questions.

[The statement of Dr. Sosin follows:]



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

**Bioresearch Labs and Inactivation of Dangerous
Pathogens**

Statement of

Daniel M. Sosin, M.D., M.P.H., F.A.C.P.

*Deputy Director and Chief Medical Officer,
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 9:00 a.m.
Friday September 23, 2016

Thank you, Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Daniel M. Sosin, Deputy Director and Chief Medical Officer with the Office of Public Health Preparedness and Response (OPHPR) at the Centers for Disease Control and Prevention (CDC). From November 2015 through August 2016, I served as Acting Director of OPHPR's Division of Select Agents and Toxins (DSAT). I appreciate the Subcommittee's continued interest in improving oversight of work with select agents and toxins to ensure that this important work is done in as safe and secure a manner as possible.

CDC's highest priority is to save lives and protect people. Scientific research in laboratories plays a critical role in accomplishing this goal and is an important part of our nation's defense against naturally occurring diseases and bioterrorism. The research done on biological select agents and toxins leads to discoveries that can save lives and help protect the American people. However, the nature of scientific laboratory work means that some risk is always present. Our goal is to reduce that risk to the maximum extent possible.

Today I am going to speak with you about CDC's role and responsibilities in implementing the Federal Select Agent Program (FSAP), including our extensive efforts over the past year to strengthen oversight of Government, academic, and private laboratories across the United States that work with select agents and toxins. This includes efforts to address challenges associated with inactivation, which is essential to conducting potentially life-saving research in areas such as detection of select agents, diagnoses of those who may have been exposed, and development of vaccines and of antidotes to mitigate the effects of possible exposure. The work of FSAP helps ensure that this critical research in laboratories across the country involving potentially dangerous and deadly pathogens is conducted as safely and securely as possible. Toward that end, FSAP recognizes and is in the process of addressing the need for improvements to the program. FSAP concurs with recent Government Accountability

Office (GAO) recommendations and is taking steps to improve oversight of inactivation and other work with select agents and toxins.

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), the U.S. Department of Agriculture (USDA), and the 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. This authority has been delegated to CDC. USDA was given similar authority to regulate select agents and toxins that pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting a security risk assessment of entities and individuals prior to their possession, use, or transfer of select agents or toxins. This oversight helps prevent access to these pathogens by terrorists or others who may wish to misuse them.

FSAP promotes laboratory biosafety and biosecurity through: (1) developing, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR Part 331); (2) providing guidance to the regulated community; and (3) inspecting facilities that work with select agents. Entities must undergo a rigorous registration process and obtain approval before they can work with select agents and toxins. At the end of 2015, 291 entities—including academic, non-Federal government, Federal Government, and private laboratories--were registered with FSAP to possess a select agent or toxin. The majority of entities (251) were registered with CDC as the lead Agency. The program currently regulates 66 select agents and toxins. This list is reviewed at least every two years to determine if agents or toxins need to be added to or deleted from the list. Key regulatory functions and activities of the FSAP include:

- Maintaining a national database that enables the U.S. Government to be aware of entities and individuals authorized to work with select agents. This registry serves several functions, including allowing FSAP to proactively reach out to entities in advance of natural disasters or other events to ensure all select agents and toxins are properly secured;
- Ensuring appropriate measures are in place at each registered entity to prevent unauthorized access to, or theft, loss, or release of, select agents and toxins;
- Receiving reports of theft, loss, or release and following up with each entity to ensure that proper actions are taken and appropriate authorities notified, and to help the entity identify ways to prevent similar incidents from happening in the future;
- Taking appropriate enforcement actions in an instance of theft, loss, or release, or when deficiencies in biosafety or biosecurity measures are identified in an inspection, 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 meet the requirements, and conducting training and outreach to increase knowledge of and compliance with the regulations.

Inactivation

Over the course of the last few years, several high-profile laboratory incidents involving select agents and toxins have occurred at Federally-regulated laboratories. As the Subcommittee is aware, some of these incidents involved inactivation at federal laboratories, including the incomplete inactivation of *Bacillus anthracis* at a CDC laboratory in 2014, potentially exposing CDC employees to live spores, as well as the May 2015 discovery by the Department of Defense (DoD) that one of its laboratories had inadvertently sent live *Bacillus anthracis* to almost 200 laboratories worldwide over the course of 12 years. FSAP worked with DoD, private laboratories, state health officials, and the Federal Bureau of Investigation to investigate all laboratories known to have received this material. FSAP's

investigations of these and other incidents yielded important insights into the challenges presented by inactivation and informed FSAP's ongoing efforts to improve the regulatory oversight of this challenging but important procedure.

The multiple episodes of inactivation failures raised questions concerning the adequacy of some inactivation and validation protocols for spore-forming bacteria. On June 2, 2015, to prevent inadvertent exposure, FSAP requested a moratorium on the use and transfer of inactivated *B. anthracis* for entities that produced and shipped inactivated *B. anthracis* to other laboratories until safer and more effective procedures regarding inactivated *B. anthracis* could be developed based on interagency scientific discussion and further research into the matter. In December 2015, FSAP issued a policy statement regarding the inactivation of *B. anthracis*, and then a revised policy statement in June 2016 that addressed feedback from subject matter experts and the regulated community.

Additionally, CDC is expecting to publish a Final Rule later this year which will address and increase oversight of inactivation. CDC's January 2016 Notice of Proposed Rule Making (NPRM) included proposed requirements to increase oversight of the inactivation of select agents, mandating registered entities use validated inactivation methods, conduct confirmatory testing before declaring a select agent "non-viable," and maintain records to facilitate tracing materials if inactivation failure is identified. During the public comment period, CDC received extensive comments on the NPRM. CDC is in the process of addressing these comments and making appropriate changes to the proposed rule. FSAP also is developing guidance to assist the regulated community in implementing the new regulatory requirements. This guidance will be significantly more detailed than previous guidance on the topic. In support of the more rigorous requirements around inactivation of biological select agents and toxins, FSAP is prepared to support the training needs for both inspectors and the regulated community. The development of this guidance aligns with GAO's recommendations to create comprehensive and consistent guidance for development, validation and implementation of inactivation protocols and better

records associated with transfer of this material. Much more work is needed on this topic, including issues that go beyond FSAP alone which will have to continue to be addressed together with the broader scientific and policy communities.

Strengthening FSAP

Following a number of high-profile laboratory incidents in 2014 and 2015, the federal government convened multiple groups to find ways to strengthen the oversight of select agents and toxins. FSAP is well underway in putting into action the recommendations derived from these efforts.

In the summer of 2015, CDC Director Dr. Tom Frieden ordered an internal 90-day review of CDC's Division of Select Agents and Toxins (DSAT) to examine the CDC-administered component of FSAP and make recommendations to improve the program. In October 2015, CDC released the full report, including recommendations in three main areas –inspections, incident reporting, and transparency and public understanding.

At the same time, Federal Departments and Agencies agreed to identify ways to strengthen policies and practices both at laboratories regulated under the FSAP and at other laboratories working with dangerous pathogens. As a result, the Report of the Federal Experts Security Advisory Panel (FESAP) provided recommendations on optimizing biosafety, biosecurity, oversight, inventory management, and control of biological select agents and toxins as well as on actions and regulatory changes to improve biosafety and biosecurity. Additionally, the Fast Track Action Committee Report on Select Agent Regulations (FTAC-SAR) provided recommendations informed by external stakeholder input. In collaboration with other Departments and Agencies, FSAP now is in the process of implementing these recommendations which will lead to program changes and improvements, many of which also are responsive to recommendations in GAO's report.

Since the release of the reports and recommendations, CDC has made significant program improvements in four key areas: inspections, customer service, incident response, and transparency and engagement. Following CDC's 90-Day internal review and the White House reports, CDC published an online resource called Progress Towards Change.¹ The website provides ongoing updates on CDC's progress towards implementing improvements recommended in the reviews. Below are examples of steps CDC is taking to address recommendations.

Improving Inspections

CDC has taken a number of important steps to improve the inspection process, relating to both the conduct of facility inspections and promoting greater consistency and clarity in the reporting of inspection findings back to the regulated entities. Key examples of our work in this area include:

- To improve the quality and consistency of FSAP inspections, FSAP identified violations that require greater judgment by inspectors and inspection teams and established an inspector training plan to address knowledge gaps and increase standardization. The establishment of this training program will support efforts to provide registered entities with clearer and more consistent information.
- To better understand and anticipate laboratory procedures and activities that are most strongly and most often associated with poor outcomes, FSAP is conducting analyses of data on inspection findings and risk in order to improve understanding of trends and associations between the two.

Improving Customer Service

FSAP efforts to more effectively support the entities working with select agents and toxins include:

¹ http://www.cdc.gov/phpr/dsat/review_initiatives.htm

- Establishing in December 2015 a formal mechanism for issuing, publicizing, and accepting entities' requests for FSAP to answer questions regarding the select agent regulations.
- Providing additional training and guidance to the select agent community, including by:
 - Establishing a training program for entities' Responsible Officials to increase education and build community. The first multiday training will be held in December 2016;
 - Establishing and updating guidance for entities on biosafety and security plan development to provide additional details and clarity on what is needed to comply with select agent regulations and increase biosafety and biosecurity measures; and
 - Developing guidance on inactivation which includes information on method development and validation, as well as safety margins; and
- Developing a new electronic information system that will increase efficiency, accuracy, and speed of interactions between the program and regulated entities and provide vital feedback for quality improvement.

Improving Incident Response

FSAP's efforts to improve our collective ability to respond to incidents when they occur include:

- Increasing outreach to state health authorities regarding incidents involving risk to workers or the community.
- Improving entity incident reporting and data collection by updating the APHIS/CDC Form 3, which is the form used to report thefts, losses, or release of select agents and toxins. The proposed new form will increase the utility of incident reports regarding the risk of reported theft, loss, and release incidents, and will allow FSAP to collect a greater level of detail on each reported event in a more consistent fashion. It will also provide the ability to clearly identify when an incomplete inactivation takes place, addressing one of GAO's

recommendations. FSAP expects that the new form (currently in draft) will ask users to indicate whether a release occurred because of a failed inactivation.

Improving Transparency and Engagement

FSAP is committed to transparency and increasing engagement with—and among—entities that work with select agents and toxins. For example:

- FSAP created a set of examples that categorize inspection violations along a spectrum of severity. This will help to ensure that enforcement actions are appropriate and consistent given the severity of the violation, and will increase compliance among the regulated community by providing more precise and transparent information on how performance and violations are graded. Instances of inactivation are included in this document. This effort helps address GAO’s recommendations to develop and implement consistent criteria for enforcement actions.
- Additionally, CDC/DSAT now identifies inspection findings as low, moderate, or high severity, and, as part of a pilot project, CDC plans to generate inspection report cards that summarize the entity’s regulatory departures and show its performance relative to other entities. This comparative analysis will also improve the targeting of FSAP oversight efforts.
- FSAP established an independent forum through ABSA International consisting of an online discussion forum, in-person workshop, and webinars to encourage routine peer-to-peer sharing regarding best practices among those working with select agents and toxins.

Conclusion

Many of the actions being undertaken to implement recommendations of the FESAP, FTAC-SAR and CDC reports also address recommendations raised in the GAO report. As noted above, CDC is in the process of developing a detailed guidance document for inactivation; APHIS and CDC have proposed changes to the form used by entities to report the theft, loss, or release of a select agent or

toxin to provide for clear identification of, among other things, incidents involving incomplete activation; and FSAP is creating a set of examples that categorize inspection violations along a spectrum of severity, which will help to ensure enforcement actions are consistent and appropriate given the severity of the violation.

FSAP is committed to continued improvement in oversight of laboratories that handle select agents and toxins. Many of the changes recommended can and will be made through FSAP. Other potential changes involve broader issues and will require additional partners—beyond FSAP—to address. We have and will continue to work diligently and thoughtfully with all of our federal partners and others who share in our commitment to protect Americans from biological threats. We look forward to the Committee's continued input as we continue to improve the system for oversight of research involving select agents and toxins.

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

Mr. MURPHY. Thank you.

Dr. Monroe, you are recognized for 5 minutes.

STATEMENT OF STEPHAN S. MONROE

Dr. MONROE. Good afternoon, Chairman Murphy, Ranking Member DeGette, members of the subcommittee. Thank you for the opportunity to testify before you today. I am Dr. Steve Monroe, CDC's associate director for Laboratory Science and Safety. I serve as the single point of accountability for the quality and safety of CDC's laboratories, and I report directly to the CDC director, Dr. Tom Frieden.

My office was created last year to provide oversight of the safety and quality of CDC's internal laboratories. This is distinct from the regulatory role of CDC's Division of Select Agents and Toxins. I exercise no authority over the Federal Select Agent Program's regulations or their enforcement activities. My office does ensure that those CDC laboratories that work with select agents comply with the select agent regulations. Moreover, our responsibility for laboratory safety includes comprehensive oversight of biological, chemical and radiation safety in all CDC laboratories whether or not they work with select agents.

CDC's laboratories play an indispensable role in protecting the public's health. Our laboratories screen newborns for rare illnesses, detect outbreaks that threaten American communities, and invent new ways to detect emerging infectious diseases. The inactivation of pathogens in CDC's laboratories is a critical part of this work.

Inactivation destroys a pathogen's ability to cause infection which allows subsequent laboratory work to occur at lower levels of containment. This both enhances safety for workers at CDC and expands the number of laboratories able to work on pathogens that would typically require higher levels of containment. Inactivation enables the generation of vaccines for viruses like influenza and polio, helps scientists find new ways to diagnose disease, and protects the safety of laboratory staff and the public.

However, it is critical that when laboratories inactivate pathogens they do so safely, completely and verifiably. The incomplete inactivation of *Bacillus anthracis* in a CDC laboratory in 2014 was a seminal event that led to major safety reforms within CDC including the creation of my position and office. I take very seriously the importance of safe inactivation of pathogens in our laboratories.

This afternoon I want to briefly highlight two ways we are strengthening pathogen inactivation at CDC. The first is the creation of the Laboratory Safety Review Board. This group is charged with reviewing every protocol for the inactivation and transfer of biological materials out of CDC's BSL-3 and BSL-4 laboratories to lower levels of containment. It examines every part of the protocol, reviews every standard operating procedure, and ensures that scientists who perform inactivation have appropriate skills and training. Its creation is a signature safety reform and represents a fundamental change in the oversight of inactivation of pathogens in CDC's laboratories.

The second way we aim to strengthen inactivation at CDC and throughout laboratories in general is through enhancements to the reference guide, "Biosafety in Microbiological and Biomedical Lab-

oratories,” or BMBL. The BMBL created in partnership with the National Institutes of Health is a comprehensive guide on biosafety practices and policies for laboratories working with pathogens.

In recognition of the BMBL’s influence with the laboratory community, the GAO report on inactivation recommended and CDC and NIH concurred that the upcoming revision to BMBL include clear definitions of inactivation and clear and consistent guidance for the development and implementation of inactivation protocols. CDC and NIH are working together to incorporate this definition and guidance in the next version of BMBL.

Laboratory safety and CDC is not a single objective that can be accomplished and checked off, but rather is an ongoing commitment to a culture of safety that demands constant dedication. Ensuring our laboratories perform effective inactivation of pathogens is an important example of CDC’s commitment to this culture. We have made major strides in strengthening the agency’s approach to inactivation and will continue to monitor and improve our efforts in this area.

Thank you for the opportunity to testify on this important matter. I welcome any questions you may have.

[The statement of Dr. Monroe follows:]



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

Bioresearch Labs and Inactivation of Dangerous Pathogens

Statement of

Stephan S. Monroe, PhD

Associate Director for Laboratory Science and Safety

Centers for Disease Control and Prevention

Department of Health and Human Services

For Release upon Delivery
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Introduction

Good morning Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee.

Thank you for the opportunity to testify before you again about the Centers for Disease Control and Prevention's (CDC) ongoing efforts to strengthen and enhance the quality and safety of the Agency's laboratories. I am Dr. Steve Monroe, the CDC Associate Director for Laboratory Science and Safety. My role and office were created last year to serve as the single point of accountability for laboratory science and safety at CDC, and I report directly to the Director, Dr. Tom Frieden. My office provides internal oversight to CDC's laboratories and is distinct from CDC's regulatory arm in the Division of Select Agents and Toxins which, along with the Animal and Plant Health Inspection Service at the U.S. Department of Agriculture, forms the Federal Select Agent Program and regulates the possession, use, and transfer of biological select agents and toxins.

CDC's laboratories serve an essential role in identifying and responding to threats to the public's health. Working with dangerous pathogens is a necessary and vital part of this task, and the effective inactivation and attenuation of pathogens is an especially important scientific and safety challenge. My office and CDC leadership are committed to providing our laboratories the support and guidance they need to meet this challenge, and our laboratories have made tremendous progress in doing so over the last two years.

Effective inactivation makes laboratories safer. A central tenet of laboratory safety is to assess, manage, and mitigate risk whenever possible. One fundamental way to do this is to work with pathogens that present the lowest level of risk without compromising the ultimate goals of a laboratory's work. This often will require working with inactivated or attenuated pathogens that pose less risk while still preserving the biological characteristics needed for scientific study.

Inactivation also expands the reach of public health laboratories. Inactivation and attenuation allow laboratories to advance public health work on pathogens outside of resource-intensive high-containment laboratories—an invaluable capacity when marshalling a public health response. Inactivated and attenuated viral and bacterial strains also are indispensable to vaccine research, the creation of positive control samples for diagnostic assays, and innumerable other scientific and public health applications. But for all the significant scientific and safety benefits provided by inactivation and attenuation, it is critical that when laboratories inactivate pathogens they do so safely, completely, and verifiably.

As this Subcommittee is aware, in 2014 there were a number of unacceptable safety incidents at CDC. The most prominent of these incidents involved the incomplete inactivation of *Bacillus anthracis* in a CDC laboratory that potentially exposed CDC staff to live bacterial spores. This incident was the seminal event that led to major safety reforms within CDC laboratories, including the creation of my position and the establishment of my office. Given this history, the seriousness with which CDC, and I, take the safe inactivation of pathogens in our laboratories cannot be overstated.

Today, I want to speak to CDC's efforts to date to ensure that when CDC's laboratories inactivate and attenuate pathogens and move them from high containment that we do so safely and effectively. In particular, I will highlight the four primary ways we advance this goal: through oversight, guidance, policy, and innovation.

Oversight

The Government Accountability Office (GAO) report emphasizes regulatory approaches to ensuring appropriate inactivation, and CDC agrees that regulations are invaluable to help ensure appropriate laboratory safety and security when working with pathogens. Oversight and regulatory compliance are fundamental to our approach to laboratory safety at CDC. One of the key reforms in the wake of the 2014 incidents was the consolidation of all internal oversight for the safe operation of CDC's

laboratories—including compliance with the requirements of the select agent and toxins program, biosafety, chemical safety, and radiation safety—in the Office of the Associate Director for Laboratory Science and Safety.

But CDC views safety regulatory requirements as a floor, not a ceiling, for putting the best scientific and safety practices into action, including those for the inactivation and attenuation of pathogens. As an agency, we are striving to go above and beyond what is required by regulation to ensure comprehensive oversight of inactivation practices and protocols. The creation of the CDC's Laboratory Safety Review Board (LSRB) in March 2015 marked an important step forward in CDC's efforts to keep our scientists and laboratories safe.

The Laboratory Safety Review Board was born out of the safety incidents in 2014. Following the anthrax safety incident that year, the CDC Director issued a moratorium on all transfers of biological materials out of Biosafety Level 3 (BSL-3) and BSL-4 laboratories. No CDC laboratory could move materials out of high containment until the specific protocols for those transfers were reviewed and approved by a temporary, newly created internal safety body called the Laboratory Safety Improvement Workgroup, or LSIW.

The LSIW regarded proper inactivation and attenuation as a fundamental part of any transfer protocol. For biological materials to leave BSL-3 or BSL-4 containment, a laboratory had to demonstrate that the pathogen had been killed or attenuated so that the unique protections afforded in a high-containment laboratory were no longer required to work with the pathogen safely. Over the course of four months, the LSIW met almost daily to review and scrutinize the transfer and inactivation protocols of every BSL-3 and BSL-4 laboratory. Those protocols that did not meet the LSIW's standards for completeness and verifiability were rejected and sent back for revision until they met the standards.

The LSIW was a temporary body to guide the Agency's response to the 2014 safety incidents; once the LSIW had completed its work and the transfer moratorium was lifted, CDC set about establishing a permanent body to continue the LSIW's vital function. This body is the Laboratory Safety Review Board, or LSRB. The LSRB is charged with reviewing every protocol for the inactivation and transfer of biological materials out of CDC's BSL-3 and BSL-4 laboratories to lower levels of containment. If a laboratory creates a new protocol or amends an existing one, that protocol must be reviewed and approved by the LSRB. Further, all existing protocols are subject to annual review by the LSRB.

The LSRB examines every part of the transfer and inactivation protocol. Laboratories submitting a protocol to the Board must describe their protocol in detail and provide every standard operating procedure (SOP) relevant to the inactivation and transfer of the pathogens they work with. The LSRB mandates two key steps to check safety- critical control points in the inactivation procedures. First, they must complete a detailed checklist of every procedural step of the inactivation and transfer; and second, they must establish a method of secondary verification of inactivation—that is, a process in which a second person or method verifies that the essential steps of the inactivation were done and done correctly. Secondary verification is a particularly important feature of this process as it provides verifiable evidence (like a second person who observed the inactivation or a label that changes color when a specimen receives an irradiation dose sufficient to inactivate the pathogen) that the inactivation process has been performed according to protocol and has been completed successfully.

The LSRB also requires that CDC laboratories rely on validated, documented methods of inactivation. The Board requires that a laboratory provide peer-reviewed scientific literature documenting the efficacy of its proposed inactivation protocol or that a laboratory perform its own internal testing of the procedure and provide sufficient data to show that it works.

Additionally, CDC recognizes that even the most rigorous and validated protocol is only as good as the people who perform it. That is why the LSRB not only reviews the inactivation protocol but requires an annual competency assessment from every individual who performs inactivation in a CDC BSL-3 or BSL-4 laboratory. Individuals are assessed by a technical monitor (who is also subject to competency assessment) who directly observes the scientist performing the inactivation method, doffing and donning personal protective equipment, decontaminating the work space, and performing any other activities relevant to the inactivation procedure.

Finally, any inactivated biological material that leaves BSL-3 and BSL-4 containment at CDC must be accompanied by a material transfer certificate, which is essentially a death certificate for the pathogen being transferred. These certificates document the method used to inactivate the pathogen and are signed by the preparer of the sample and a secondary verifier attesting to the fact that the protocol was followed. Each certificate is also signed by the laboratory branch chief to ensure laboratory leadership is accountable for the materials leaving their laboratories.

Having seen the LSRB perform its important mandate, I can attest that the Board is exacting in its scrutiny and will send back for revision any protocol that it finds does not meet its standards. The creation of the LSRB is a signature reform of the Agency in the wake of the 2014 incidents and represents a fundamental change in CDC's oversight of the creation and implementation of inactivation protocols.

Guidance

In addition to CDC's direct oversight of inactivation in its laboratories, CDC is also committed to providing scientific guidance both to its own laboratories and to the field generally. CDC is in the process of updating all of its manuals for laboratory safety. In the fall of this year, a new CDC

Biological Safety Manual will be rolled out to all CDC campuses. This manual includes important guidance to accompany agency-level policies regarding the proper use of personal protective equipment, as well as the use of biological risk assessments for experimental laboratory work. This manual will complement new agency-level policies to enhance laboratory safety at all CDC campuses.

CDC also provides safety guidance to external laboratories. The primary instrument for this guidance is a manual created in partnership with the National Institutes of Health (NIH), *Biosafety in Microbiological and Biomedical Laboratories*, or BMBL. BMBL is a comprehensive guide on biosafety practices and policies for laboratories working with pathogens. In recognition of the influence that BMBL's voluntary guidance has with microbiological and biomedical laboratories, the GAO report on inactivation recommended—and CDC and NIH concurred—that the upcoming revision of BMBL include clear definitions of inactivation and include clear and consistent guidance for the development and implementation of inactivation protocols. CDC and NIH are working to incorporate this definition and guidance in the next revision of BMBL.

Policy

In addition to the direct oversight of laboratory safety and inactivation practices and the guidance CDC and NIH provide to the field through the BMBL, CDC is also working to establish agency-wide laboratory safety and quality policies to impact and strengthen inactivation and other crucial safety and quality practices in CDC laboratories.

Policy at the agency level goes beyond the day-to-day oversight of safety and inactivation practices provided by the LSRB and my office; it places these important practices in a broader context by shaping the Agency's overall approach to laboratory quality and safety. Through effective agency-wide policies, we can ensure that inactivation and transfer protocols are part of a larger structure and culture of laboratory safety at the Agency.

For instance, CDC is in the final stages of establishing an agency-wide policy requiring CDC laboratories to conduct a risk assessment for any new process or procedure. This policy will necessitate laboratory scientists to think through steps they can take to reduce and mitigate risk—whether it is substituting an inactivated or less pathogenic organism in an experiment, using evidence-based decontamination procedures, or determining what personal protective equipment is necessary to prevent possible exposures. By making risk assessment a routine practice at the heart of every laboratory's work, this policy will ensure that safety practices like effective inactivation are a foremost priority for laboratories and are reviewed for every new or changed procedure.

Similarly, CDC is finalizing a policy outlining the required steps for the transfer of biological materials between CDC laboratories on the same campus. This policy outlines the specific safeguards laboratories must take to protect against potential hazards while transferring materials and further integrates requirements like material transfer certificates into everyday routine practice. The goal of these and other policies is to ensure that best practices around inactivation and other key safety practices are not just standalone requirements but fully woven into the culture, practices, and policies of the Agency's diverse laboratories.

Innovation

Finally, CDC recognizes that just as the threats to the public's health are never static, we as an agency must be thinking about tomorrow's response to these threats and how to meet these threats safely. This applies equally to inactivation practices. Tomorrow's prevention research may demand new methods of inactivation that preserve structures within a pathogen that we never needed to look at before. The emergence of a new public health threat may require we find ways to inactivate a pathogen on a scale never before required. Or a new method of inactivation may be needed to create a new vaccine.

To promote these and other innovations, my office launched the Laboratory Safety, Science, and Innovation Intramural Research Fund, which is funded with existing agency resources with the office. This fund provides one-time awards to laboratories across the Agency that propose innovative research or solutions to laboratory safety challenges.

Inactivation is a primary subject of many of the funded innovation projects. We are funding projects to pioneer faster, better, and more efficient inactivation of bacteria; compare different heat virus inactivation methods to improve safety and better preserve DNA structures; establish new inactivation methods for Zika virus; and systematically evaluate inactivation procedures for the highest risk viral pathogens. We are also funding a project that looks beyond inactivation by creating non-infectious pseudoviruses for the Middle East Respiratory Syndrome coronavirus and poliovirus, which would help develop safe assays to detect outbreaks of these and other viruses.

Conclusion

Inactivation is not a standalone procedure, isolated from the other work of the laboratory; it is a process integral to a functional culture of laboratory safety and excellence. When inactivation is done correctly, it amplifies the impact of public health laboratories by allowing lower containment laboratories to contribute to the prevention and control of dangerous pathogens. It facilitates breakthroughs in testing assays or vaccines. And it protects the safety of laboratory staff and the public.

When I first appeared before this subcommittee in April of this year, I stated that laboratory safety at CDC is not a single objective that can be accomplished and checked off, but an ongoing commitment to a culture of safety that demands constant and vigilant dedication. Ensuring our laboratories perform effective, verifiable inactivation of pathogens is an especially important example of CDC's commitment to a culture of safety.

This is why CDC has made such concerted efforts to ensure that our laboratories employ the best available science and practices of inactivation. We advance this work by providing oversight and rigorous scrutiny of every inactivation protocol, guidance to both internal and external laboratories through the BMBL, agency-wide policies that codify inactivation's role in a culture of safety, and support for innovations in the science of inactivation. Safer, more effective inactivation is and will remain a priority for CDC and my office. We have made major strides in strengthening the Agency's approach to inactivation practices, and we look forward to continuing to improve our efforts in this area.

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

Mr. MURPHY. Thank you.

Dr. Davidson, you are recognized for 5 minutes.

STATEMENT OF MARK DAVIDSON

Dr. DAVIDSON. Mr. Chairman, Ranking Member DeGette, and members of the subcommittee, I thank you for the opportunity to testify at today's important hearing. I'm Dr. Mark Davidson, associate deputy administrator for Veterinary Services within the U.S. Department of Agriculture's Animal and Plant Health Inspection Service.

APHIS and the Centers for Disease Control and Prevention jointly oversee the Federal Select Agent Program. We ensure that anyone possessing, using, or transferring biological select agents or toxins that have the potential to pose a severe threat to the public, plant, or animal health does so safely and securely. This is a role that we take very seriously.

With my agency's focus on protecting and preserving American agriculture, APHIS scientists understand well the consequences these select agents and toxins can have. We recognize the gravity of recent incidents and I can assure you that our actions have strengthened the Federal Select Agent Program. While we cannot completely eliminate all risk, we have overlapping safeguards and processes in place to reduce the risk to low as possible.

In addition to today's GAO review, the Federal Select Agent Program has participated in a broad stakeholder review and other Federal-level studies of the program. These reviews have given us a robust set of recommendations to strengthen our oversight of the program. We have implemented a majority of these recommendations and are diligently addressing the remaining recommendations. This includes the five recommendations for APHIS in today's GAO report.

We are in the process of finalizing a proposed rule and regulated guidance that will provide clarity for the regulated community and the Select Agent Program about the roles and responsibilities for the inactivation of select agents. The rule will clarify what is required to achieve inactivation, and the related guidance will lay out standards to help researchers and others validate inactivation protocols. Once these inactivation standards are in place we will hold those that we regulate accountable for meeting the standards.

To that end, we are finalizing revisions to the standard incident reporting forms the program uses. We will now collect information about incomplete inactivation and other causes of release so that we can monitor and track issues that arise ensuring accountability for those who work with select agents and increasing our ability to analyze trends to reduce the risk of future incidents.

We are also in the final stages of developing a new enforcement system to ensure consistency across the Federal Select Agent Program. The three-tiered system assigns violations into categories based on severity and standardizes how the Federal Select Agent Program will respond to those violations. With implementation of the system which will include consistent consequences for violations related to the new inactivation guidance, enforcement under the Federal Select Agent Program will be more consistent and our

stakeholders will have a clearer understanding of their responsibility.

Again APHIS takes any potential release of a select agent or toxin very seriously, but I assure you we are working closely with our Federal partners and the regulated community to develop strong cultures of safety and responsibility and policies and procedures that are science-based and to the maximum extent possible ensure the safety and security of these potentially dangerous select agents while allowing the valuable research to continue.

Mr. Chairman, this concludes my statement and I would be happy to answer any questions you or the members of the committee may have.

[The statement of Dr. Davidson follows:]

Testimony of

Dr. Mark Davidson
Associate Deputy Administrator, Veterinary 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
September 23, 2016

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) in the operation of the Federal Select Agent Program (FSAP). APHIS, through its Agriculture Select Agent Services (AgSAS), and the Centers for Disease Control and Prevention's (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. I assure you that we recognize the gravity of incidents involving the inappropriate release of regulated select agents and have been taking actions to strengthen the select agent program.

USDA has a long history of safely working with select agents through our domestic pest and disease programs as well as our efforts to prevent dangerous disease agents from impacting U.S. agriculture and the environment—including zoonotic diseases that impact human as well as animal health. For decades, APHIS has safely operated high containment laboratories that handle select agents. This includes the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, which is operated in conjunction with the Department of Homeland Security, and the United States' animal health reference laboratory, the National Veterinary Services Laboratories, in Ames, Iowa. Our personnel are leading diagnosticians and experts in the effective operation of high-containment laboratories.

We take the safety and security of select agents and toxins with the level of seriousness they deserve given their potentially devastating impacts to plant, animal, and human health. Accordingly, through our oversight role, we are regularly and proactively evaluating and assessing the select agent program and taking steps to ensure that these agents and toxins are handled and transferred securely.

The most prominent of these efforts is the Federal Experts Security Advisory Panel (FESAP). President Obama created FESAP in July 2010 to examine and provide recommendations to the Secretaries of Agriculture, Health and Human Services (HHS) and the Attorney General regarding the security of biological select agents and toxins¹. The group was re-chartered in July 2014 to further evaluate approaches to enhance biosafety and security². The panel is chaired by USDA and HHS and includes members from numerous agencies throughout the government. Overall the panel concluded that the U.S. government has developed a robust set of rules, regulations and practices to inform safe, secure and responsible work and research with infectious agents and toxins. However, it also identified several improvements that would further mitigate the risks of working with these agents and toxins.

¹ <http://www.phe.gov/Preparedness/legal/boards/fesap/Documents/fesap-recommendations-101102.pdf>

² <http://www.phe.gov/s3/Documents/fesap.pdf>

Additionally in August 2014, the White House Office of Science and Technology Policy created the Fast Track Action Committee on the Select Agent Regulations (FTAC-SAR)³ to examine – with input from the research community, interested stakeholders, and the public – the select agent regulations in order to identify challenges and make recommendations to improve and strengthen the regulations. FTAC-SAR recommendations included increased transparency of research and laboratory-related incidents; standardization of the inspection process; categorization of inspection findings so as to distinguish between administrative and direct safety findings; and timeliness and better communication surrounding inspection reports.

Broadly, these two panels and their recommendations address the need for a culture of responsibility; oversight, outreach and education; applied biosafety research; incident reporting; materials accountability; inspection process improvements; and regulatory changes and guidance documents to improve biosecurity and safety. Together, the FESAP and FTAC-SAR recommendations were included in an October 2015 implementation plan.⁴ USDA and our partners have made significant progress in accomplishing and implementing many of these recommendations.

Chief among these is the development of a rule to strengthen and improve the select agent regulations. The proposed rule, which USDA published in January 2016, would amend the select agent regulations to add provisions to address the inactivation of select agents, biocontainment and biosafety, and would clarify regulatory language concerning security, training, incident response, and records. These changes would help regulated entities better understand their responsibilities under the select agent regulations as well as provide for enhanced program oversight. USDA is finalizing the rule as quickly as possible, and we are coordinating with HHS to ensure that the rule is in line with CDC regulations.

USDA and HHS have also committed to increasing transparency and the public's understanding of the FSAP. In June, we published the first annual report of aggregate program data⁵. These data provide insight into work conducted with biological select agents and toxins at laboratories across the nation, as well as the regulatory functions of the FSAP. The report summarizes program data in areas such as:

- Numbers and types of registered entities
- Security risk assessments performed
- Number of inspections conducted
- Top select agents or toxins registered by entities
- Key observations related to inspection findings and compliance with the select agent regulations
- Identifications and transfers of select agents or toxins
- Thefts, losses, and releases of select agents or toxins

Beyond providing a snapshot of the program, the data, through the collection process, ensures a level of accountability, and can help USDA and HHS identify trends and other areas of concern on which we can take action.

APHIS has also taken actions to strengthen the performance and build the capabilities of its select agent program. The President's fiscal year 2017 budget includes a \$4.71 million increase, for a total of about \$9.6 million. The proposed increase will enhance our select agent program and allow us to hire additional personnel with strong scientific, security and policy backgrounds. It is critical that we have personnel

³ <http://www.phe.gov/s3/Documents/ftac-sar.pdf>

⁴ <http://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf>

⁵ http://www.selectagents.gov/resources/FSAP_Annual_Report_2015.pdf

with the expertise to address the increasing scientific complexity of the regulatory issues related to research with select agents and toxins. The additional personnel funded by this request would allow APHIS to strengthen the inspection program – addressing critical incidents while also carrying out the daily responsibilities associated with overseeing these agents.

Another effort to strengthen the program was APHIS' own internal audit. The agency's auditors reviewed AgSAS in December 2015 in an effort to improve program efficacy and efficiency. Overall, the audit found that AgSAS has designed its program to effectively carry out its program objectives and mandates. However, the review made several recommendations, which included suggestions to improve program documentation and to strengthen policies related to incident reporting and permitting. APHIS has begun implementing those recommendations.

Beyond these internal USDA and Executive Branch reviews, we appreciate the recommendations of the Government Accountability Office (GAO). GAO has provided regular reviews and recommendations to strengthen the select agent program, and we value their independent perspective.

The report GAO is releasing today, "High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk" includes five recommendations for USDA. As our response to the audit indicates, we are already taking significant actions to address all of the recommendations. In particular, under FSAP, USDA is working to finalize a rule to strengthen the select agent regulations, which will include additional clarification around the inactivation of select agents. Specifically, the rule will provide regulatory definitions of inactivation and viability testing. We feel that the rule, along with guidance documents on inactivation and viability testing, will help regulated entities understand what they need to do to ensure that the materials they are working with are handled in accordance with the regulations, protecting human, animal and plant health.

The report also highlights the gaps in the science of inactivation and viability testing. APHIS and CDC, as part of the FESAP interagency working group, examined current gaps in scientific knowledge and agreed with the importance of a robust federally-supported program of biosafety research. The working group has been working with researchers and laboratories, per FESAP recommendation 1.3, to try to ensure that a qualified review entity validates local policies and protocols regarding the inactivation, sterilization or decontamination of biohazardous materials at research institutions. The group continues to make progress in this area, and when combined with the pending regulatory changes and guidance documents, the government and regulated entities will have more consistent understanding of the processes for inactivation and sterilization of select agents and other biohazards.

We are taking other steps in accordance with the recommendations of this report and other reviews. We are committed to updating APHIS/CDC Form 3 to better identify incidents involving incomplete inactivation. The increased information we collect on this form will allow FSAP to analyze trends to reduce the risk of future incidents. We have also developed a three-tier risk scoring system to ensure consistency in enforcement actions, particularly for those involving incomplete inactivation. We have shared this proposed system with the regulated community to gather feedback and to indicate the seriousness with which we take incidents involving incomplete inactivation. Our intent is to finalize the system and to use it as a tool within the FSAP.

APHIS takes any potential release of a select agent or toxin very seriously. While we cannot completely eliminate all risk of a potential release, we can develop overlapping safeguards and processes to reduce the risk to as low as possible. By working closely with our Federal partners and the regulated community, we can develop strong cultures of safety and responsibility and policies and procedures that are science-based and, to the maximum extent possible, ensure the safety and security of these potentially dangerous agents.

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

Mr. MURPHY. Thank you, Dr. Davidson.
I now recognize Mr. Potts for 5 minutes. Turn your microphone on, please, and bring it close.

STATEMENT OF JEFFREY POTTS

Mr. POTTS. Good afternoon, Mr. Chairman, Ranking Member DeGette, and distinguished members of the subcommittee. It is an honor to appear before you today to discuss NIH's role in the oversight of biosafety and biosecurity measures in high containment laboratories, including those that work with biological select agents and toxins.

The GAO report released today provides valuable analysis and recommendations that will inform policies and procedures on inactivation moving forward. NIH is committed to working with our Federal partners in implementing these recommendations. I am the NIH Biorisk Manager, and I'm responsible for providing regulatory compliance oversight and expert guidance to the intramural research community for matters involving high-consequence pathogens.

Consistency is essential to biosafety practice. At NIH all high containment laboratories are held to the same operational standards. Working with a team of certified biological safety professionals, we oversee laboratories on the main campus in Bethesda, Maryland; Frederick, Maryland; and Hamilton, Montana. The NIH has an important mission to conduct research that will lead to the development of new treatments, diagnostics, and vaccines to address public health needs, including medical countermeasures to address the ever-evolving threat of infectious diseases.

Methods for inactivating pathogens are an essential component of this research. Inactivation methods allow for the removal of a biological material from a high containment laboratory for downstream use. At NIH, inactivation methods and viability testing protocols are developed through collaboration of investigators and Biorisk Management staff, reviewed by the Biosafety Officer, and ultimately review and approval by the NIH Institutional Biosafety Committee. These policies and procedures are applicable to all pathogens that may be removed from a high containment laboratory.

The research community at large looks to two essential publications when conducting biological research: the "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules," commonly referred to as the NIH Guidelines; and the Centers for Disease Control and Prevention/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," referred to as the BMBL.

In addition to these guidance documents, work with select agents is regulated by either CDC and/or USDA. NIH will look to these two agencies to establish minimum criteria and definitions for inactivation. It is important that every effort is made to harmonize language to ensure a clear and consistent message, as well as provide guidance for development, validation, and implementation of inactivation protocols.

The GAO report called for greater consistency in the collection of data related to biosafety incidents involving incomplete inactivation

or failures. In order to provide greater accuracy in data collection and retrieval concerning inactivation failures, NIH revised its “Template for Reporting Incidents” subject to the NIH Guidelines. Internally, NIH has begun keeping records on the destination to which inactivated samples are distributed or shipped. In the upcoming revision of the BMBL, guidance will be included on documenting the shipment of such inactivated material.

NIH is committed to biosafety outreach to the broader research community. NIH will once again sponsor National Biosafety Month this October. Throughout the month, all research institutions are encouraged to refocus their attention on their biosafety policies, practices, and procedures.

This year, the outreach effort will encourage institutions to evaluate their biosafety programs, collaborate with other biosafety professionals, and commit resources to ensure they have a robust biosafety governance structure in place. In an effort to foster continuous discussion on this topic, in May 2017 the NIH will host its third Safety by Design Symposium and Workshop. The topic of the symposium will be “Microbial Inactivation—Lessons Learned, and a Way Forward.” This symposium will provide a venue for scientific and safety personnel to share experiences regarding the use of various inactivation modalities, successes and failures, and scientific information gaps.

In closing, I want to ensure the subcommittee that NIH remains committed both to the safety of the public and the scientists whose mission it is to find new ways to enhance health, lengthen life, and reduce illness and disability. We remain committed to preserving the public’s trust in NIH research activities through best safety practices and strong leadership. Thank you for the opportunity to testify. I’ll be glad to answer any questions you may have.

[The statement of Mr. Potts follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Lab Safety and Inactivation of Microbiological Agents at NIH

Testimony before the
House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Jeffrey Potts, MPH, CBSP
Biorisk Manager,
NIH

September 27, 2016

Good morning Mr. Chairman, Ranking Member DeGette, and distinguished Members of the Subcommittee, it is an honor to appear before you today to discuss the National Institutes of Health's (NIH) efforts to improve oversight of biosafety and biosecurity measures in high-containment laboratories, including those that work with biological select agents and toxins. My testimony today will focus on the General Accountability Office's (GAO) report, "High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk" and its recommendations related to the inactivation of microbiological agents – a process that renders these organisms safe for downstream research outside a high containment laboratory.

I am Jeffrey Potts, NIH Biorisk Manager for the Biorisk Management Branch within the NIH Division of Occupational Health and Safety (DOHS). The DOHS at NIH provides leadership in the development and implementation of occupational health policies, standards, and procedures applicable to biomedical research that is conducted through our intramural program, including laboratories on the main campus in Bethesda, Maryland; Research Triangle Park, North Carolina; Baltimore, Maryland; Frederick, Maryland; Hamilton, Montana; and Phoenix, Arizona. The Biorisk Management (BRM) Branch is responsible for providing regulatory compliance oversight and expert guidance to the NIH community for matters involving research with high-consequence pathogens. Among other activities, the BRM is responsible for implementing the NIH Biosurety Program and the NIH Select Agent Program.

NIH has an important mission to conduct research that will lead to the development of treatments, diagnostics, and vaccines to address public health needs, including medical countermeasures to address the ever-evolving threat of newly emerging and re-emerging

infectious diseases caused by pathogens including those that are select agents. While appreciating the value of studying these select agents, NIH also recognizes the importance of appropriate precautions and containment measures to ensure the research is conducted in the safest manner possible. Compliance with and constant vigilance over the implementation of biosafety standards is extremely important to our mission.

Consistency is essential to biosafety practice. At NIH, all high containment laboratories are held to the same high operational standards whether or not select agents are being worked with or stored in these laboratories. My role at NIH is the oversight of these operational requirements such as; semi-annual inspections, annual training of research and support personnel, annual engineering validations, participation in Personnel Reliability Programs, and annual review of laboratory specific standard operating procedures, including the inactivation of infectious agents. NIH has been and remains a proponent of rigorous inactivation protocols tailored to the research being conducted. Pathogen inactivation procedures are undertaken to enable important biomedical research such as the development of vaccines, development or use of diagnostic assays, or removal from a high containment laboratory to facilitate research using procedures not requiring a viable organism. Rigorous testing for verification of inactivation protocol efficacy is required. At NIH, inactivation and testing protocols are developed through collaboration of investigators and Biorisk Management staff, review by the biosafety officer, and ultimately review and approval by the NIH Institutional Biosafety Committee. Investigations of any inactivation method failures and recommended corrective actions are also the responsibility of the BRM. These policies and procedures extend beyond select agents to all infectious agents that may be removed from a high containment laboratory for downstream use.

Enhanced coordination among Federal partners is advancing biosafety and biosecurity at NIH laboratories and others across the country. The research community at-large looks to two essential publications when conducting biological research: the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), which are a term and condition of NIH funding; and the Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). As the BMBL is a joint publication of the CDC and NIH, we are committed to continuing our work with the CDC's Office of the Associate Director of Laboratory Science and Safety to achieve consistency and standardization of the definition used for inactivation in these guidance documents used by the research community.

In addition to these guidance documents, work with select agents is regulated by either CDC and/or USDA. As the regulatory authorities, NIH will look to these two offices to establish minimum criteria and definitions. It is critically important that every effort is made to harmonize language to ensure a clear and consistent message. NIH is committed to working with CDC and USDA to ensure comprehensive and consistent guidance for development, validation, and implementation of inactivation protocols.

Among other recommendations, the GAO report called for greater consistency in the collection of data related to biosafety incidents involving incomplete inactivation or failures. Under the *NIH Guidelines*, incidents involving recombinant and synthetic nucleic acid molecules must be reported to NIH. In order to provide greater accuracy in data collection and retrieval concerning inactivation failures, NIH revised its Template for Reporting Incidents subject to the *NIH Guidelines*. Now, the reporting template includes "incomplete inactivation" as a category of reportable incident. NIH has also begun keeping records regarding all infectious materials

subjected to inactivation procedures in our own high containment laboratories, including the destination to which these materials are distributed or shipped. To provide for broader application of this practice, in the upcoming revision of the BMBL, guidance will be included on documenting the shipment of such inactivated material.

The GAO report provides a valuable analysis and recommendations that will inform policies and procedures on inactivation moving forward. To fully implement the GAO recommendations and the guidance that will be in the BMBL, outreach to the research community to reinforce the importance of effective inactivation and associated record-keeping is critical. In May 2017, NIH will be holding its third Safety by Design Symposium and Workshop, the topic of which will be "Microbial Inactivation – Lessons Learned and a Way Forward." This Symposium will provide scientific personnel an opportunity to share experiences regarding the use of various inactivation modalities (physical, chemical, and irradiation); successes and failures; and scientific information gaps. The Symposium format will allow an opportunity for participants to discuss and recommend ways to improve current practices.

NIH is committed to biosafety outreach to the broader research community. An example is NIH's National Biosafety Month, which will occur in October. National Biosafety Month is a period during which NIH-funded research institutions are encouraged to refocus their attention on their biosafety policies, practices, and procedures. This year, the outreach effort will encourage institutions to evaluate their biosafety programs, collaborate with their peers on biosafety, and commit resources to ensure they have robust biosafety governance structure in place.

I want to assure the Subcommittee that NIH remains committed both to the safety of the public and the scientists whose mission it is to find new ways to enhance health, lengthen life,

and reduce illness and disability. We remain committed to preserving the public's trust in NIH research activities through best safety practices and continuing strong leadership.

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

Mr. MURPHY. Thank you, Mr. Potts.
General Holcomb, you are recognized for 5 minutes.

STATEMENT OF BARBARA R. HOLCOMB

MG HOLCOMB. Good afternoon, Chairman Murphy, Ranking Member DeGette, distinguished members of the subcommittee. Thank you for this opportunity to brief you on the DoD's actions since the last hearing on the 20th of April 2016 concerning the safe handling of biological select agents and toxins, or BSAT.

I'm the commanding general of the U.S. Army Medical Research and Materiel Command, and I am here in support of the Army Surgeon General who is the DoD Executive Agent Responsible Official for the DoD BSAT Biosafety Program. The Executive Agent Responsible Official oversees BSAT biosafety policy, technical review, and inspection guidelines across the DoD.

Today, I will briefly describe several actions the DoD accomplished since the last hearing, and also describe our plans for future validation procedures, oversight, and implementation of governance policies for biosafety. The Executive Agent Responsible Official chartered the DoD BSAT's Biosafety Program office in March of 2016 and is now establishing processes and hiring staff. This office advises the Executive Agent Responsible Official on all biosafety matters pertaining to BSAT lab operations, risks, and oversight. This office also serves as the DoD interface with regulatory agencies, ensures standardization of safety procedures, and identifies best practices to enhance biosafety across the full spectrum of DoD BSAT operations.

The Life Science Division production facility, from which the inadvertent live anthrax shipments were sent, was reassigned to the Dugway Proving Ground in the U.S. Army Edgewood Chemical Biological Center this past July. The transfer places the facility under a chain of command and direct administrative control which has a robust BSAT experienced staff assigned under the Research, Development and Engineering Command in the Army Materiel Command.

We established a BSAT Biosafety and Scientific Review Panel in February 2016. Since its establishment, this panel has met face-to-face and has conducted multiple teleconferences to review and assess biosafety concerns associated with procedures conducted at DoD BSAT laboratories, review and assess scientific evidence that supports mitigation of biosafety concerns, and provide recommendations on their acceptability for continued use or initiation of use to enhance biosafety across DoD BSAT programs.

On the 25th of July 2016, the Secretary of the Army signed the Army directive 2016-24 titled, "Department of Defense Biological Select Agents and Toxins Biosafety Program." This directive establishes policy and assigns several responsibilities to applicable DoD and service activities. This directive replaces the previous Secretary of the Army BSAT moratorium with additional safeguards regarding production, handling, testing, and shipment of inactive, live and derivatives of BSAT, and also critical reagent program associated materials. However, the Deputy Secretary of Defense moratorium for inactivated anthrax remains in effect for production, handling, and shipment.

We are working on several initiatives which are intended to enhance harmonization and standardization of practices and procedures across the DoD network of laboratories. We initiated studies to better define conditions for inactivation and viability testing of BSAT, and irradiation inactivation study for anthrax is underway and is scheduled for completion in October 2016.

The BSAT Biosafety Program office is planning for a contract for the development of a quality management system focused on monitoring critical biosafety and biosecurity control points in BSAT operations at all DoD laboratories. Other initiatives include development of a joint inspection team, biosafety and scientific review of all BSAT protocols and procedures, and possible unified oversight for biosafety and biosecurity to enhance risk management for BSAT operations. My written testimony provides a description of these and other initiatives.

We value the analysis provided by the GAO. Their observations will inform DoD BSAT Biosafety Program efforts and improve oversight. The DoD is addressing our BSAT oversight of inactivation documentation, improving guidance for development and validation of inactivation protocols, and developing consistent enforcement of investigations and referrals.

We look forward to coordinating and cooperating with the Department of Health and Human Services and the Department of Agriculture as they respond to the GAO recommendations. Thank you for the opportunity to testify today and I am happy to answer your questions.

[The statement of Major General Holcomb follows:]

RECORD VERSION

STATEMENT BY
MAJOR GENERAL BARBARA R. HOLCOMB
COMMANDER, U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
IN SUPPORT OF THE
EXECUTIVE AGENT RESPONSIBLE OFFICIAL
FOR THE DEPARTMENT OF DEFENSE
BIOLOGICAL SELECT AGENTS AND TOXINS BIOSAFETY PROGRAM

BEFORE THE

HOUSE ENERGY AND COMMERCE
OVERSIGHT AND INVESTIGATIONS SUBCOMMITTEE
SECOND SESSION, 114TH CONGRESS

BIORESEARCH LABS AND INACTIVATION OF DANGEROUS PATHOGENS

SEPTEMBER 23, 2016

NOT FOR PUBLICATION UNTIL RELEASED BY THE
COMMITTEE ON HOUSE ENERGY AND COMMERCE

Chairman Murphy, Ranking Member DeGette, Distinguished Members of the Subcommittee, thank you for this opportunity to brief you on the Department of Defense's (DoD) and the Army's actions since the last hearing on April 20, 2016. The DoD has accomplished several actions and is in the process of completing several additional near term changes to address the development and implementation of oversight policy and procedures for the safe handling and transfer of Biological Select Agents and Toxins (BSAT) among DoD laboratories and affiliated institutions.

Following the May 2015 reporting of the incomplete inactivation and shipments of *Bacillus anthracis* (anthrax) spores by an Army laboratory, the DoD implemented a moratorium on anthrax production, handling, testing, and shipment. The Army also issued a similar moratorium on all BSAT. The DoD instituted an immediate realignment of authorities and oversight for BSAT activities. By direction of the Deputy Secretary of Defense, the Secretary of the Army is designated the Executive Agent (EA) for the DoD BSAT Biosafety Program. By the direction of the Secretary of the Army, The Surgeon General of the Army is designated the Executive Agent Responsible Official (EA RO) for the DoD BSAT Biosafety Program and is delegated the authority to act on the Secretary's behalf for all DoD EA responsibilities, functions, and authorities the Deputy Secretary of Defense assigned to the Secretary of the Army.

As the Commanding General of the U.S. Army Medical Research and Materiel Command, I also support The Surgeon General of the Army, the DoD EA RO for BSAT. In this support role, I oversee the management for harmonization of BSAT policy, technical review, and inspection guidelines across DoD.

Background

In April 2016, my predecessor, Major General (MG) Lein testified before this committee describing the Army and the DoD's response to the improper inactivation and shipping of anthrax spores by an Army laboratory. MG Lein explained that the DoD and other government agencies store, study, and ship BSAT materials for research, development, testing and evaluation of medical and physical countermeasures to biological and bioterrorism threats. MG Lein noted that it is DoD's goal to develop a system that incorporates the fundamentals of quality policies and systems. We believe that the systems under development will provide for the necessary checks and balances to prevent future challenges.

Today, I will briefly describe several of the actions accomplished since April and also describe our anticipated plans for future validation procedures, oversight and implementation of governance policies for biosafety. I also look forward to working with the other federal agencies as they develop new national standards for oversight of dangerous pathogens and high-containment laboratories participating in the Select Agent Program.

Recent Actions

The EA RO created the BSAT Biosafety Program Office (BBPO). The BBPO will advise the EA RO for the DoD BSAT Biosafety Program on biosafety for all matters that pertain to risk associated with BSAT operations, provide oversight of DoD BSAT laboratory biosafety operations, serve as a unified DoD interface with regulatory agencies, ensure standardization of safety elements of procedures used in DoD BSAT

laboratories, and identify best practices to enhance biosafety across the full spectrum of DoD BSAT operations.

As of July this year, the Life Science Division production facility, from which the inadvertent live Anthrax shipments were sent, was reassigned from Dugway Proving Ground and placed under the U.S. Army Edgewood Chemical Biological Center. This transfer provides a chain of command which has a robust, BSAT experienced staff, assigned under the Research Development and Engineering Command and the Army Materiel Command.

A BSAT Biosafety and Scientific Review Panel (BSRP) was established. On an as needed basis, minimum two times per year, the BSAT-BSRP will review and assess biosafety concerns associated with currently established and new procedures conducted at DoD BSAT laboratories, review and assess scientific evidence that supports mitigation of the biosafety concerns identified, and provide recommendations to the EA RO for BSAT Biosafety Programs on their acceptability for continued use or initiation of use to enhance biosafety across DoD BSAT programs. This panel is also intended to serve in an advisory capacity to the EA RO on any matters that pertain to biosafety associated with BSAT-related research.

As per direction of the Deputy Secretary of Defense, a credentialed biosafety professional was designated to advise the executive agent and is a member of the BBPO staff.

A joint DoD inspection team was established by the Department of Army Inspector General. This joint inspection team will ensure that all DoD BSAT laboratories are inspected to a common standard and best practices identified by the BBPO are

uniformly implemented. The team will report and provide findings to laboratory leadership, to the Service responsible official, to the EA RO, and the Secretary of Defense Office of Primary Responsibility for biosecurity. They will also obtain inspection results from both the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service and provide the results to the EA RO.

Army Directive 2016-24

Most recently, on July 25, 2016, the Secretary of the Army signed Army Directive 2016-24, the "Department of Defense Biological Select Agent and Toxins Biosafety Program." This directive establishes policy and assigns several responsibilities to applicable DoD, Service, and Army activities with the oversight and governance of the DoD BSAT Biosafety Program delegated to The Surgeon General of the Army. It applies to any DoD activity that provides oversight to use, produce, store, handle, transport, transfer, or destroy BSAT. Applicable provisions of this directive will also be incorporated into contracts which provide for DoD to prohibit transfer of inactivated BSAT and derivatives of BSAT beyond the initial customer receiving the material and an annual inquiry by DoD until the material is consumed or destroyed.

This new Army Directive and the requirements stated in the U.S. Department of Health and Human Services publication, "Biosafety in Microbiological and Biomedical Laboratories" apply to all DoD activities and facilities in which BSAT are used, produced, stored, handled, transported, transferred, or destroyed. Army Directive 2016-24 has mandatory procedures and guidance, as well as preferred and acceptable methods of accomplishment.

The Army Directive removes the previous Secretary of the Army moratorium. The Deputy Secretary of Defense July 2015 moratorium on the production, handling, testing, and shipment of inactivated anthrax will remain in effect, until rescinded. The Federal Select Agent Program issued an updated policy statement for work with *Bacillus anthracis* spores and DoD laboratories will comply with the updated guidance.

GAO-16-642

The DoD appreciated the opportunity to review the draft report dated June 8, 2016, and had no comments. We value the analysis provided by the Government Accountability Office (GAO); their observations will inform efforts of the DoD Biological Select Agents and Toxins Biosafety Program and improve oversight. Similar to the new GAO-16-642 recommendations, the DoD is addressing our BSAT oversight of inactivation documentation, improving guidance for development and validation of inactivation protocols, and developing consistent enforcement of investigations and referrals. We look forward to coordinating and cooperating with the U.S. Department of Health and Human Services and the U.S. Department of Agriculture as they respond to the GAO recommendations.

Way Ahead

Several initiatives are intended to enhance harmonization and standardization of practices and procedures across the DoD network of laboratories. These initiatives include development of a joint Service inspection team, the review process previously described for all BSAT protocols and procedures, and the establishment of unified oversight for biosafety and biosecurity to enhance composite risk management for BSAT operations.

The Office of the Deputy Assistant Secretary of Defense for Chemical and Biological Defense initiated studies to better define conditions for inactivation and viability testing of BSAT. Current studies are focused on the causative agent for anthrax, *Bacillus anthracis*. An irradiation inactivation study on *Bacillus anthracis* is under way and is scheduled for completion in October 2016. Additional studies, based on what is learned from the initial study, are planned for fiscal year 2017.

The BSRP will primarily focus on conducting critical review of all DoD BSAT protocols and procedures and will identify scientific gaps related to safety to focus future research initiatives. Through this process, we will gain assurance that all procedures are properly validated and/or verified. This panel is an intra-governmental committee made up of DoD Biosafety Officers and scientists along with similar representation from the CDC and the U.S. Department of Agriculture.

Working with the Assistant Secretary of the Army (Acquisition, Logistics & Technology), we anticipate development of a Defense Business System that will integrate information from current BSAT management databases and provide additional capabilities for tracking inactivated BSAT and products derived from BSAT. Capturing critical information from a Bio-Risk Quality Management System is also planned for development. Completion of the Defense Business System development is anticipated by September 2017.

In conclusion, the DoD realigned activities, developed policy and implemented procedural steps to create systems of checks and balances to improve the efficiency, oversight, and governance of BSAT biosafety programs. The DoD will continue to improve and develop standardized procedures. The DoD looks forward to coordinating

with other federal agencies to develop and implement national Select Agent Program oversight guidance for high containment laboratories and the handling of dangerous pathogens.

Mr. MURPHY. I thank you, General, and thank you, panel. I now recognize myself for 5 minutes of questions. And I want to start by saying, as Ms. DeGette and Mrs. Blackburn and others in this committee have said, we have been here before. With these agencies we have seen some of these problems occur. We are hearing again you take it seriously. We hear about the number of scientists with advanced degrees, the rules of accountability, et cetera.

But this is a pretty severe threat, and we have had more cases here of anthrax and pathogens being released than we have had done by terrorists in this country. Now at this level, luckily, we have not seen somebody die from this, but it is serious and you all recognize the seriousness. But let me just start off with this important question here.

Dr. Monroe, should the CDC put out a public announcement that any lab scientist who fails to implement the policies or inactivation of dangerous pathogens is subject to personnel action?

Dr. MONROE. So whenever there's an issue that we recognize with inactivation failures or other issues related to dangerous pathogens, we immediately, my office is involved in finding out what the root cause is.

Mr. MURPHY. But I mean from the onset, the onset, employees notified. This could have been gross negligence. It could have been willful disregard, reckless endangerment, something else. Do the employees understand now the seriousness of this and that they will be held personally accountable if they do not respond to the rules you are setting forth?

Dr. MONROE. That is a part of our cultural responsibility. The disciplinary action is a management decision that's outside of my office.

Mr. MURPHY. We just want to make sure. Dr. Davidson, how about within the USDA and APHIS?

Dr. DAVIDSON. All of our scientists have an important role to uphold the integrity, and each case will be investigated for the release and then if management action would be needed.

Mr. MURPHY. Mr. Potts, how about NIH? Has it clearly been stated to the employees there?

Mr. POTTS. So in our training with all of our employees we stress the importance of following the standard operating procedures, and all protocols are to have been previously approved. Like Mr. Davidson, or Dr. Davidson—I'm sorry—based on the investigation, if we find that there is a willful or negligence involved we would pursue those actions.

Mr. MURPHY. That is better. General Holcomb.

MG HOLCOMB. DoD scientists authorized to work with Tier 1 BSAT are required to be enrolled in a biological personnel reliability program. Failure to comply with applicable regulations and policies are grounds for disqualification from the personnel reliability program and the privilege to work with Tier 1 BSAT agents.

Mr. MURPHY. Thank you. I appreciate that. That is the kind of clear message I think we need to hear, and I appreciate the Army standing up and doing that because there can't be any ifs, ands, or buts on that. There can't be anything. We are here as a committee to protect the safety of our country and you too. And so we

don't want to hear anymore equivocating on this because where there is a tiny bit of leeway here, it is a problem.

Look, we all understand. We know people make mistakes. But when we have heard time and time again everything from what, we have heard refrigerators left unlocked, people coming in with the same passkey, people putting things through Ziploc bags. The messes continue and we are just not really clear yet and convinced that things are taking place.

Dr. Sosin and Dr. Davidson, so your agencies are in agreement with the GAO recommendations but it still comes down to it. Help us understand, why do we trust you? Why should we trust you now? What is different in this culture?

Dr. SOSIN. Many aspects of our program have changed. I'd be happy to talk to you more about how inspections have improved, how the work with the regulated community including opportunities for best practice sharing, training, have improved, how incident response activities have improved, and transparency. All of these called in a broader range of Federal reports. I think you can look at what has happened in the year since we have been here and see many changes, including each one of the GAO recommendations that came out in the recent report.

Mr. MURPHY. Dr. Davidson.

Dr. DAVIDSON. As Dr. Sosin said, we work very closely together in implementing the changes, and through the different reviews—the Federal reviews, the GAO—we have found gaps that we needed to address. And we've been very active in the work we've done with our inspectors, you know, through the steps we're taking for the GAO in addressing the regulations' clear guidance and policies. And we've got to continue to always look towards improvement.

Mr. MURPHY. Well, let me ask one of those areas. So the GAO report said that there needed to be specific coding and tracks on reports. Is this issue solved now, Dr. Sosin?

Dr. SOSIN. I didn't understand, specific tracking?

Mr. MURPHY. With regard to the specific coding to track reports of the inactivation cases. Is there a specific way, do you have that in concrete now?

Dr. SOSIN. So yes, we have—

Mr. MURPHY. OK. Dr. Davidson, do you have that concretely set up now?

Dr. DAVIDSON. Yes, we've worked together to—

Mr. MURPHY. I have only got a few seconds. Mr. Potts, do you have that concrete, specifically set up now when there is an inactivation case, clear reporting set up?

Mr. POTTS. Yes, the NIH recombinant DNA guidelines were updated in August of this year to include a specific category for inactivation failures.

Mr. MURPHY. And General Holcomb, you have that too?

MG HOLCOMB. Yes, we do.

Mr. MURPHY. Thank you. I am out of time. I recognize Ms. DeGette.

Ms. DEGETTE. Thanks.

In reviewing the GAO's August 2016 report, there is now six additional recommendations to improve oversight of these high containment laboratories in the Select Agent Program. And we have

seen a number of recommendations, you know, I have been on this subcommittee 20 years, so over the last 10 years we have seen a number of recommendations that were always trying to improve on the program.

And so having seen this over all these years, I have to ask. Does the existing structure with responsibilities spread across the different agencies really provide the oversight we need despite ongoing efforts? So I want to ask you a couple of questions about this, Dr. PERSONS. Successfully addressing the six recommendations is going to require considerable coordination across several agencies; is that correct?

Dr. PERSONS. That is correct.

Ms. DEGETTE. Do you believe that can be achieved, and if so, how?

Dr. PERSONS. I believe that it is possible to do coordination. Of course, GAO does a good deal of work not just on this topic but on Government coordination in general. I would simply say often coordination's easy to conceive of, sometimes challenging to do on these things. And I think as our recommendations show, we had key things that we found to try and address that; coordination being essential to most if not all of them.

Ms. DEGETTE. In earlier work you found that existing oversight of high containment laboratories is, quote, fragmented, at times duplicative, and relies on self-policing, end quote; is that correct?

Dr. PERSONS. That's correct.

Ms. DEGETTE. And given these ongoing efforts, I guess I am wondering if you believe the current structure provides adequate oversight with the adjustments that people are testifying about here today, or rather do we need a single oversight entity for this program?

Dr. PERSONS. So thank you for the question, Ms. DeGette. I think that the current system, it's important to go back and answer this in context. The way the Federal Select Agent Program evolved really goes back to the post-Oklahoma City bombing and then it layered in with legislation through the Patriot Act in post-9/11 and so on. And I think what was important, and this was confirmed by several of our experts that we spoke with, is just the context of biosecurity vis-a-vis biosafety, overimposed against, I mean.

So I think there is work to be done in the biosafety arena and, one, since inactivation is largely a biosafety related issue and I think it, as one type of incident, I think it exposed the challenges in the regulatory structure which is largely built around select agents, meaning those things that were a concern or a threat in a national homeland security sense.

Ms. DEGETTE. So to reiterate my question, given those challenges that you just described and the time frame, do you think it would be practicable to have a new, single oversight entity for oversight of these high containment labs?

Dr. PERSONS. Well, ma'am, we're right now, as you know for this committee, on our follow-on work companion to this we are looking at a comparative structure and we'll be able to say more in an evaluative sense about the sufficiency and the efficacy of what we're doing. We're looking internationally with partners who do this.

Ms. DEGETTE. So you don't—excuse me. You don't have a conclusion about whether we would need a single entity or not yet, but you are working on it. Is that fair?

Dr. PERSONS. I believe it would be a thing to seriously consider given the need in terms of again the biosafety domain and inculcating that.

Ms. DEGETTE. OK. Are there ways short of a single entity to better centralize the oversight and regulation of the Select Agent Program and high containment labs?

Dr. PERSONS. I'm not able to comment on that other than working within the existing system on our recommendations to make it better, which we do, as the various witnesses have testified here.

Ms. DEGETTE. Thank you. I would like to ask the rest of the witnesses what they think about this concept of a centralized agency to oversee this program. Dr. Sosin.

Dr. SOSIN. Ranking Member DeGette, I believe there's a misunderstanding about what the Federal Select Agent Program is authorized to do. It's authorized to oversee a specific set of select agents and toxins, not the laboratories. So the Federal Select Agent Program is not authorized.

Ms. DEGETTE. Right, but you could authorize some agency to oversee it. Hi, I am Congress. Congress could authorize that. Do you think that is a good idea, yes or no?

Dr. SOSIN. I don't have enough information to know whether the benefit over—

Ms. DEGETTE. OK.

Dr. Monroe?

Dr. MONROE. There's not currently one agency that has the breadth of expertise that would be needed to run that oversight.

Ms. DEGETTE. So we would have to set it up.

Dr. DAVIDSON.

Dr. DAVIDSON. I agree. You know, as we work as a single entity, the breadth that we all bring from our scientists and our multidisciplinary expertise is robust, and the key is the factors we work on in coordination.

Ms. DEGETTE. Mr. Potts.

Mr. POTTS. So I think the current structure is working. I think each agency that has a voice at the table is providing their expert opinion and their guidance to—

Ms. DEGETTE. And you think we can coordinate enough to make it work?

Mr. POTTS. I think we can coordinate it and there's efforts ongoing—

Ms. DEGETTE. General Holcomb.

MG HOLCOMB. Within DoD we have done that work. We've consolidated oversight over all of the DoD labs regardless of service, so for us that's what makes sense.

Ms. DEGETTE. Thank you. Thank you, Mr. Chairman.

Mr. MURPHY. I recognize the gentleman from New York, Mr. Collins.

Mr. COLLINS. Thank you, Mr. Chairman. I know we have met before, and again with all full disclosure I was the founder and CEO of a company that operates two level 3 containment labs with a select agent license. So I am very familiar with what you have been

doing, and we have been inspected certainly by the CDC and USDA, and I give everyone kudos for the type of inspectors that went out, the thoroughness of them and so forth. And speaking from the private sector, would never have any real concerns on the oversight that I have seen by the CDC and the USDA over private labs.

So my concerns fall into two areas. One, it is very simple to deactivate, inactivate virus, very straightforward especially if you are not trying to protect the RNA or DNA and you are just killing it off. I mean it is simple, straightforward. Hard to imagine anyone would go through that process and ship anything that wasn't inactivated. That would just be, I think, gross negligence.

If you are trying to protect the RNA and DNA that gets a little trickier. And certainly, when you are into anything like bacteria where you could have spores, so you test it. You grow it, you test it, it is inactivated but you have got spores. The spores pop later, germinate. We have had some discussion before. We found it could be months down the road. And I know, Dr. Sosin, you thought it might be days, but our finding was it was months; certainly with tuberculosis we did find that.

So I guess one thing I would urge, and we have talked before, is to have a very, very rigid inactivation procedure for bacteria in particular which can be grown, inactivated, tested, it is inactivated and then subsequently, especially, you know, down the road when the spores pop. So could you maybe speak to that a little bit especially on the bacteria side?

Dr. SOSIN. Sure. The viability testing of agents following inactivation procedures is absolutely critical, will be a part of the new requirements. Specific to spore formers, specific to *Bacillus anthracis*, since the Dugway incident we have disallowed the treatment of, or the inactivation of *Bacillus anthracis* spores to be used for future use as non-select agents. So until we have clarity of the science of how long that period of viability testing needs to be, we will not lift that prohibition on treating *Bacillus anthracis* spores as inactivated.

Mr. COLLINS. I would just encourage you, really, to test that out and look months down the road not days down the road. I mean it can't hurt, and maybe not just anthrax but other things like tuberculosis.

Now the other thing that we have gotten into here, and I suppose maybe just for clarification the committee should know and we all know we ship live virus all the time. You know, that is including Zika and dengue and others. This is not an uncommon thing in the United States today to have private labs including ones I was involved with growing virus and shipping live virus. There is no prohibition against that.

To some extent I get the feeling people think all pathogens should be inactivated and that is just not the way it is. Some researchers need live virus and we rely on safety protocols within the industry. And I think they are very tight, and by and large folks who work in a laboratory in a spacesuit realize how dangerous the materials are they are working with.

But one thing I read here, Dr. Monroe, and I worry a little about when Federal Government wants to compete with the private sec-

tor when the private sector is doing things fine. And so today there are technologies I know of where you can treat virus, totally protect the RNA and DNA but inactivate it, patent it, and it would beg the question why the Federal Government wouldn't look to license those technologies as opposed to trying to compete with the private sector and look for funding, as I read here, to establish new inactivation methods for something like Zika where those inactivation methods are already available in the private sector covered by patents that totally protect the RNA and DNA and make it inactive. So why would the Government be looking to do something that is already available in the private sector?

Dr. MONROE. Thank you, sir. So what you're referring to, I believe, is a program that we established this fiscal year to do intramural research to look at this issue of inactivation, disinfection and other activities around the science behind the laboratory safety that we're involved with. And we do have a project that includes looking at alternative ways to inactivate Zika and other arthropod-borne viruses as a part of that work.

Mr. COLLINS. Yes. You are aware the private sector can already do this?

Dr. MONROE. Yes, sir. But again it depends on what the specific use is for the material that's going to be used downstream. And so for our scientists it's important to have a method that'll work for their activities.

Mr. COLLINS. OK. I would just encourage you to make sure that you know, you look at the private sector options too.

Dr. MONROE. Very good.

Mr. COLLINS. Fair enough. Thank you, Mr. Chairman. I yield back.

Mr. MURPHY. Thank you. Ms. Castor, you are recognized for 5 minutes.

Ms. CASTOR. Well, thank you, Mr. Chairman. And thank you to our witnesses for being here today.

GAO made six recommendations in its August 2016 report to reduce the risk of incidents involving incomplete inactivation of dangerous pathogens. I would like to hear from each of the agencies on your reaction to GAO's recommendations and the length of time you believe it will take you to implement them.

First, GAO suggested that to increase the scientific information on inactivation and viability testing, the Secretaries of Health and Human Services and Agriculture should coordinate research efforts. This will help close gaps in the science of inactivation across high containment laboratories.

So I would like to ask CDC and NIH, APHIS and DoD, at this point what are the specific scientific gaps that need to be addressed, in other words what is still unknown about the science of inactivation and what is the significance of that lack of knowledge, and what will be involved in closing these gaps? When do you believe this recommendation could be substantially achieved?

Why don't we start on this side with CDC.

Dr. MONROE. So as I just alluded to, within CDC we did allocate funds within this fiscal year for some intramural work to look at specific issues around inactivation and other issues with laboratory safety. Part of the problem here is again the notion that there's not

one perfect way to inactivate any pathogen because it really depends on what you're going to do with that pathogen in the downstream uses.

There has been some coordination among agencies, for instance, and Major General Holcomb can describe this, alluded to this already in her testimony that the efforts at DoD to look specifically at using irradiation to inactivate *Bacillus anthracis*. Because we were aware that that work was going on at DoD, there's no work that's comparable to that that's going on currently at CDC.

Dr. DAVIDSON. So at USDA, as Dr. Monroe talked about, we each have individual areas that we work. One of the things that we're doing with inactivation is training at conferences to help people understand everything that has to go into an inactivation protocol and the steps that have to be taken to validate that protocol. From there our specific research is for individual agents that we work with within our high containment laboratories.

Mr. PORTS. So NIH has active research projects and some external collaborations which have addressed some scientific gaps. At NIH we are constantly looking at new science, new techniques. There are new pathogens that are discovered or reemerging, so the science is always going to be following that. So we're committed to constantly pursuing this.

At NIH we have a process where every pathogen, every inactivation protocol, is brought before the IBC and is rigorously looked at for viability testing to make sure that the protocol is actually effective. We have ongoing collaborations with other agencies within the Federal Government to align the guidance documents and the verbiage for some of the definitions.

MG HOLCOMB. The DoD is currently conducting a series of experiments to validate an optimal dose for irradiation of *Bacillus anthracis* spores. The initial study has identified a method for standardization of spore preparations, a radiation dose that will produce a sterility assurance level of 10 to the negative 6 which is the equivalent to a probability of one in a million, and a method to validate the radiation dose received by samples for optimal inactivation of spores.

The sterility assurance level of 10 to the negative 6 was achieved with a radiation dose of 42 kilograys in the current study, and the upper range was 50, the lower range used was 25. The sterility assurance level is a measure of confidence for sterility that's commonly used by the medical device industry. We must continue to address the confounding variables that can be used in various types of samples, and until those are completed and reviewed and accepted by the Select Agent Program we will continue to manage irradiated spores as BSAT.

Ms. CASTOR. Terrific.

Dr. Persons, it would appear that before implementing some of your other recommendations, such as the creation of a comprehensive and consistent guidance on inactivation protocols, the agencies must first increase their scientific understanding on inactivation and close the gaps that we have been discussing and they have identified. Would you agree, are you hopeful this can be done in a timely way, and will GAO monitor these agencies for progress in closing the scientific gaps?

Dr. PERSONS. So thank you for the question, Ms. Castor. Yes, we believe it's possible. We do believe that extensive coordination is necessary, and it sounds from the witnesses' statements today that's begun. And yes, GAO will keep an eye on this moving forward for this committee.

Ms. CASTOR. Thank you very much.

Mr. MURPHY. Thank you.

Ms. Brooks, you are recognized for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman. And I am really pleased at the level of attention this committee, in particular the subcommittee, has given over the past year to our biodefense enterprise. As the chairman knows, I am focused along with my colleague across the aisle, Congresswoman Eshoo, on strengthening our Nation's biodefense enterprise with the Bill 3299 which would help us get at the problem by incentivizing responsible procurement of vaccinations and treatments needed to combat an outbreak or an attack.

However, as we have focused on in past hearings on this subject, breaches undermine the entire biodefense enterprise and are as much a matter of public health security as they are of national security. And fortunately we haven't had lapses like this leading to widespread contamination, but I am just curious and want to explore a little bit with respect to the lab safety and inconsistent enforcement.

And while I am focused on Federal Government and industry partnering to develop medical countermeasures and bolster our national strategic stockpile, I am curious. And if we use anthrax as an example, a pathogen for which we obviously, is currently stockpiled, are the lab workers and the scientists and other staff given the necessary vaccines before working around these dangerous pathogens? I would ask Major General Holcomb, are they given vaccines?

MG HOLCOMB. Most are, the military are. The civilian and contractors it's not a requirement. They're offered the opportunity. They certainly have all the PPE, the personal protective equipment, needed to work, but we cannot force them to take a vaccine for something that they don't choose to do.

Mrs. BROOKS. How about Dr. Monroe and CDC, what is the status of vaccines for those working in the space?

Dr. MONROE. At CDC, likewise, specifically for anthrax, workers who work with live anthrax are offered the vaccine as a prophylactic, and then we do keep supplies in our occupational health clinic of the appropriate antibiotics in case there would be an exposure in the lab.

Mrs. BROOKS. And that is what I wanted to follow up. So are there sufficient antivirals and antitoxins on site in case of exposure, for everybody?

Dr. MONROE. There are for, you know, the workers who are working in the laboratory. With the incident that we had in 2014, where there was the potential that there were workers who were exposed in other parts of the agency who would not normally, we may not in all cases have a stockpile on site within CDC to treat, you know, essentially every employee at the agency.

Mrs. BROOKS. What is the process in place if that were to be necessary?

Dr. MONROE. But we would have access through the Strategic National Stockpile. If there were truly an incident where there was widespread release of an agent, we would be able to with the other resources available bring in enough antibiotic to treat the appropriate population.

Mrs. BROOKS. Dr. Sosin, you seem as if you wanted to add.

Dr. SOSIN. Congresswoman, thank you. The process is that the jurisdiction, in this case CDC Atlanta, would be the jurisdiction of the State of Georgia, would recognize a need for countermeasures, would make a request to the secretary of HHS, and those materials would be provided to CDC through the State to ensure that the staff received the prophylaxis needed.

Mrs. BROOKS. Thank sounds like a lot of different Government entities.

Dr. SOSIN. It goes very fast. It's all HHS.

Mrs. BROOKS. Well, that is what I—but then you mentioned the State.

Dr. SOSIN. We routinely respond to botulinum toxin, for example, under the same mechanism.

Mrs. BROOKS. OK, but you mentioned the State of Georgia as well being involved in that. And so when you said it all goes very fast, how fast are you talking about a process like that taking if there were to be exposure?

Dr. SOSIN. Within hours.

Mrs. BROOKS. OK.

Dr. SOSIN. That can be done and it has been done. And the State of Georgia would defer to CDC to carry out the work that needed to be done and that would increase the speed of it.

Mrs. BROOKS. OK, thank you.

Major General Holcomb, with respect to DoD, with respect to sufficient antivirals and antitoxins if there were exposure?

MG HOLCOMB. We also have access to the same supplies of the national stockpile. And so we keep enough on hand to address potential initial exposure for those working in with the agent, but again have the same access that the other Federal agencies have to the stockpile.

Mrs. BROOKS. OK, thank you.

Dr. Monroe or Dr. Sosin, 5 of the 21 identified incidents in 2003 to '15 were result of equipment issues, malfunctions or failures. Would you briefly explain the alert systems built into these machines should an issue occur?

Dr. SOSIN. I'm not familiar with the specific equipment issues associated with the findings that you mention. But the process is when the laboratory identifies a failure of inactivation or an exposure of a worker in general, because of a breach of personal protective equipment or failure of equipment, the notification goes through their responsible official at the facility directly to CDC to notify us of the event and we begin a process of investigating with that facility to make sure that all necessary protective measures are taken to protect the workers as well as secure agents. And if necessary, if it's a significant exposure we'll bring in State authorities and local authorities to be involved in that process.

Mrs. BROOKS. Thank you.

Dr. Monroe, are there alert systems in place? And I guess that is what I am curious about with respect to the functioning of the alert systems.

Dr. MONROE. Right. So what I can say is for the four incidents of the 21 that did occur at CDC facilities, three of those involved chemical inactivation, so the material was not fully inactivated by the chemical processing so there was no equipment per se that was involved. The fourth one was a mixup of samples such that the non-inactivated samples were brought out of the lab. So in our experience we have not had an issue that we would relate to an equipment failure.

Mrs. BROOKS. Thank you. I yield back.

Mr. MURPHY. The gentlelady yields back. I now recognize the gentleman from Texas, Mr. Green, for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman.

Dr. Persons, your August 2016 report makes six recommendations to the CDC, NIH, APHIS to address the inactivation issue. If these are implemented it should improve safety and help mitigate the risk involved in handling these dangerous pathogens. Dr. Persons, have the three agencies, CDC, NIH, and APHIS, fully accepted GAO's recommendations?

Dr. PERSONS. Yes, sir. That's correct.

Mr. GREEN. Can they be implemented in a timely fashion?

Dr. PERSONS. I'm not able to say about the timeliness of these. I'm going on their witness statements and testimony that they are working on that. But I have no way to evaluate the amount of energy or time it might take to adopt all of them.

Mr. GREEN. Doctor, I would like to have you expand on the importance of GAO's recommendations as they relate to safe handling of these pathogens. Dr. Persons, GAO recommended that these three agencies develop clear and consistent definitions of inactivation for use in their respective guidance documents. Why is that recommendation important and what will it do to improve safety?

Dr. PERSONS. Thank you, sir, for the question. It just boils down to definitions are important. Understanding what these things are in a very scientific, pristine way so that you can manage these labs effectively is central to this. So if you can't identify it or define it you can't manage it or mitigate risk against it. Thank you.

Mr. GREEN. Can you talk about how the lack of clear definition of inactivation contributes to the issues at both HHS and USDA? Would a uniform definition of inactivation reduce future incidents?

Dr. PERSONS. I think, sir, it won't guarantee. There's never a way of reducing all of risk, but I do think that one of the things we found within the report that this would do, coming up that is with a clear definition, is bringing canonicity, bringing sameness to the language even within the same institution, much less when you start talking about this department or agency interconnecting with that department or agency I think it will help indeed.

Mr. GREEN. You also recommend these three agencies should identify when incidents involving incomplete inactivation occur and analyze the information reported to help identify the causes of the incomplete inactivation to mitigate the risk of future incidents. Why is it important to do that and how will that improve safety?

Dr. PERSONS. So the safety culture that's needed that we're endorsing that we have seen in parts but would like to see in the entire enterprise is the idea of lessons learned, sharing, so that you work through scientifically all of the "it depends," because you'll hear from one lab, they'll say it depends on my lab and that.

And that makes sense to a degree, but in terms of what you need to do fundamentally inactivate on a given pathogen, a select agent and so on, there should be some common understanding of that and some general way, or a tool in the toolbox to be able to approach that and achieve the desired outcome.

Mr. GREEN. And some of the recommendations, whether it is one agency or the other, it is just a matter of safety from GAO's opinion?

Dr. PERSONS. That's correct. We're encouraging an increase and improvement of the coordination, the activities towards safety including a science basis and greater validation, verification efforts, and a more tracking, more documentation.

Mr. GREEN. Regarding the issue of increasing scientific information or inactivation and viability testing, you recommend that the secretaries of the Health and Human Services, Agriculture, and I quote, coordinate research efforts and take actions to help close gaps in the science of inactivation and viable testing. What kinds of resources are required to implement that recommendation and close this knowledge gap?

Dr. PERSONS. Sir, I'm not able to say in a quantifiable way what that would take. That would be something, I believe, as part of the coordination to identify what the gaps are, and then naturally of those identified gaps be able to estimate resources to that go through the natural process for requesting authorization, appropriations and so on. So I'm not able to speak to that other than it does need to be done and more needs to be done according to the agencies and the scientific community itself.

Mr. GREEN. OK. Do you have any sense of how long it might take these three agencies along with other scientists to close these gaps in the science of inactivation?

Dr. PERSONS. No, sir. I don't have a specific time, although it'll be something that'll be worked on, I'm sure, for years to come.

Mr. GREEN. And it depends on appropriations though.

Dr. PERSONS. Yes, sir.

Mr. GREEN. OK. Thank you, Mr. Chairman. I thank all our panelists for being here and for their testimony, and particularly the GAO for your work on this subject.

Dr. PERSONS. Thank you, sir.

Mr. GREEN. And I yield back my time.

Mr. MURPHY. The gentleman yields back. I just want to make a clarification. We are going to have some Members who are going to want to have questions for afterwards, too, and I also want to make sure we have unanimous consent to put two letters of the FDA and NIH into the record. Without objection, we will have that.

[The information appears at the conclusion of the hearing.]

Mr. MURPHY. One of the things I want to note too, and Mr. Collins had brought this up briefly. Do you have protocol for the non-select agents then and when you deactivate those, so whether it is

tuberculosis, Zika, things like that, do you have protocols now for deactivation? Does CDC have the protocols in?

Dr. MONROE. Yes. The Laboratory Safety Review Board that I mentioned reviews all protocols for any BSL-3 or 4 agent regardless of whether or not it's a select agent, including tuberculosis.

Mr. MURPHY. But those with the non-select agents, for the non-select agents?

Dr. MONROE. Yes, including tuberculosis and others.

Mr. MURPHY. And DoD, you have protocols now for non-select agents then also for some of those other diseases?

MG HOLCOMB. We do, and we also have an interagency, intergovernmental panel that is reviewing all the protocols to make sure that they're consistent and make sense based on scientific evidence over.

Mr. MURPHY. Thank you, then. I just want to say that in conclusion I want to thank all our panelists for being here today. And then recognize the members have, again if they have other questions they will submit them and we ask that you all respond to them fairly quickly. We thank the panel. We thank you for the progress here. We hope you don't have to come back again. We don't want to hear about any other incidents. Please convey to all of your employees the seriousness of which this issue is out there. And with that, this hearing is adjourned.

[Whereupon, at 4:01 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today's hearing examines a very important issue to ensure safety at bioresearch laboratories—the inactivation of dangerous pathogens. In order for the Federal Government to conduct critical research on diagnostic tests or vaccines to protect us from diseases while safeguarding national security against bioterrorism, inactivation is a safety matter we need to get right.

In recent years, several lapses at HHS agency and Defense Department labs potentially exposed personnel and other individuals to hazardous biological agents, all because these agents were not effectively inactivated, as had been believed. We cannot risk repeats of such episodes. Without improvements, another incident is likely to happen, and the consequences could be dire.

I recognize that the executive branch has taken several steps to improve lab safety since these lapses were detected, beginning in 2014. We are pleased to see agencies moving forward in the right direction, and I believe GAO's recent report on inactivation provides a major step in the right direction. The nonpartisan watchdog has addressed an issue that has not gained enough attention, and today, we will hear how this report will provide much needed guidance for the regulators of the Federal Select Agent program to conduct proper oversight.

I thank the witnesses for their participation, and look forward to working in a bipartisan way to improve oversight and management of the Federal Select Agent program. Lives are on the line, and there is zero margin for error. We can and must do a better job.



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

September 21, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Bioresearch Labs and Inactivation of Dangerous Pathogens"

The Subcommittee on Oversight and Investigations will hold a hearing on Friday, September 23, 2016, at 9:00 a.m. in 2322 Rayburn House Office Building, entitled "Bioresearch Labs and Inactivation of Dangerous Pathogens." The Subcommittee will hear testimony on the Government Accountability Office's (GAO) recent report on the need for improving the Federal Select Agent Program's oversight of incomplete inactivation,¹ as well as the steps taken by the Centers for Disease Control and Prevention (CDC), the U.S. Department of Agriculture (USDA), the National Institutes of Health (NIH), and the Department of Defense (DOD) to strengthen their policies. In recent years, the Subcommittee has examined numerous safety lapses at bioresearch high-containment labs.

I. WITNESSES

- Timothy M. Persons, Ph.D., Director, Applied Research and Methods, GAO;
- Daniel Sosin, M.D., Deputy Director and Chief Medical Officer for the Office of Public Health Preparedness and Response, CDC;
- Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety, CDC;
- Mark Davidson, Associate Deputy Administrator with the Veterinary Services program, USDA;
- Jeff Potts, MPH, CBSP, ARO, BioRisk Manager, NIH; and
- MG Barbara R. Holcomb, Commanding General, U.S. Army Medical Research and Material Command and Fort Detrick, MD; Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology; and Chief, U.S. Army Nurse Corps, Department of the Army.

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. 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.

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II. BACKGROUND

The purpose of this hearing is to examine the conclusions of a recent GAO report on the need for more comprehensive policies for, and stronger oversight of, the inactivation of dangerous pathogens in high-containment laboratories.² Inactivation is the process to render highly dangerous pathogens incapable of causing disease, but still useful for research purposes. Several incidents involving the shipment of live pathogens, thought to be inactivated, have recently occurred, potentially exposing people to dangerous pathogens that cause infectious diseases, such as the bacterium that causes anthrax. In a May 7, 2015 bipartisan request (and coincidentally, about two weeks before the discovery of inactivation problems at a DOD lab), the Committee asked GAO to evaluate issues related to inactivation of pathogens in high-containment labs.³

a. 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 and two U.S. senators, killing five people and infecting seventeen others.⁴ 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.⁵ GAO had recommended in 2009 that the National Security Advisor make a single Federal agency responsible for assessing lab standards,⁶ 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.”⁷

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.⁸ 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

² GAO, “High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk,” GAO-16-642 (August 2016).

³ Letter from The Honorable Fred Upton, Chairman of the House Energy and Commerce Committee the Honorable Frank Pallone, Jr., the Honorable Tim Murphy, and the Honorable Diana DeGette to the Honorable Gene L. Dodaro, Comptroller General, GAO, (May 7, 2015) available at: <https://energycommerce.house.gov/hearings-and-votes/hearings/review-cdc-anthrax-lab-incident>

⁴ In 2009, there were over 240 entities with at least 1,362 BSL-3 laboratories in the United States registered under the Federal select agent program. This expansion has continued. As already noted in the memorandum, CDC reported to the Committee that there are 324 entities registered.

⁵ 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>.

⁶ GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

⁷ 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>.

⁸ 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/>

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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 labs was increasing in different sectors throughout the United States.⁹ The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.¹⁰ Since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.¹¹ GAO has continued to recommend a government-wide strategy for the requirements of high-containment labs and the need for national standards for designing, constructing, commissioning, and maintaining such laboratories.¹²

b. Subcommittee's previous oversight

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 CDC laboratory where as many as eighty-four CDC employees were exposed to live anthrax because established safety practices were not followed.¹³ 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.¹⁴

In July 2015, the Subcommittee held a hearing on the Department of Defense's 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.¹⁵ 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

⁹ GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-1036T (September 21, 2009) <http://gao.gov/assets/130/123358.pdf>.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.*

¹³ *Review of CDC Anthrax Lab Incident: Hearing before the Subcommittee on Oversight and Investigations, House Comm. on Energy & Commerce*, 113th Cong. (2014).

¹⁴ 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 full operations.

¹⁵ *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).

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process was working had failed to detect the live anthrax spores. This past April, the Subcommittee held a hearing on the need for comprehensive and stronger oversight at high-containment laboratories, specifically at NIH, CDC, and DOD.

c. 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 (FSAP). This law required the Department of Health and Human Services (HHS) to identify a list of organisms and toxins (known as select agents) that could potentially be used for bioterrorist attacks and to regulate their transfer, though not their possession. The FSAP regulates 65 select agents and toxins. The select agent list is reviewed at least every two years to determine if agents need to be added or deleted from the list.¹⁶ 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.¹⁷ This 2001 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.¹⁸

Congress later enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which (1) expanded the select agent program to include the regulation of the transfer and the use and possession of select agents and (2) increased safeguards and security requirements.¹⁹ 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 such items to an unregistered person.²⁰

d. GAO Report on Inactivation of Dangerous Pathogens

The recent safety lapses at DOD and CDC involved the shipment of live pathogens that were not completely inactivated, and therefore, potentially exposed people to dangerous pathogens that cause infectious diseases, including the bacterium that causes anthrax. As previously noted, the Committee requested last year that GAO evaluate issues related to inactivation of pathogens in high-containment laboratories and examine the extent to which incomplete inactivation incidents occurred. The GAO also reviewed the extent to which the Federal Select Agent Program referred violations and enforced regulations related to incidents involving incomplete inactivation.

¹⁶ Federal Select Agent Program, About Us, <http://www.selectagents.gov/about.html>.

¹⁷ USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).

¹⁸ *Id.*

¹⁹ 42 U.S.C. § 262a.

²⁰ *Id.*

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GAO found that the total number of incidents involving incomplete inactivation that occurred from 2003 through 2015 is unknown.²¹ GAO specifically noted that, according to the Select Agent Program, ten incidents occurred from 2003 through 2015. However, GAO identified an additional eleven incidents that the program did not initially identify.²²

One key reason is that the Select Agent Program—operated by the Departments of HHS and USDA—does not require laboratories to identify such incidents on reporting forms. Because the program cannot easily identify incidents involving incomplete inactivation, it does not know the frequency or reason they occur, making it difficult to develop guidance to help mitigate future incidents.²³

Gaps in scientific knowledge and limited guidance were found by GAO to affect the implementation of inactivation in high-containment labs. GAO noted that there is limited federal guidance for researchers on the development and validation of inactivation protocols. Validation helps ensure protocols are scientifically sound and produce consistent results. Due to limited guidance, laboratories varied in their interpretation of validated methods of inactivation, resulting in researchers applying differing levels of rigor.²⁴

GAO also found that the Select Agent Program did not consistently refer incidents involving incomplete inactivation for further investigation and enforcement for violations of select agent regulations. Specifically, it found that the program referred incidents involving incomplete inactivation at various laboratories, but did not refer two incidents in 2014 that occurred at HHS.²⁵ In responding to a draft of this report, the program provided a draft, joint CDC-APHIS (Animal and Plant Health Inspection Service) document that provides some guidance on when to refer violations and options for enforcement actions; however, program officials did not provide GAO with a time frame or plan for finalizing and implementing this draft document.

Furthermore, a previous finding by GAO, that existing federal oversight of high-containment laboratories is fragmented and self-policing, was highlighted when it noted that the program does not have a consistent, written set of criteria for handling incidents. Without such criteria, the program risks inconsistent enforcement of select agent regulations.²⁶

GAO made six recommendations to HHS and to USDA to mitigate the risk to human and animal health due to incidents involving incomplete inactivation of dangerous pathogens used in high-containment labs, and to improve the Select Agent Program's oversight of inactivation. With respect to both HHS and USDA, GAO recommended that the Secretary of Health and

²¹ GAO, "High-Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk," GAO-16-642 (August 2016).

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

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Human Services direct CDC and NIH, and that the Secretary of Agriculture direct APHIS, in their respective parts, to:

- Develop clear definitions of inactivation for use within their respective guidance documents that are consistent across the Select Agent Program, NIH's oversight of recombinant pathogens, and the *Biosafety in Microbiological and Biomedical Laboratories* manual;²⁷
- Revise reporting forms within their respective areas of oversight to help identify when incidents involving incomplete inactivation occur and analyze the information reported to help identify the causes of incomplete inactivation to mitigate the risk of future incidents;
- Coordinate research efforts and take actions to help close gaps in the science of inactivation and viability testing across high containment laboratories;
- Create comprehensive and consistent guidance for the development, validation, and implementation of inactivation protocols—to include the application of safeguards—across the Select Agent Program, NIH's oversight of recombinant pathogens, and the *Biosafety in Microbiological and Biomedical Laboratories* manual;
- Develop and implement consistent criteria and documentation requirements for referring violations to investigative entities and enforcing regulations related to incidents involving incomplete inactivation.

Also, with respect to HHS, GAO recommended that the Secretary, in part:

- Direct the Directors of CDC and NIH, when updating the *Biosafety in Microbiological and Biomedical Laboratories* manual, to include guidance on documenting the shipment of inactivated material.

III. ISSUES

The following issues may be examined at the hearing:

- How serious are the science gaps in the inactivation of dangerous pathogens? Is there sufficient scientific information to support the complete inactivation of all dangerous pathogens, especially the historical challenge of completely inactivating anthrax?
- How should gaps in scientific understanding of inactivation be addressed?

²⁷ *Id.*

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- What steps are being taken by key Federal agencies to know when incomplete inactivation occurs and how to properly identify, analyze, and respond to such incidents?
- How will the Federal Select Agent Program ensure that its oversight of the inactivation process, as well as over other program requirements, is applied consistently, particularly between federal and nonfederal laboratories?

IV. STAFF CONTACTS

If you have any questions regarding the hearing, please contact Alan Slobodin, David Schaub, or Ryan Coble at (202) 225-2927.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, D.C. 20515-6115

SEP 09 2016

Dear Mr. Chairman:

Thank you for your letter of May 18, 2016, cosigned by Mr. Murphy, Chairman of the Subcommittee on Oversight and Investigations, regarding laboratory safety and security at the Food and Drug Administration (FDA or the Agency). Laboratory safety and security is one of our highest priorities at FDA and we are fully committed to ensuring the safety of our laboratory scientists, the employees of FDA, and the surrounding community.

We appreciate the opportunity to respond to your questions, and have restated them below in bold, followed by FDA's responses.

1. What level of funding and staffing for the Office of Laboratory Science and Safety will the FDA commit to for the next fiscal year budget? Please explain the justification for the level of funding and staffing.

FDA's Office of Laboratory Science and Safety (OLSS) provides leadership, oversight, and coordination of laboratory policies and operations across FDA to ensure laboratory safety and security. In FY 2017, consistent with the President's Budget, OLSS will receive \$5.2 million in support to cover 13 full-time employees (FTEs) – one senior executive office director, four GS-15 level positions, five GS-14 level positions, two GS-13 level positions, and one GS-11 level position – as well as operational costs. This level of support will allow OLSS to continue to make progress on achieving FDA's goals of augmenting, consolidating, and standardizing laboratory safety and security at FDA.

2. Does FDA agree with the ELSW recommendation that the sources of funding should be independent from other FDA centers or offices? If so, will the FDA commit to independent funding for the Office of Laboratory Safety?

FDA believes that OLSS should have a dedicated level of funding to allow for proper oversight of FDA's labs. OLSS will sit in the Commissioner's Office, and will be managed and operated independently from the other Centers and Offices. FDA will work with existing funding in FY 2016 and funding received in FY 2017 to fund OLSS. FDA is working to determine the long-term resource requirements needed for this important priority.

3. In accordance with the ELSW recommendation, will the FDA commit to having the Director of Lab Safety report directly to the FDA Commissioner?

As previously shared, ensuring the safety and security of our laboratory scientists, employees, and the public at large is one of our highest priorities at FDA. To support FDA with this critical mission, FDA will realign OLSS such that the Director of OLSS will report directly to the Commissioner. OLSS will serve as the Agency's coordinator and lead for implementation of policies and procedures, centralized training, and oversight for operations of all laboratory science, safety, and security related activities. OLSS will work very closely with the Office of the Chief Scientist, the Office of Operations, the Office of Regulatory Affairs, and the other product centers and directorates across the Agency.

4. Will the FDA commit to producing to the Committee a written report of its internal investigation into the root causes and systemic weaknesses that contribute to the lapse related to the unaccountable smallpox vials discovered in July 2014?

Yes. FDA is currently conducting its internal investigation into the root cause and systemic weaknesses that contributed to the lapse related to the unaccountable smallpox vials and other pathogens discovered in July 2014. This investigation is expected to be completed by Fall 2016. Upon the completion of this investigation a final report will be issued, which will be shared with the Committee.

5. Will the FDA commit to issuing a written procedure for the safe transport and securing of select agent materials on-site at FDA or between FDA laboratories, such as when select agents are discovered in locations unregistered with the Federal Select Agent Program?

Yes. FDA is fully committed to ensuring the safety and security of our laboratory scientists and the public. FDA has already issued a Staff Manual Guide (FDA SMG 2130.8) that addresses, among other things, the reporting of select agents and toxins associated with certain discoveries or inventory discrepancies. We are also committed to revising that Staff Manual Guide to include a procedure for the safe and secure transport of select agent materials associated with a discovery or incident. OLSS is working aggressively to ensure that the appropriate policies and protocols are integrated into the SMG for the safe and secure transport of select agent material on-site at FDA and between FDA laboratories when they are discovered in locations unregistered with the Federal Select Agent Program.


If you have further questions, please contact Meghan Scott or Melissa Safford in FDA's Office of Legislation. Meghan may be reached at 301-796-4675 or Meghan.Scott@fda.hhs.gov. Melissa may be reached at 301-796-8914 or Melissa.Safford@fda.hhs.gov.

Page 3 – The Honorable Fred Upton

Thank you for your interest in this matter and your patience in allowing us to respond to your requests. The same letter has been sent to your cosigner.

Sincerely,

for


Dayle Cristinzio
Acting Associate Commissioner
for Legislation

cc: The Honorable Frank J. Pallone, Jr., Ranking Member
Committee on Energy and Commerce

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

July 28, 2016

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Thank you for your May 18, 2016 letter regarding the National Institutes of Health's (NIH) commitment to laboratory safety. I agree with you and Subcommittee Chairman Murphy that laboratory safety and security must consistently be a high priority for federal research agencies. I assure you that the NIH takes this commitment very seriously, and as Dr. Lawrence Tabak, Principal Deputy Director of NIH, outlined in his testimony before the April 20, 2016 hearing of the Subcommittee on Oversight and Investigations, we have taken and continue to take actions to preserve the public's trust by ensuring safety practices and strong leadership.

The Government Accountability Office (GAO) in its March 2016 Report entitled, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Needed," identified six policy elements that are key for managing high-containment laboratories and are consistent with federal internal control standards. In the March 2016 report, and as referenced in its April 20 testimony before the Subcommittee, the GAO found that the NIH met all six key elements for managing hazardous biological agents in high-containment laboratories, including reporting incidents to senior department officials.

I am pleased to have this opportunity to respond to your inquiry and provide you information to clarify any remaining questions concerning our lab safety practices and oversight structure. The NIH actions since 2014 illustrate our continued commitment to building and maintaining a culture of safety.

Below are responses to your specific questions:

1. What is the justification for the level of funding and staffing for the laboratory safety activities of the NIH? Does the NIH have appropriate funding and staffing for executing critical tasks associated with laboratory safety?

Response:

The NIH Division of Occupational Health and Safety (DOHS) – NIH's laboratory safety program – provides leadership and guidance in the development, promulgation, and

implementation of comprehensive occupational safety and health policies, standards, and procedures consistently across NIH Institutes and Centers (ICs). The current level of funding and staffing is appropriate to meet the safety needs of the NIH's complex research portfolio.

2. Does the NIH agree with the ELSW recommendation and the CDC approach that the safety of all NIH laboratories should be overseen by one centralized office using uniform and consistent safety standards? If yes, how does the NIH plan to implement this recommendation?

Response:

While this Extramural Lab Safety Working Group (ELSW) recommendation was directed to the CDC, the NIH supports the centralization of laboratory safety programs. In fact, the May 4, 2015, ELSW Advisory Committee to the Director report to the HHS Secretary stated that:

"The Division of Occupational Health and Safety (DOHS) is recognized across the NIH as the central authority in support and promotion of laboratory and research safety programs at the NIH."

However, we recognize that unique situations do exist within the NIH structure that offer opportunities for further centralization. First, the National Cancer Institute's (NCI) Frederick National Laboratory for Cancer Research (FNLCR) in Frederick, Maryland, is a contractor-operated Federally Funded Research and Development Center (FFRDC). The contractor is Leidos Biomedical Research, Inc. The NCI Office of Scientific Operations serves as the NCI Project office for the Frederick National Lab Operations and Technical Support (OTS), Computer and Statistical Service, and Scientific Library contracts. Because the FNLCR is a contractor-operated FFRDC, the OTS contractor – Leidos – provides all aspects of laboratory safety and security, with significant interactions with the NIH DOHS to ensure that the operations are consistent with all HHS/NIH and other applicable requirements. In consultation with NCI management, we are exploring how and when we could modify the Leidos contract so that moving forward the safety and health portion of the contract could be overseen by a contracting officer's representative within the NIH DOHS. This would allow direct interface and collaboration between the centralized NIH safety organization – DOHS – and the contract organization. This approach will help increase our ability to ensure consistency in application and implementation of NIH safety and health policies.

Additionally, the National Institute of Environmental Health Sciences (NIEHS), located in Research Triangle Park, North Carolina, maintains an environmental, health, and safety program. To provide consistent NIH laboratory oversight, laboratory safety functions will continue to be located onsite in North Carolina, but will report to the NIH DOHS located in Bethesda, Maryland.

Accomplishing these steps will fully centralize the NIH safety and health program and ensure that uniform and consistent safety standards are applied.

3. Does NIH agree with the ELSW recommendation that the source of funding should be independent from other NIH institutes, centers, and offices? If so, will the NIH commit to independent funding for office responsibility for laboratory safety?

Response:

It is important to note that the ELSW made no such recommendation for the NIH. However, implementing the changes mentioned in question 2 will further centralize the control of funding for the NIH safety and health program by providing the DOHS with oversight of all laboratory safety budgets.

4. In accordance with ELSW recommendations, will the NIH commit to having the Director of Lab Safety report directly to the Director of NIH?

Response:

It is important to note that the ELSW made no such recommendation for the NIH. The current reporting structure at the NIH assures that incidents and important reporting matters rapidly come to the attention of the NIH Director. This is evidenced by the reporting of the smallpox incident in 2014. The ELSW found that, "[The] finding was promptly communicated to the NIH Director." Further, the ELSW stated "This incident and the response to it are demonstrative of clear and prompt reporting of incidents and local responsibility to respond appropriately." Nevertheless, in the interest of further streamlining the reporting structure, the NIH Director will establish a Laboratory Safety Officer (LSO) designation for an individual that directly reports to the NIH Director. The DOHS Director will be designated as the LSO. Organizationally, the DOHS will remain in the NIH's Office of Research Services and maintain the Designated Agency Safety and Health Official reporting structure, as well. The DOHS Director maintaining both roles ensures consistency.

5. Will the NIH commit to producing the Committee a written report of its internal investigation into the root causes and systemic weaknesses that contributed to the lapse related to the unaccountable small pox vials discovered in July 2014?

Response:

Yes, the NIH will provide a written report to the Committee.

The Honorable Fred Upton
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6. Will the NIH commit to issuing a written procedure for the safe transport and securing of select agent materials on-site at NIH or between NIH laboratories, such as when select agents are discovered in locations unregistered with the Federal Select Agent Program?

Response:

The NIH is committed to safeguarding select agent materials. Our agency has had established written procedures since 2006 for the safe transport and security of registered select agent materials on-site at the NIH and between NIH laboratories. The NIH has issued a separate standard operating procedure specific to the safe transport and security of select agent materials that may be discovered in locations not registered with the Federal Select Agent Program.

Thank you for your interest in supporting our efforts to ensure the highest level of laboratory safety at the NIH. A copy of this response is being sent to the co-signer of your letter.

Sincerely yours,



Francis S. Collins, M.D., Ph.D.
Director

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

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

October 17, 2016

Dr. Mark Davidson
Associate Deputy Administrator
Veterinary Services
U.S. Department of Agriculture
4700 River Road
Riverdale, MD 20737

Dear Dr. Davidson:

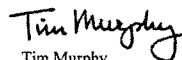
Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, September 27, 2016, to testify at the hearing entitled "Bioresearch Labs and Inactivation of Dangerous Pathogens."

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 Monday, October 31, 2016. Your responses should be mailed to Elena Brennan, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Elena.Brennan@mail.house.gov.

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

Sincerely,



Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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 Bioresearch Labs and Deactivation of Dangerous Pathogens
September 27, 2016

The Honorable Tim Murphy

Dr. Davidson, APHIS' response to the Committee last night indicated that the Investigative and Enforcement Services (IES), APHIS' law enforcement arm, has levied fines against entities suspected of violating select agent regulations but provided no further information.

- 1. How many times has IES levied fines for select agent regulations?**
 - a. What was the nature of these violations and fines?**

Since 2003, APHIS' Investigative and Enforcement Service (IES) has entered into pre-litigation stipulations that included civil penalties for alleged violations of the Agency's select agent regulations 8 times for a total of \$116,750. These fines were assessed to resolve allegations such as failing to register with the Federal Select Agent Program when knowingly in possession of a select agent or toxin, or transferring select agents and toxins without authorization.

- 2. How many referrals has APHIS provided to IES?**

Since 2003, APHIS has referred 49 entities to IES for further investigation.

- a. How many referrals has IES provided to USDA's Office of the General Counsel to institute an administrative proceeding, or possible referral to DOJ?**

None. However, since 2003, IES or the Agency's Agriculture Select Agent Services (AgSAS) has referred 4 cases to USDA's Office of the Inspector General for further investigation into potential criminal charges.

- 3. Does IES maintain this data? If so, where is this data maintained?**

IES maintains data about the cases referred to the program as part of its standard record-keeping system, which includes a database and document repository.

- a. Does APHIS document its oversight on select agent violations and referrals?**

APHIS maintains a record of referrals to IES. The records contain case information such as the entity name, IES case number, the date of the possible violation, a description of the possible violation, and enforcement actions taken.

- 4. Why did the USDA Internal Review recommend documenting case referrals?**

APHIS' internal review found that the Agency lacked a formal, written standard office procedure for when to refer cases to IES. To improve consistency of decision-making, the group recommended and the select agent program is implementing a formal written process.

5. The internal review recommended formally documenting policies and procedures related to Theft Loss or Release reporting and case referrals to IES. What was the basis for this recommendation?

APHIS' internal review found that, while there are formal policies on theft, loss, or release reporting for the Federal Select Agent Program as a whole, the Agency lacked its own formal written policy for when to refer incidents involving the theft, loss, or release of select agents to IES. A written policy would ensure consistency in what types of violations are referred from year-to-year, and could help the program identify and monitor trends.