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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, D.C.

The Subcommittee met, pursuant to call, at 2:00 p.m., in Room 2322 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; Charles Ingebretson, Chief Counsel,

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Oversight & Investigations; Jennifer Sherman, Press Secretary; Alan Slobodin, Deputy Chief Counsel, Oversight; Gregory Watson, Legislative Clerk, Communications & Technology; Ryan Coble, Detailee, Oversight & Investigations; David Schaub, Detailee, Oversight & Investigations; Jeff Carroll, Minority Staff Director; Ryan Gottschall; Chris Knauer; Elizabeth Letter, Minority Professional Staff Member; and Miles Lichtman, Minority 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.

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 lever 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 trioplex 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 it 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 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.

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

[The statement of Mr. Murphy follows:]

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

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 statement of Ms. DeGette follows:]

**********COMMITTEE INSERT 2**********

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.

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.

[Whereupon, at 2:13 p.m., the subcommittee recessed, to reconvene at 2:54 p.m., the same day.)

Mr. Murphy. All right. Okay, 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.

[The information follows:]

**********COMMITTEE INSERT 3**********

Mr. Murphy. 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 infectious 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.

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

STATEMENT OF TIMOTHY PERSONS

Mr. 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 Timothy Persons follows:]

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

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

STATEMENT OF DR. 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 Agent 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 perform 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 PhDs in microbiology and most of the rest masters 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. Daniel M. Sosin follows:]

**********INSERT 5**********

Mr. Murphy. Thank you.

Dr. Monroe, you are recognized for 5 minutes.

STATEMENT OF STEPHAN S. MONROE

Mr. 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 Laboratories," 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 Stephan S. Monroe follows:]

**********INSERT 6**********

Mr. Murphy. Thank you.

Dr. Davidson, you are recognized for 5 minutes.

STATEMENT OF DR. 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. Mark Davidson follows:]

**********INSERT 7**********

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 who 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 Jeffrey Potts follows:]

**********INSERT 8**********

Mr. Murphy. Thank you, Mr. Potts.

General Holcomb, you are recognized for 5 minutes.

STATEMENT OF MAJOR GENERAL BARBARA R. HOLCOMB

General Holcomb. Good after noon, 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 Barbara R. Holcomb follows:]

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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?

Mr. 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?

Mr. 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 protocol is 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.

General 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 since the year that 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. Okay. 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?

General 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?

Mr. Persons. That is correct.

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

Mr. 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?

Mr. 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?

Mr. 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?

Mr. 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?

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

Mr. 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. Okay.

Dr. Monroe?

Mr. 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.

General 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 sector 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?

Mr. 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?

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

Mr. 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.

Mr. 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. Potts. 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 protocol is actually effective. We have ongoing collaborations with other agencies within the federal government to bring aligned the guidance document and the verbiage for some of the definitions.

General 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?

Mr. 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?

General 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?

Mr. 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?

Mr. Monroe. There are for, you know, the workers who are working in the laboratory. With the incident that we had in 2014 where was the potential that there were workers who were exposed in other parts of the agency who would not normally, we made 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?

Mr. 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. Okay, 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. Okay.

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. Okay, thank you.

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

General 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. Okay, thank you.

Dr. Monroe or Dr. Sosin, five 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.

Mr. 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?

Mr. Persons. Yes, sir. That's correct.

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

Mr. 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?

Mr. 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?

Mr. 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?

Mr. 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?

Mr. 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?

Mr. 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. Okay. 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?

Mr. 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.

Mr. Persons. Yes, sir.

Mr. Green. Okay. 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.

Mr. 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 follows:]

**********COMMITTEE INSERT 10**********

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?

Mr. 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?

Mr. 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?

General 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.]