HOW SECURE ARE U.S. BIORESEARCH LABS? PREVENTING THE NEXT SAFETY LAPSE

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

APRIL 20, 2016

Serial No. 114–139

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE
20–712 PDF WASHINGTON : 2016

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON ENERGY AND COMMERCE

FRED UPTON, Michigan
Chairman

JOE BARTON, Texas
Chairman Emeritus
ED WHITFIELD, Kentucky
JOHN SHIMKUS, Illinois
JOSEPH R. PITTS, Pennsylvania
GREG WALDEN, Oregon
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
Vice Chairman
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
GREGG HARPER, Mississippi
LEONARD LANCE, New Jersey
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. MCKINLEY, West Virginia
MIKE POMPEO, Kansas
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
RENEE L. ELLMERS, North Carolina
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
KEVIN CRAMER, North Dakota

FRANK PALLONE, JR., New Jersey
Ranking Member
BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
GENE GREEN, Texas
DIANA DEGETTE, Colorado
LOIS CAPPS, California
MICHAEL F. DOYLE, Pennsylvania
JANICE D. SCHAKOWSKY, Illinois
G.K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJAN, New Mexico
PAUL TONKO, New York
JOHN A. YARMUTH, Kentucky
YVETTE D. CLARKE, New York
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY, III, Massachusetts
TONY CÁRDENAS, California

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

TIM MURPHY, Pennsylvania
Chairman

DAVID B. MCKINLEY, West Virginia
Vice Chairman
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
H. MORGAN GRIFFITH, Virginia
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
KEVIN CRAMER, North Dakota
JOE BARTON, Texas
FRED UPTON, Michigan *(ex officio)*

DIANA DEGETTE, Colorado
Ranking Member
JANICE D. SCHAKOWSKY, Illinois
KATHY CASTOR, Florida
PAUL TONKO, New York
JOHN A. YARMUTH, Kentucky
YVETTE D. CLARKE, New York
JOSEPH P. KENNEDY, III, Massachusetts
GENE GREEN, Texas
PETER WELCH, Vermont
FRANK PALLONE, JR., New Jersey *(ex officio)*

C O N T E N T S

WITNESSES

SUBMITTED MATERIAL

[1] The information has been retained in committee files and also is available at *http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104823.*

HOW SECURE ARE U.S. BIORESEARCH LABS? PREVENTING THE NEXT SAFETY LAPSE

Wednesday, April 20, 2016

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

The subcommittee met, pursuant to call, at 10:16 a.m., in room 2122 Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, McKinley, Burgess, Griffith, Brooks, Mullin, Hudson, Castor, Kennedy, Green, and Welch.

Staff present: Jen Barbian, Counsel, Oversight and Investigations; Rebecca Card, Assistant Press Secretary; Ryan Coble, Detailee, Oversight and Investigations; Paige Decker, Executive Assistant; Giulia Giannangeli, Legislative Clerk, Commerce, Manufacturing, and Trade; Brittany Havens, Legislative Associate, Oversight; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Chris Santini, Policy Coordinator, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Ryan Gottschall, Democratic GAO Detailee; Christopher Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; Elizabeth Letter, Democratic Professional Staff Member.

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

Mr. MURPHY. Good morning, and welcome to the Oversight and Investigation Subcommittee of Energy and Commerce hearing on "How Secure are U.S. Bioresearch Labs: Preventing the Next Safety Lapse," which I think I can dub "Overturning the Culture of Compliancy."

Because this is the third time in as many years that this subcommittee has held a hearing on the Federal Select Agent Program and the Federal Government's high-containment laboratories.

And each time, a panel of witnesses appear before us to testify about changes made in response to one failure or another.

Two years ago, CDC Director Tom Frieden testified about changes made at the CDC after failing to follow safety procedures, which consequently potentially exposed dozens of CDC employees to anthrax.

Dr. Frieden told us then that the CDC was implementing every step possible to make sure that the problems are addressed comprehensively in order to protect our own workforce and to strengthen the culture of safety and to continue our work protecting Americans.

And I might add that that echoed a statement he had made perhaps a year or so before on the same issue, saying that he was going to impose other things to change the culture.

But last year, then, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense came before us to explain how at least 192 labs across the world received live anthrax from the Dugway Proving Ground, an Army lab in Utah. The Army undertook a comprehensive review of the incident and the deputy secretary told us that the department was "committed to ensuring that this doesn't occur again," and that last statement is in quotes.

Sweeping improvements and policy changes only work if the policies are effective and, in this area, past policy reviews have not brought about the changes necessary to improve safety.

For that reason, Ms. DeGette and myself, along with Chairman Upton and Ranking Member Pallone, asked the GAO to evaluate the biosafety, biosecurity and oversight policies for the eight departments and 15 component agencies that own and operate the Federal Government's high-containment laboratories.

GAO has been issuing recommendations for years on the need for better policies and standards at high-containment labs, recommendations that have not been implemented. So the agency was well-positioned to receive our request.

GAO found that while the departments and agencies have improved on their biosecurity procedures in recent years, comprehensive policies and better oversight of the labs are still needed.

High-containment laboratories, which store the most dangerous pathogens, must have tight inventory control, rigorous training and required incidence reporting, and agencies and departments must have strong oversight of their laboratories with accountability for those who fail to follow the policies.

While GAO has been doing its work, the committee has been conducting its own review into the discovery of smallpox vials at the NIH in 2014. The preliminary findings of the majority staff are discussed in a supplemental memorandum released yesterday.

We found a number of flash points here where, if NIH or FDA had done just a little more than what their policies required or thought outside the box just a little bit, those agencies could have discovered the smallpox vials years earlier.

For example, the NIH experienced a major event in 2011 when it learned that a researcher received an unauthorized transfer of antibiotic resistant plague specimens, and in 2012 when it discovered unregistered antibiotic-resistant anthrax included at an FDA lab in this very same building where the smallpox was discovered 2 years later.

The 2012 discovery was prompted by a disclosure of two investigators during a retraining exercise prompted by the 2011 discovery by the CDC's Division of Select Agents and Toxins not by any investigative work on the part of the NIH and the 2012 dis-

covery resulted in the CDC putting NIH on a Performance Improvement Plan.

These discoveries, including two different dangerous pathogens, should have spurred NIH and FDA to conduct a comprehensive sweep of all laboratories and a comprehensive review of its policies at the time.

But they didn't. When we informed NIH and FDA of our findings, we found agencies still reluctant to acknowledge the full extent of their failings.

NIH did not even acknowledge its failings in how it registered into the Federal Select Agent Program, a historical collection of select agent samples held in sealed envelopes unopened since 1960.

NIH registered the materials without opening the envelopes. The agency did not confirm the materials inside the envelopes or even verify that the samples were still secure, and they registered these materials not once, but twice, without opening the envelopes.

When they finally did open the envelopes, they discovered seven additional vials of one select agent than previously reported. These failures just defy common sense.

This is a culture of complacency, and it shows that it is not enough to change the policies. We must also change the culture at NIH.

While the Department of Defense is holding 12 people accountable for the factors that led to the Dugway shipments, in contrast HHS and its agencies have not been fully accountable and transparent with the committee on disciplinary and personnel actions resulting from lab safety incidents.

For example, the committee requested documents from the CDC as part of our investigation regarding the four instances of improperly stored anthrax at NIH. Unfortunately, the CDC produced redacted documents, blacking out key information.

There was no legal basis for these redactions and CDC offered no explanation. This type of response is designed to delay and stymie congressional oversight on behalf of the American people and this committee will not stand for that. When we request documents, we expect unredacted documents.

If these agencies are not being forthcoming with this committee and this Congress, then they are certainly not being forthcoming with the American people. For all the CDC rhetoric about transparency, redactions of key details in requested investigative documents prove otherwise.

We all deserve better. Neither NIH nor FDA ever conducted an internal review of the smallpox incident along the lines of the reviews conducted by the CDC or the DoD, deferring instead to an outside review by the CDC and FBI.

I urge these agencies to initiate internal reviews of their own failings leading up to the smallpox discovery and if we learn nothing from all of the incidents involving select agents over the years, it is that we can't find the next safety lapse if we don't go looking for it.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

This is the third time in as many years that this subcommittee has held a hearing on the Federal Select Agent Program and the Federal Government's high-containment laboratories. Each time, a panel of witnesses appears before us to testify about changes made in response to one failure or another.

Two years ago, CDC Director Tom Frieden testified about changes made at the CDC after failing to follow safety procedures potentially exposed dozens of CDC employees to anthrax. Dr. Frieden told us then that the CDC was implementing every step possible to "make sure that the problems are addressed comprehensively in order to protect our own workforce, and to strengthen the culture of safety, and to continue our work protecting Americans."

Last year, the Deputy Assistant Secretary of Defense for Chemical and Biological Defense came before us to explain how at least 192 labs across the world received live anthrax from the Dugway Proving Ground, an Army lab in Utah. The Army undertook a comprehensive review of the incident and the Deputy Secretary told us that the Department was "committed to ensuring that this doesn't occur again."

Sweeping improvements and policy changes only work if the policies are effective. And, in this area, past policy reviews have not brought about the changes necessary to improve safety. For that reason, Ms. DeGette and myself, along with Chairman Upton and Ranking Member Pallone, asked the GAO to evaluate the biosafety, biosecurity, and oversight policies for the 8 departments and 15 component agencies that own and operate the Federal Government's high-containment laboratories. GAO has been issuing recommendations for years on the need for better policies and standards at high-containment labs-recommendations that have not been implemented-so the agency was well-positioned to receive our request.

GAO found that, while the departments and agencies have improved on their biosecurity policies in recent years, comprehensive policies and better oversight of the labs are still needed. High-containment laboratories, which store the most dangerous pathogens, must have tight inventory controls, rigorous training, and required incidence reporting. And agencies and departments must have strong oversight of their laboratories with accountability for those who fail to follow the policies.

While GAO has been doing its work, the committee has been conducting its own review into the discovery of smallpox vials at the NIH in 2014. The preliminary findings of the majority staff are discussed in a supplemental memorandum released yesterday. We found a number of flash points where, if NIH or FDA had done just a little more than what their policies required, or thought outside the box just a little bit, those agencies could have discovered the smallpox vials years earlier.

For example, the NIH experienced a major event in 2011, when it learned that a researcher received an unauthorized transfer of antibiotic resistant plague specimens, and in 2012, when it discovered unregistered, antibiotic resistant anthrax, including at an FDA lab in the very same building where the smallpox was discovered 2 years later. The 2012 discovery was prompted by a disclosure of two investigators during a re-training exercise prompted by the 2011 discovery by the CDC's Division of Select Agents and Toxins, not by any investigative work on the part of the NIH. And the 2012 discovery resulted in the CDC putting NIH on a Performance Improvement Plan. These discoveries, including two different dangerous pathogens, should have spurred NIH and FDA to conduct a comprehensive sweep of all laboratories, and a comprehensive review of its policies, at the time. But they didn't.

When we informed NIH and FDA of our findings, we found agencies still reluctant to acknowledge the full extent of their failings. NIH did not even acknowledge its failings in how it registered into the Federal Select Agent Program a historical collection of select agent samples held in sealed envelopes unopened since 1960. NIH registered the materials without opening the envelopes. The agency did not confirm the materials inside the envelopes, or even verify that the samples were still secure. And they registered these materials not once, but twice, without opening the envelopes. When they finally did open the envelopes, they discovered 7 additional vials of one select agent then previously reported. These failures defy common sense. This is a culture of complacency, and shows that it is not enough to change the policies-we must also change the culture at NIH.

While the Department of Defense is holding 12 people accountable for the factors that led to the Dugway shipments, in contrast HHS and its agencies have not been fully accountable and transparent with the committee on disciplinary and personnel actions resulting from lab safety incidents. For example, the committee requested documents from the CDC as part of our investigation regarding the four instances of improperly stored anthrax at NIH. Unfortunately, the CDC produced redacted documents, blacking out key information. There was no legal basis for these

redactions, and CDC offered no explanation. This type of response is designed to delay and stymie Congressional oversight on behalf of the American people. When we request documents, we expect unredacted documents. If these agencies are not being forthcoming with Congress, then they are certainly not being forthcoming with the American people. For all the CDC rhetoric about transparency, redactions of key details in requested investigative documents prove otherwise. We all deserve better.

Neither NIH nor FDA ever conducted an internal review of the smallpox incident along the lines of the reviews conducted by the CDC or the DOD, deferring instead to an outside review by the CDC and FBI. I urge these agencies to initiate internal reviews of their own failings leading up to the smallpox discovery. If we've learned nothing from all of the incidents involving select agents over the years, it is that we can't find the next safety lapse if we don't go looking for it.

Mr. MURPHY. I now recognize the ranking member pro tem, Ms. Castor, for her opening.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Well, thank you, Mr. Chairman, for calling this important hearing, and welcome to our witnesses today.

The House Energy and Commerce Committee has been monitoring high-containment biolabs and the select agent program for nearly a decade and I believe that it is vital that we continue our oversight of these critical programs.

The committee held a hearing earlier this year about the importance of biodefense preparedness and we know that high-containment laboratories play a valuable role in that effort by conducting research, to improve our defenses against biological attacks and strengthening our response capabilities.

The Federal Government's work on identifying and containing public health risks from these type of biological agents is essential but it also poses many risks.

Everyone has been disturbed by the news of accidental releases or transfers of select agents such as anthrax, ebola and avian flu over the past few years. These incidents raise broader questions about the safety of our high-containment laboratories across the country.

And while I'm encouraged that no one has fallen ill as a result of those incidents, these pathogens need to be handled with the utmost safety and security. They could be extremely dangerous if they fell into the wrong hands or if infection spread to the general public.

The labs that handle these dangerous pathogens must be held to the highest standards. Yet, these recent incidents raise questions about whether or not we can trust high-containment labs to safely handle select agents and other dangerous pathogens.

I want to understand what these recent lapses can teach us about broader problems within the agencies and departments that handle select agents across the Federal Government as well within the private sector.

So we've asked the GAO to appear before us today to testify about their latest report on the need for up to date policies and stronger oversight mechanisms at our high-containment labs.

I look forward to hearing from you about your findings and recommendations and how they can be used to enhance safety and security at all of our nation's high-containment labs.

This GAO report underscores the need to strengthen our Federal oversight of labs that are working with dangerous pathogens. I also want to hear from witnesses about the role that Congress can play in making sure this program operates safely and without more of the operational lapses that seem all too common for such a serious program.

Is the current regulatory framework sufficient? Do the enforcement agencies have sufficient resources to ensure that oversight is robust? What are the agencies in front of us doing to improve their labs and prevent future incidents?

I look forward to hearing your testimony and I yield back.

Mr. MURPHY. Gentlelady yields back. Is there anyone on our side who wants to make an opening statement? And I guess there's no one else on your side either, just want to read your statement again.

To the panel, there was another hearing going on at Energy and Commerce in which two subcommittees are—many of us are on both, so you may see people coming and going.

I may stay here for the whole thing because I want to hear. This is just so you're aware. It may look a little chaotic at times, but that's how it is.

I ask unanimous consent that members' written opening statements from other members be introduced in the record, and without objection the documents will be entered into the record.

Now let me introduce today's panel. First witness on today's panel is Mr. John Neumann, director of natural resources and environment at the Government Accountability Office.

He currently leads efforts in the science and technology area including the management and oversight of Federal research and development programs and we appreciate this time today.

We'd also like to welcome Dr. Lawrence Tabak, principal deputy director with the National Institute of Health. He previously served as the acting principal director of NIH in 2009. We look forward to hearing his insights. Good to see you again, Doctor.

Dr. Stephen Monroe serves as the associate director for laboratory science and safety at Centers for Disease Control and Prevention. Previously, he was the acting associate director for the Laboratory of Science and Safety.

We look forward to learning from his expertise today on today's hearing and thank you for being here.

Dr. Segaran Pillai serves as director of the Office of Laboratory Science and Safety, the director of the Office of Commissioner and director of the Office of Chief Scientist at the Food and Drug Administration, and look forward to hearing your insights as well.

And finally, we welcome Major General Brian Lein, Commanding General, U.S. Army Medical Research and Materiel Command in Fort Detrick and Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics and Technology, Department of the Army at the U.S. Department of Defense. Appreciate you being here today. I believe Eisenhower was a logistics guy, too. Good for you. Good work.

Well, to all of you today, you are aware that the committee is holding an investigative hearing. When doing so it's the practice of

taking testimony under oath. Do any of you have any objections to testifying under oath?

Seeing no objections, the chair then advises 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 today?

And seeing no request for that, in that case would you all please rise and raise your right hand and I'll swear you in.

[Witnesses sworn.]

Mr. MURPHY. Thank you. You may all be seated.

You are now all under oath and subject to the penalties set forth in Title 18 Section 1001 of the United States Code. I call upon you each to give a 5-minute opening statement.

In so doing, make sure your microphone is on, pull it as close to you as possible when you speak into it, and if you can see the red light on the table—when that goes on, your 5 minutes is up.

Can I just have yourself about 2 or 3 inches from the microphone? You have to pull it really close. Bring it close to your mouth. Thank you very much. You may begin, Mr. Neumann.

STATEMENTS OF JOHN NEUMANN, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE; LAWRENCE A. TABAK, PH.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH; STEPHAN S. MONROE, PH.D., ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEGARAN PILLAI, PH.D., DIRECTOR, OFFICE OF LABORATORY SCIENCE AND SAFETY, OFFICE OF THE COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; MAJOR GENERAL BRIAN C. LEIN, COMMANDER, ARMY MEDICAL RESEARCH AND MATERIEL COMMAND, BIOLOGICAL SELECT AGENTS AND TOXINS BIOSAFETY PROGRAM, DEPARTMENT OF DEFENSE

STATEMENT OF JOHN NEUMANN

Mr. NEUMANN. I want to thank you, Chairman Murphy and Ranking Member DeGette and members of the subcommittee, for inviting me here today to discuss GAO's report on the oversight of high-containment laboratories, which was publicly released for this hearing.

Over the last 2 years, safety lapses at Federal high-containment laboratories have raised concerns about department and agency oversight of these facilities.

These labs work with hazardous biological agents such as the virus that causes smallpox, a contagious and sometimes fatal infectious disease to humans, as well as live anthrax bacteria which has the potential to seriously threaten both human and animal health.

High-containment labs do important work with pathogens such as developing vaccines and counter measures and conducting research to understand emerging infectious diseases.

However, some of these pathogens also have the potential for high-consequence accidents if handled improperly. Today, I would like to briefly highlight the findings from our report.

First, we found that most of the eight departments and 15 agencies with high-containment labs do not have comprehensive or up to date policies.

We considered policies to be comprehensive if they included the following six key elements for managing pathogens in high-containment labs, the first one being incident reporting, inventory control, inspections, clear roles and responsibilities, training and adherence to the leading biosafety guidance for laboratories published by CDC and NIH.

While departments and agencies had policies in place, as I noted most were not comprehensive, meaning that they did not include all these elements.

In addition, some policies were not up to date as they had not been reviewed and updated in accordance with their internal review schedules and in some cases these policies had not been reviewed in close to 10 years.

These policies and the six key elements are an important foundation for lab safety. But policies alone will not ensure the lab personnel are adhering to them. This brings me to our second finding.

Most of the department's agencies were using inspections or audits as a primary way of overseeing their high-containment labs. But they were often not routinely reporting inspection results to senior officials.

Getting these inspection results to senior officials is important because these results can be used to identify trends and systemic safety issues and ensure that needed improvements are made across all the labs.

Finally, at the time of our review, DoD and HHS were making some progress in implementing recommendations from previous laboratory safety reviews that they conducted after the 2014 and 2015 safety lapses.

However, we found that DoD and CDC had not developed time frames for implementing some of these recommendations and without time frames DoD and CDC will be limited in their ability to track progress towards implementing these needed improvements.

We made a total of 33 recommendations to the Federal departments and agencies with these high-containment labs to ensure that they have comprehensive and up to date policies as well as stronger oversight mechanisms at their labs.

There was brought agreement by the eight departments with our recommendations and several have already begun taking actions to address them.

In closing, I would like to note that our report that we are discussing today is the latest in a body of work that GAO has developed over the last 10 years on the Federal oversight of high-containment laboratories.

We continue to monitor this issue by drawing on expertise from across our agency including our health care experts, our chief scientists and experts from my own group, the science and technology area.

As you know, we are conducting additional work for the subcommittee specifically looking at the inactivation of pathogens in high-containment labs and we expect to issue that report to you in the next several months.

Thank you, Chairman Murphy, and members of the subcommittee for holding this hearing and continuing your oversight of this important issue.

This concludes my prepared remarks. I would be pleased to respond to any questions you may have.

[The statement of Mr. Neumann follows:]

United States Government Accountability Office

GAO

Testimony

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

For Release on Delivery
Expected at 10:15 a.m. ET
Wednesday, April 20, 2016

HIGH-CONTAINMENT LABORATORIES

Comprehensive and Up-to-Date Policies and Stronger Oversight Needed

Statement of John Neumann, Director,
Natural Resources and Environment

Marcia Crosse, Director, Health Care

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

We are pleased to be here today as you examine the oversight and management of biological agents in federal high-containment laboratories. Researchers in high-containment laboratories work with hazardous biological agents that may cause serious or lethal infection in humans and animals. These agents include the bacteria that cause anthrax, the virus that causes smallpox, and highly pathogenic influenza viruses, all of which have the potential to seriously threaten human and animal health and disrupt the U.S. economy. Laboratories that conduct research on hazardous biological agents are assigned one of four biosafety levels (BSL), with those at BSL-3 and BSL-4 referred to as high-containment laboratories for the purposes of this statement.[1] Eight federal departments and 15 agencies—including the Department of Defense (DOD) and the Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS)—own and operate the federal government's high-containment laboratories.[2] These departments and agencies conduct research to identify and characterize biological threats that pose risks to civilians, servicemembers, agriculture, and wildlife; develop detection and response systems to improve preparedness for a biological attack; test

[1]Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular biological agents. BSL-3 laboratories work with indigenous or exotic agents with known potential for airborne transmission or those agents that may cause serious and potentially lethal infections. BSL-4 laboratories work with exotic agents that pose a high individual risk of life-threatening disease by airborne transmission and for which treatment may not be available. Animal and agricultural laboratories have similar safety designations.

[2]The 8 departments and 15 agencies are DOD and its Air Force, Army, and Navy; HHS and its CDC, Food and Drug Administration (FDA), and National Institutes of Health (NIH); Department of Energy (DOE) and its National Nuclear Security Administration and Office of Science; Department of Homeland Security (DHS); Department of the Interior (DOI) and its Fish and Wildlife Service and U.S. Geological Survey; Department of Veterans Affairs (VA) and its Veterans Health Administration; United States Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS), Agricultural Research Service, and Food Safety and Inspection Service; and Environmental Protection Agency (EPA) and its Office of Pesticide Programs. Federal departments have various terms for their component agencies. For example, DOI refers to its agencies as "bureaus." For the purposes of this statement, we refer to the departments' components as "agencies."

evidence to assist law enforcement investigations; and conduct diagnostic testing for human and animal diseases, among other activities.

Federal departments' management of hazardous biological agents in their laboratories is primarily guided by the principles and practices of biosafety and biosecurity, as well as federal regulations governing biological select agents and toxins. The principles and practices of biosafety and biosecurity are outlined in the widely-accepted leading guidance for laboratories, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), published in partnership by CDC and National Institutes of Health (NIH).[3] Select agent regulations govern the possession, use, and transfer of certain hazardous biological agents and toxins—designated as select agents and toxins—that have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.[4] CDC and the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) regulate facilities that possess, use, or transfer biological select agents and toxins, as part of their responsibilities under the select agent program.[5]

In 2014 and 2015, HHS and DOD reported multiple lapses in laboratory safety that could have exposed personnel and other individuals to hazardous biological agents. These lapses also illustrated multiple breakdowns in compliance with established policies and inadequate oversight, as well as scientific gaps in effective procedures to inactivate hazardous biological agents. For example, in 2014, CDC reported several safety lapses, one of which was also a result of inadequate inactivation

[3]Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Washington, D.C.: December 2009). Biosafety practices are intended to reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents. Biosecurity practices are intended to prevent the loss, theft, release, or misuse of hazardous biological agents and research-related information by limiting access to facilities and this information.

[4]For select agent regulations, see 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73 (2015). Research on select agents and toxins may require BSL-3 or BSL-4 containment.

[5]CDC and APHIS were delegated authority by their respective department secretaries to regulate the use, possession, and transfer of select agents. As part of their regulatory responsibilities, CDC and APHIS conduct inspections of facilities that possess, use, or transfer biological select agents and toxins, as well as other activities.

procedures that potentially exposed personnel to live anthrax bacteria. Other safety lapses occurred at CDC and NIH in 2014. In May 2015, DOD announced that it had inadvertently shipped samples containing live anthrax bacteria to laboratories in the United States and overseas as a result of inadequate procedures to fully inactivate the anthrax samples.[6] HHS and DOD convened workgroups and committees to conduct reviews of the 2014 and 2015 safety lapses identified at their laboratories, and these workgroups and committees made recommendations intended to improve policies and oversight, in addition to other activities. One of CDC's workgroups—an external advisory group—also reviewed the laboratory safety programs at the Food and Drug Administration (FDA) and NIH in 2015 and made recommendations to those agencies.

Our testimony today summarizes our March 2016 report, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, which is being released today.[7] Accordingly, this testimony addresses

1. the extent to which federal departments and agencies have comprehensive and up-to-date policies for managing hazardous biological agents in high-containment laboratories,
2. how federal departments and agencies oversee the management of hazardous biological agents in high-containment laboratories, and
3. the extent to which HHS and DOD have implemented recommendations from their laboratory safety reviews.

This testimony also includes a summary of our report recommendations intended to improve oversight and management of high-containment laboratories.

For our report, we examined the laboratory management policies and oversight activities at the 8 departments and 15 component agencies that

[6]For the purposes of this statement, inactivation is defined as a procedure to render hazardous biological agents unable to cause disease but still useful for research purposes, including, for example, vaccine development.

[7]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).

own and operate the federal government's high-containment laboratories. To determine whether policies were comprehensive, we first identified six policy elements that are key for managing high-containment laboratories and are consistent with federal internal control standards.[8] We interviewed department and agency officials about their policies and oversight. We also obtained and reviewed HHS and DOD planning documents for implementing recommendations from their laboratory safety reviews and interviewed officials about their progress in implementing these recommendations. Additional information on our scope and methodology is available in our report. Our work was performed in accordance with generally accepted government auditing standards.

Most Departments and Agencies Have Policies for Managing Hazardous Biological Agents in High-Containment Laboratories That Are Not Comprehensive or Up to Date

Most of the departments and agencies we reviewed did not have comprehensive policies. We considered a department's policies to be comprehensive if requirements for all six elements we identified as key to managing hazardous biological agents in high-containment laboratories existed in department-level policies or in agency-level policies for each of the department's component agencies. The key policy elements are (1) incident reporting, (2) roles and responsibilities, (3) training, (4) inventory control, (5) inspections, and (6) requiring adherence to, or referencing, the BMBL.[9]

Our review found that most of the 8 departments and 15 agencies had policies for managing hazardous biological agents in high-containment laboratories, but those policies were not comprehensive—that is, they did not contain all six elements or were not applicable to all of a department's or agency's high-containment laboratories. Only one agency—HHS's

[8]GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999), and *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014). GAO/AIMD-00-21.3.1 was effective through the end of fiscal year 2015 (Sept. 30, 2015). GAO-14-704G is the 2014 revision of GAO/AIMD-00-21.3.1 and became effective the first day of fiscal year 2016 (Oct. 1, 2015). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

[9]For the incident reporting element, if department-level policies did not contain requirements for reporting incidents to senior department officials, our assessment required agency-level policies to do so.

NIH—had policies that included all six key elements, including reporting incidents to senior department officials. Five departments—DOD, Department of Energy (DOE), Department of Homeland Security (DHS), Environmental Protection Agency (EPA), and USDA—had department-level policies. Ten agencies—DOD's Air Force, Army, and Navy; EPA's Office of Pesticide Programs; HHS's CDC, FDA, and NIH; USDA's APHIS and Agricultural Research Service; and Department of Veterans Affairs' (VA) Veterans Health Administration—had agency-level policies. Department of the Interior (DOI) did not have laboratory management policies at either the department or agency level. Table 1 shows the extent to which the departments and agencies had policies that contained each of the six key elements, as of December 2015, based on our analysis.

Table 1: Summary of Six Elements Key for Managing Hazardous Biological Agents in High-Containment Laboratories in Department and Agency Policies, as of December 2015

Department Agency	Incident reporting	Roles and responsibilities	Training	Inventory control	Inspections	BMBL	Key elements (count)
DHS[a]	●	●	●	◐	●	◍	5
DOD	●	●	●	◐	●	◍	5
Air Force[a]	○	◐	◐	◐	◐	◍	1
Army	●	●	●	◐	●	◍	5
Navy	◐	◐	◐	◐	◐	◍	1
DOE[a]	●	●	●	●	○	◍	5
National Nuclear Security Administration	–	–	–	–	–	–	-
Office of Science	–	–	–	–	–	–	-
DOI	–	–	–	–	–	–	-
Fish and Wildlife Service	–	–	–	–	–	–	-
U.S. Geological Survey	–	–	–	–	–	–	-
EPA	●	●	●	○	●	○	4
Office of Pesticide Programs	○	●	●	○	○	○	2
HHS	–	–	–	–	–	–	-

Department Agency	Incident reporting	Roles and responsibilities	Training	Inventory control	Inspections	BMBL	Key elements (count)
CDC	○[b]	●	◐	●	◐	◍	3
FDA	○	●	●	●	●	◍	5
NIH	●	●	●	●	●	◍	6
USDA	○	●	●	●	●	◍	5
APHIS[c]	○	●	●	○	○	○	2
Agricultural Research Service	●	●	●	○	●	◍	5
Food Safety and Inspection Service[a]	–	–	–	–	–	–	-
VA	–	–	–	–	–	–	-
Veterans Health Administration	○	●	●	◐[d]	●	◍	4

Legend:

● Policies contained requirement for key element for all high-containment laboratories.
◐ Policies contained requirement for key element only for select agent-registered laboratories.
◍ Policies required adherence to the BMBL or referenced it as guidance.
○ Policies did not contain key element.
– Department or agency did not have policies.

APHIS Animal and Plant Health Inspection Service
BMBL *Biosafety in Microbiological and Biomedical Laboratories*
CDC Centers for Disease Control and Prevention
DHS Department of Homeland Security
DOD Department of Defense
DOE Department of Energy
DOI Department of the Interior
EPA Environmental Protection Agency
FDA Food and Drug Administration
HHS Department of Health and Human Services
NIH National Institutes of Health
USDA United States Department of Agriculture
VA Department of Veterans Affairs

Source: GAO analysis of department and agency information. | GAO-16-566T

[a]Departments' and agencies' high-containment laboratories are all select agent-registered laboratories, according to officials.

[b]In July 2015, CDC issued a memorandum to agency personnel that included incident reporting procedures and a risk assessment flow chart for reporting potential incidents in its select agent and infectious disease laboratories, and officials stated that these requirements are available on the agency's internal laboratory safety website. However, CDC has not incorporated these requirements into agency-level laboratory safety policies.

[c]At the time of our review, APHIS was in the process of revising and finalizing its agency-level biosafety policy. APHIS finalized this policy in February 2016, after we completed our analysis, and the revised policy contains new requirements for the key elements of incident reporting, inventory control, inspections, and the BMBL.

[d]According to officials from VA's Veterans Health Administration, the agency's BSL-3 capable clinical laboratory is not permitted to store biological inventory.

We also found that some departments and agencies did not have up-to-date policies for managing hazardous biological agents in high-containment laboratories. Some departments and agencies also lacked general requirements and time frames for reviewing and updating their policies or lacked expiration or recertification dates on their policies. Of the 5 departments and 10 agencies that had policies for managing high-containment laboratories, 2 departments and 5 agencies had not updated all of their policies consistent with their internal review schedules, as of December 2015.[10]

Departments and Agencies Use Inspections as Their Primary Oversight Activity, but Results Are Not Routinely Reported to Senior Officials

We found that the 8 departments and 14 agencies in our review were using inspections or audits as the primary activity to oversee the management of hazardous biological agents in high-containment laboratories, as of December 2015.[11] Some department and agencies were also using additional oversight activities, such as verifying laboratories' inventory of hazardous biological agents and analyzing inspection results and incident reports to identify trends or recurring safety issues. Some departments and agencies—including DOD, HHS's CDC and FDA, and USDA's APHIS were taking various steps to strengthen their inventory controls, verify completion of training, and formalize inspection processes. Table 2 provides an overview of department and agency activities for overseeing the management of hazardous biological agents in high-containment laboratories.

[10]Specifically, DOE and USDA had one or more department-level policies that were not up to date. In addition, DOD's Air Force and Army, HHS's NIH, USDA's Agricultural Research Service, and VA's Veterans Health Administration had one or more agency-level policies that were not up to date. DHS, EPA, HHS's FDA, and USDA's APHIS lacked review requirements and time frames or specific policy expiration dates; these departments and agencies review their policies on an as-needed basis.

[11]We excluded DOE's Office of Science from this part of our review because the agency has not operated its laboratory at a high-containment level since 2006; this exclusion reduced the number of agencies for which we reviewed oversight activities from 15 to 14.

Table 2: Department and Agency Activities Used to Oversee the Management of Hazardous Biological Agents in High-Containment Laboratories, as of December 2015

Department Agency	Routine inspections or audits	Training records review	Inventory verification	Trend analysis of inspection results or incident reports
DHS	✓	✓[a]	✓[a]	✓
DOD	—[b]	—	✓[c]	—
Air Force	✓	✓[a]	✓[a]	✓
Army	✓	✓[a]	✓[a]	✓[d]
Navy	✓	✓[a]	✓[a]	—
DOE	—[e]	—	—	—
National Nuclear Security Administration	✓	✓	✓[a]	✓
DOI	—[e]	—	—	—
Fish and Wildlife Service	✓	✓	✓	—
U.S. Geological Survey	✓	✓[a]	✓[a]	—
EPA	✓	—	—	✓
Office of Pesticide Programs	✓	✓	✓	—
HHS	—	—	—	—
CDC	✓	✓[a]	✓	✓
FDA	✓	✓	✓	✓
NIH	✓	✓[a]	✓[a]	✓
USDA	✓[f]	—	✓	—
APHIS	—[g]	—	✓	✓
Agricultural Research Service	✓	✓[a]	✓	✓
Food Safety and Inspection Service	✓	✓[a]	✓	✓
VA	—	—	—	—
Veterans Health Administration	✓	✓[a]	✓[a]	✓
Departments (count)	**3**	**1**	**3**	**2**
Agencies (count)	**13**	**13**	**14**	**10**

Legend:
✓ Conducted activity

— Did not conduct activity

APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
DHS	Department of Homeland Security
DOD	Department of Defense
DOE	Department of Energy
DOI	Department of the Interior
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
NIH	National Institutes of Health
USDA	United States Department of Agriculture
VA	Department of Veterans Affairs

Source: GAO analysis of department and agency information | GAO-16-566T

[a]This activity was conducted during regular inspections and audits.

[b]The department delegated responsibility for conducting laboratory inspections to its agencies.

[c]The department assessed its inventory of select agents only; officials said the department has no plans to assess the inventory of non-select agents.

[d]The agency conducted trend analyses of incident reports but did not analyze inspection results.

[e]The department did not conduct formal, periodic laboratory inspections but may evaluate some laboratory activities as part of broader reviews of the overall program under which the laboratory resides.

[f]The department's inspections of high-containment laboratories were primarily focused on security-related issues, such as access to the facility, facility security systems, and security operations and administration.

[g]The agency conducted inspections but not on a routine schedule.

Although many of the departments and agencies were conducting internal inspections and other oversight activities, we found that senior officials at 5 departments and 8 agencies did not routinely receive the results of these laboratory inspections, and senior officials at 4 departments did not routinely receive reports of laboratory safety or security incidents that occurred at agency laboratories, as of December 2015. For example, for internal laboratory inspections, 2 departments and 4 agencies reported the results to senior agency officials but not to senior department officials.[12] Eight agencies did not routinely report the results of these inspections to either senior agency or senior department officials.[13] For inspections conducted by the select agent program, we found similar

[12]These 2 departments and 4 agencies are DOD's Air Force, DOI's Fish and Wildlife Service, EPA and its Office of Pesticide Programs, and USDA and its Agricultural Research Service.

[13]These 8 agencies are DOD's Army and Navy; DOI's U.S. Geological Survey; HHS's CDC, FDA, and NIH; and USDA's APHIS and Food Safety and Inspection Service.

variation in departments' and agencies' routine reporting of the results to senior agency and senior department officials.[14] In addition to inspection results, we found that all 14 agencies reported laboratory safety and security incidents to senior officials within their own agencies, but senior officials at 4 departments—DOD, DOI, HHS, and USDA—did not routinely receive reports of any safety and security incidents that occurred at agency laboratories. DOI, HHS, and USDA either did not have any department policies for laboratory management or policies did not contain incident reporting requirements.

HHS and DOD Have Made Some Progress in Implementing Recommendations from Laboratory Safety Reviews, but Have Not Developed Sufficient Implementation Plans

At the time of our review, HHS and DOD were making progress in implementing recommendations from the laboratory safety reviews they conducted after the 2014 and 2015 safety lapses. However, they had not developed specific time frames for implementing some recommendations. Our report provides additional details, including examples of HHS and DOD recommendations; specific numbers of recommendations that CDC, FDA, and NIH had implemented as of November 2015 (the date of the most recent information available); and additional steps DOD was taking to address weaknesses in laboratory safety. Although CDC and DOD officials told us that they plan to address all of the recommendations from the safety reviews, CDC had not developed time frames for implementing the recommendations from the agency's October 2014 internal working group report.[15] DOD's and Army's implementation plans for the recommendations made by the review committee include time frames for the three overarching areas in which the committee made recommendations—quality assurance, scientific peer review, and program management for inactivation and viability testing of anthrax

[14]Of the departments and agencies that operated select agent-registered laboratories, 5 agencies—HHS's CDC and NIH, USDA's Agricultural Research Service and APHIS, and EPA's Office of Pesticide Programs—told us that the agencies routinely reported the results of select agent inspections to senior agency officials but not to senior department officials. Three agencies—DOI's U.S. Geological Survey, HHS's FDA, and USDA's Food Safety and Inspection Service did not routinely report select agent inspection results to either senior agency or senior department officials. DOD's Air Force, Army, and Navy routinely reported the results of select agent inspections to senior department officials, but Army and Navy did not report these results to senior agency officials.

[15]CDC developed time frames for implementing open recommendations from the external advisory group report and CDC's individual after-action assessments of the three 2014 safety lapses.

bacteria—as well as for the additional tasks assigned to DOD and Army. However, the DOD and Army implementation plans and other planning documents do not include time frames for each of the detailed 19 recommendations in these three areas.

Summary of Recommendations to Improve Oversight and Management of High-Containment Laboratories

Our report made 33 specific recommendations intended to help ensure that all 8 federal departments and 15 agencies we reviewed have comprehensive and up-to-date policies and stronger oversight mechanisms for their high-containment laboratories. For example, we recommended that departments and agencies develop and update policies to include missing policy elements and ensure that oversight activity results are reported to senior agency and senior department officials. We also recommended that CDC and DOD develop plans with time frames for implementing recommendations from the reviews of recent safety incidents. Of the 8 departments to which we made recommendations, 6 (DHS, DOD, DOI, HHS, USDA, and VA) generally agreed with all of our recommendations for them. The remaining 2 departments (DOE and EPA) did not believe that further action was needed to respond to some of the recommendations we made to them, but we maintain that recommended actions are needed to assure that the departments have comprehensive and up-to-date policies and adequate oversight. In March 2016, NIH updated its policy in accordance with the recommendation we made to the agency.

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 Contacts and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact John Neumann, Director, Natural Resources and Environment at (202) 512-3841 or neumannj@gao.gov; or Marcia Crosse, Director, Health Care at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. GAO staff who made key contributions to this testimony are Mary Denigan-Macauley (Assistant Director); Karen Doran (Assistant Director); Nick Bartine; Colleen Corcoran; Shana R. Deitch; Melissa Duong; Holly Hobbs; and Terrance Horner, Jr.

Mr. MURPHY. Thank you, Mr. Neumann.

Dr. Tabak, you're recognized for 5 minutes. Again, pull the microphone very close to you so we can hear.

STATEMENT OF LAWRENCE A. TABAK

Dr. TABAK. Good morning, Mr. Chairman, Ranking Member Castor and distinguished members of the subcommittee. It is an honor to appear before you today to discuss how the NIH implements biosafety and biosecurity measures for high-containment laboratories.

I know I speak for Dr. Collins when I say that our concerns for safety must equal our passion for research. I can attest that senior leadership at the NIH is committed to the principle that safety lapses provide concrete opportunities for thorough critical self-assessment and self-improvement.

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 counter measures.

The study of biologic-select agents and toxins is necessary to develop new interventions with the potential to save millions of lives. NIH also recognizes the importance of ensuring that the research is conducted in the safest manner possible.

In the summer of 2014, six sealed decades-old ampules of smallpox were found in a cold storage room in an FDA laboratory building located on the NIH campus. The presence of smallpox was alarming to the entire NIH community and initiated much action on the part of NIH leadership.

Upon making this discovery, all of the proper notifications and security steps were taken. The CDC and the FBI were contacted and joint custody of the ampules was transferred to the CDC.

NIH has established protocols and procedures which included proper training regarding select agent handling ensured that at no time was anyone on campus or the public at risk.

NIH takes this incident very seriously and we have implemented new policies and procedures to prevent such an event from occurring again.

First, NIH identified and inventoried all potential hazardous biological material stored in all NIH-owned and leased facilities. During this sweep, which took place from July through September 2014, nearly 35 million samples were inventoried.

Additionally, NIH and other Federal agencies launched a National biosafety stewardship month. Extramurally funded institutions were asked to voluntarily join the Federal laboratories and reviewing their procedures, training and inventories of infectious agents and toxins.

Longer term, NIH has strengthened our inventory management controls. We have developed and implemented the potentially hazardous biological material management plan which addresses accountability at all levels of NIH. The plan establishes a mandatory centralized database of all potentially hazardous biological materials as well as procedures for annual updates of inventories and random audits of laboratories' hazardous biological holdings.

Each institute and center was required to appoint an individual to be responsible for common shared use and storage areas and

there are new policies in place requiring participation of personnel who work in secure select agent laboratories.

In February 2015, the external laboratory safety work group to the CDC advisory committee to the director reviewed our policies and practices.

The ELSW affirmed that NIH's response to the discovery of smallpox was prototypical and that NIH had implemented all of the recommendations made. The report states, and I quote, "The NIH intramural DOHS program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies."

The GAO review of high-containment laboratories that we meet here today to discuss found NIH's policies for laboratory management to be comprehensive. NIH implemented all of the GAO's recommendations and we addressed all of the six elements that the GAO identified as being key.

In closing, as principal deputy director of the NIH, I can assure this subcommittee that the senior leadership at NIH took appropriate action in 2014 and continues to act today to ensure the safety of the public and the scientist 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 and NIH-supported research activities through best safety practices and strong leadership.

Thank you, Mr. Chairman.

[The statement of Dr. Tabak follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Laboratory Safety at NIH

Testimony before the

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Lawrence A. Tabak, D.D.S., Ph.D.

Principal Deputy Director, NIH

April 20, 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 how the National Institutes of Health (NIH) implements biosafety and biosecurity measures in high containment laboratories.

The 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 pathogen exposure. Studying biological select agents and toxins – so-called "select agents" – that have been declared by the Federal Government to have the potential to pose a severe threat to public health and safety is necessary to develop new vaccines and treatments with the potential to save millions of lives. While appreciating the value of studying these select agents, the 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. The Division of Occupational Health and Safety (DOHS) at the 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 research 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 NIH Institutional Biosafety Committee provides recommendations to the NIH Director in matters pertaining to intramural use of microbial agents, their vectors, and recombinant DNA. In addition, each NIH Institute and Center (IC) has an active Safety Committee that assists the IC Scientific Director in assuring that employee

participation is emphasized in laboratory safety management and implementation. DOHS safety professionals serve on each of these committees to provide advice and guidance, and help ensure consistency in operationalizing NIH safety policies. Scientific Directors are routinely engaged in assuring rigorous adherence to procedures and developing solutions when any safety issues are identified. It is important to note that this activity happens at the level of the IC, particularly because safety measures must be tailored to the specific agents involved.

In addition to IC leadership, all scientists are responsible for protecting themselves, their co-workers, the public, and the environment as they conduct their research. Scientists take a personal risk when they choose to work with these agents, and they do so to protect the public, so their vigilance over safety measures is critical for maintaining public confidence in the research enterprise.

In the summer of 2014, six sealed, decades-old, ampules of smallpox were found in a cold storage room in a Food and Drug Administration (FDA)-occupied and leased laboratory building located on the NIH campus. The presence of smallpox on the NIH campus was alarming to the entire NIH research community, and initiated much action on the part of the NIH leadership. Upon making this discovery, all of the proper notifications and security steps were taken according to our safety protocols. The Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation was contacted and joint custody of the ampules was transferred to the CDC. NIH's established protocols and procedures, which included training regarding select agent handling, ensured that at no time was anyone on campus or the public at risk. NIH takes this incident very seriously and we have implemented new policies and procedures in the intervening years to prevent such an event from happening again.

First, NIH identified and inventoried all potentially hazardous biological materials stored in all NIH owned and leased facilities including all infectious agents, non-regulated toxins, poisons, and venoms. During this sweep, which took place from July to September 2014, nearly 35 million samples were inventoried. Subsequent to this first step, a quality assurance check was performed on a sampling of all reported material. Additionally, NIH and other Federal agencies launched a National Biosafety Stewardship Month. Under this initiative, extramurally funded institutions were asked to voluntarily join the Federal laboratories in similarly reviewing their own procedures, training, and inventories of infectious agents and toxins – all with an eye toward optimizing their programs of biosafety oversight.

For the long-term strategy, NIH developed the *Potentially Hazardous Biological Materials Management Plan*, which addresses accountability at all levels of NIH and has been fully implemented. This management plan has established:

- A mandatory centralized inventory of all potentially hazardous biological materials;
- Procedures for annual updates of inventories and more frequent updates if necessary;
- Procedures for transferring ownership/responsibility of biological materials when a researcher leaves the NIH;
- Procedures for random audits of laboratories' potentially hazardous biological holdings against the inventories;
- Appointment of an individual to oversee and be responsible for each common shared use and storage area, as well as implementation of an assurance process so that these appointments continue to be filled during the NIH annual management control review;
- Revised NIH policies for safety and health management and for working safely with potentially hazardous biological materials;

- Implementation of a biological surety policy requiring participation of personnel who work in secure select agent laboratories;
- Requirements for registering all stored biological materials with the DOHS (*previously NIH registered only active work with infectious agents*).

In February 2015, the External Laboratory Safety Workgroup (ELSW) to the CDC Advisory Committee to the Director reviewed our policies and practices as a follow-up to the 2014 incident. The ELSW affirmed that NIH's response to the discovery of the smallpox was prototypical and that NIH has implemented all of the recommendations made. The report states, "The NIH Intramural DOHS Program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies. The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined by the ELSW."

In addition to the affirmation of our safety and health program by ELSW, the GAO review of high containment laboratories that we meet here today to discuss, found NIH's policies for laboratory management of hazardous biological agents to be comprehensive.

In October 2015, the Assistant to the President for Science and Technology, John Holdren, initiated parallel Federal and non-Federal reviews that resulted in specific recommendations to strengthen our government's biosafety practices and oversight system for Federally-funded activities. The Federal Expert Security Advisory Panel (FESAP) was tasked with conducting coordinated federal review to evaluate our intramural research safety practices. For the non-Federal review, the National Science and Technology Council established an interagency Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) to conduct a comprehensive review of the impact that the select agent regulations have had on science, technology, and national security more broadly. These comprehensive reviews provided a set of

recommendations that address many of the factors associated with recent laboratory incidents in the United States and that will inform future policy to advance biosafety and biosecurity at NIH. Further, the NIH also supported the HHS Biosafety and Biosecurity Coordinating Council, which on behalf of the Secretary, provides a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department.

In closing, as Principal Deputy Director of the NIH, I can assure this Subcommittee that the senior leadership at NIH took appropriate action in 2014 and continues to act today to ensure 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, Mr. Chairman.

Mr. MURPHY. Thank you.

Before I recognize Dr. Monroe, I just want to clarify something I think was admitted from your testimony. The six sealed decades-old ampules of smallpox were found and two of those were viable. Am I correct?

Dr. TABAK. That was discovered afterwards, yes.

Mr. MURPHY. OK. But that was left out. I think that's critical for your testimony and I hope you would amend it to say that they were still alive.

Dr. Monroe, you are recognized for 5 minutes, please.

STATEMENT OF STEPHAN S. MONROE

Dr. MONROE. Good morning, Chairman Murphy, Representative Castor, other members of the subcommittee. Thank you for the opportunity to testify before you today on CDC's ongoing effort to strengthen the quality and safety of our laboratories.

I'm Dr. Steve Monroe, associate director for laboratory science and safety at CDC. In this new position, I serve as the single point of accountability for laboratory science and safety and I report directly to the CDC director, Tom Frieden.

I come to this role with 29 years of experience as a microbiologist at the agency. CDC laboratories remain an indispensable link in protecting the public's health.

Recently, we were pleased to welcome Chairman Murphy to our NIOSH facility in Pittsburgh and Ranking Member DeGette to our vector-borne diseases facility in Colorado where she saw first hand our frontline laboratory staff working 24/7 to address the ongoing Zika crisis.

Ensuring that all our laboratory work is performed with the utmost commitment to quality and to the safety of our workers and the community is and will remain of top priority for the agency.

In July 2014, Dr. Frieden testified before this subcommittee in the wake of a number of unacceptable safety incidents at CDC laboratories. Following the incident, CDC received multiple rigorous reviews of the agency's laboratory safety practices.

We continue to implement and track progress on each of the more than 200 recommendations we received through that process. While more work remains to be done, the progress made to date has been significant, particularly in CDC's laboratory oversight structure and approach.

My office oversees safety at all CDC laboratories. This includes overseeing our select agent compliance but it's distinct from CDC's Division of Select Agents and Toxins, which along with USDA regulates laboratories as part of the Federal select agent program.

My office ensures that CDC complies with select agent regulations in our own laboratories but it does not have authority over and is not involved in overseeing or enforcing the Federal select agency program.

An integral part of our reforms has been to foster a culture of safety in CDC's laboratories. Transparency and reporting are fundamental to such a culture.

One of my first acts in this role was to issue an agency wide memorandum to reiterate CDC's requirement for staff to report all safety issues and to provide clear direction on how to do so.

Another key achievement was the creation of the Laboratory Safety Review Board which is reviewing and approving all protocols from the transfer of biological materials out of BSL–3 and BSL–4 high-containment laboratories, a key issue identified in the 2014 incident.

CDC also established the laboratory leadership service, a fellowship program that prepares early career scientists to become future laboratory leaders.

Finally, CDC is committed to advancing the science of safety, applying the same rigorous scientific methods to laboratory safety that we use to confront threats to the public's health.

Last month, my office launched an intramural research fund to support agency laboratories in pursuing innovative solutions to laboratory safety challenges.

Last month, we saw a test of CDC's new laboratory oversight structure when a CDC worker was diagnosed with a salmonella infection that was likely acquired from their work in a CDC BSL–2 laboratory.

The worker has fully recovered and no other people appear to have been exposed. While the exposure should not have happened, CDC responded to this incident with urgency and transparency.

We will continue to strive to prevent incidents from happening. But if they do, we will do everything we can to identify and address the factor that contribute to the incident and do so swiftly, comprehensively and openly.

GAO's report on high-containment laboratories provides additional and valuable feedback on areas where CDC is succeeding and where continued improvements are required.

We already hard at work to address the issues GAO highlighted including finalizing our time lines for the remaining safety recommendations and working with HHS and our sister agencies on the Biosafety and Biosecurity Coordinating Council which will address some of the policies called for by GAO.

For CDC, laboratory safety is not a singular objective that can be checked off once completed. Rather, it is an ongoing commitment to a healthy and functioning culture of safety where monitoring and reporting are valued, issues are rapidly and openly addressed and efficient systems are in place to prevent a safety issue from becoming a safety incident.

Since Dr. Frieden testified before this subcommittee, CDC has made great progress in advancing this culture of safety at our laboratories. But more work remains to be done.

While the risks of working with these pathogens can never be completely eliminated, we will continue to reduce risks wherever possible. This includes diligently working to address the recommendations from the GAO.

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

[The statement of Dr. Monroe follows:]

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

Laboratory Safety at the Centers for Disease Control and Prevention

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
Expected at 10:00a.m.
Wednesday April 20, 2016

Introduction

Good morning Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. Thank you for the opportunity to testify before you today on the Centers for Disease Control and Prevention's (CDC) ongoing efforts to strengthen the quality and safety of the critically important work at the agency's laboratories. I am Dr. Steve Monroe, the Associate Director for Laboratory Science and Safety, a new position at CDC. 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, Tom Frieden. I come to this role with 29 years of experience as a microbiologist at the CDC, including serving as the Deputy Director for the National Center for Emerging and Zoonotic Infectious Diseases and Director for the Division of High-Consequence Pathogens and Pathology.

With laboratories across the United States from Atlanta, Georgia, and Ft. Collins, Colorado, to San Juan, Puerto Rico, and Anchorage, Alaska, CDC laboratories play a crucial part in identifying and responding to threats to the public's health. For example, CDC laboratories maintain a vast library of identified pathogens that laboratories from around the world depend on to identify dangerous microbes; these laboratories keep first responders and mine workers safe by evaluating the effectiveness of protective equipment; they screen newborns for rare illnesses and disabilities; they invent new assays for diagnosis of emerging infectious diseases such as Zika and Dengue virus; and they monitor the spread of antimicrobial resistant microbes. Ensuring that this vital work is performed with a commitment to safety and excellence is and will remain a top priority for CDC.

In July 2014, Dr. Frieden testified before this Subcommittee in the wake of a number of safety incidents at CDC laboratories. He testified that those incidents were completely unacceptable, and discussed the agency's response to the incidents and the need for changes both to address the circumstances that contributed to those incidents and to reform and restructure the agency's oversight and management of its laboratories. I am pleased to testify before you today on the progress we have made since then and to discuss the ongoing work at CDC to further strengthen and improve the safety and scientific quality of our laboratories.

Comprehensive Reviews of CDC Laboratory Safety

Following the 2014 incidents, CDC initiated intensive efforts to strengthen safety and quality in the agency's laboratories. That process began with comprehensive reviews of laboratory practices and structure, and identification of needed reforms. Separate comprehensive reviews by an internal CDC workgroup and a workgroup of experts external to the agency were conducted.

A key part of the reform process was the formation of the external Laboratory Safety Workgroup, a workgroup of the Advisory Committee to the Director of CDC. The eleven members of this workgroup were experts and leaders in the fields of biosafety, laboratory science, and research from outside of CDC. In 2014, this workgroup spearheaded an in-depth engagement with CDC, reviewing extensive documentation on our laboratories and safety protocols, surveying laboratory staff, visiting our high-containment laboratories, and meeting in-person with CDC laboratory staff and their leadership. Using the workgroup's findings, the Advisory Committee to the Director issued 19 recommendations to CDC to improve laboratory safety. These recommendations remain a roadmap for our ongoing efforts to strengthen laboratory quality and safety at the agency. CDC tracks progress on the recommendations on a monthly basis and reports this progress to HHS leadership. To date, CDC has completed or initiated action on all 19 of these recommendations, with 11 recommendations having been fully implemented.

Also essential to reforming laboratory safety at CDC was a deep and critical examination from within the agency of our laboratory safety practices. In August 2014, Dr. Frieden established the internal Laboratory Safety Improvement Workgroup and charged it with expediting improvements in laboratory safety and quality and developing its own detailed recommendations for strengthening laboratory safety at the agency. This workgroup developed 148 discrete recommendations, and CDC has initiated action on 138 of these, including fully implementing 44 recommendations. We continue efforts to implement and closely monitor progress on all of the remaining recommendations. We are in the process of developing timeframes for implementation of the remaining recommendations, where applicable.

In addition to the recommendations from internal and external groups, CDC also learned from and made changes based on specific recommendations in after-action reviews it conducted following the 2014 *Bacillus anthracis*, influenza A (H5N1), and Ebola virus laboratory incidents. The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service, or APHIS, also provided inspection reports and a list of corrective actions regarding each of the three incidents. For the CDC after-action reports, 8 of 8 Ebola recommendations, 23 of 26 the H5N1 recommendations, and 7 of 8 of the *Bacillus anthracis* recommendations have been fully implemented, with work underway on the remaining recommendations. Of the APHIS corrective actions, 22 of 25 have been completed, with actions on the remaining three items in progress. We also launched a box by box and vial-by-vial inventory of more than seven million samples in long-term storage for the infectious disease laboratories and rolled out a new electronic specimen inventory system.

The rigorous internal and external reviews of CDC's laboratory safety practices have been extensive in their scope, depth, and comprehensiveness. The recommendations spanned a broad range of structures and practices that impact laboratory safety including establishment of organizational changes to improve oversight and strengthen regulatory compliance; improvement of communication with laboratory staff; adoption of incident management protocols; and expansion of the use of risk assessments. We continue to implement and track progress on each of the more than 200 recommendations we have received in this process. While more work remains to be done, the progress made to date has been significant, particularly in CDC's laboratory oversight structure and approach.

A Single Point of Accountability for Laboratory Science and Safety

The creation of the position in which I serve—the Associate Director for Laboratory Science and Safety—is the most fundamental change implemented in the wake of the 2014 incidents. When Dr. Frieden testified before this Subcommittee in July 2014, he promised to establish a permanent, CDC-wide single point of accountability for laboratory science and safety. The internal and external workgroups also called for the creation of this role as a critical step to centralize and standardize laboratory safety practices and oversight across the agency. Creating this position and defining its role and function became a top priority for the agency. This new structure is essential to

our ability to assess potential implications of an incident or situation in one lab on other labs, and prevent problems before they occur by learning from experiences in laboratories in other parts of the agency.

The position of Associate Director for Laboratory Science and Safety, or ADLSS, was officially created in 2015 and I assumed this position permanently in September of last year, after having served in the role since May 2015 in an acting capacity. The ADLSS reports directly to the CDC Director and provides high-level oversight and coordination of critical laboratory policies and operations, particularly those associated with laboratory safety and quality management at all CDC campuses.

My office directs two key functions: oversight and direction of CDC laboratory science, quality, and training; and oversight of CDC's laboratory safety and compliance programs. This latter function is especially important to improving laboratory safety and aligns with the recommendations of the internal and external workgroups. My office now provides direct oversight of chemical, radiological, and biological safety, including compliance with select agent regulations, in laboratories across all CDC campuses. This is a key organizational improvement, as these compliance functions were formerly divided across multiple offices. I want to note that my office's role in select agent compliance is distinct from the role of CDC's regulatory arm in the Division of Select Agents and Toxins (DSAT). DSAT is part of the Federal Select Agent Program which, along with USDA's APHIS, regulates the possession, use, and transfer of biological select agents and toxins and enforces those regulations. CDC laboratories that handle select agents and toxins are subject to the requirements of the Federal Select Agent Program, and my office is responsible for ensuring that CDC complies with those regulations in our own select agent laboratories. However, my office does not have authority over and is not involved in overseeing or enforcing requirements of the Federal Select Agent Program in select agent labs in other Federal agencies and departments.

A Culture of Safety

A core recommendation of both the internal and external workgroups was to establish and strengthen a culture of safety in CDC's laboratories. This remains an overarching goal and vision for CDC and my office, and I want to highlight some specific initiatives that have advanced this culture of safety.

An integral part of a culture of safety is transparency about potential safety issues in our laboratories. One of my first acts as the ADLSS was to issue an agency-wide memorandum to reiterate CDC's requirement for staff to report any and all safety issues, and provide clear direction on what channels workers should use to report incidents. Included with the memorandum was a flow chart to clarify incident reporting channels and a Laboratory Infectious Agent Exposure Risk Assessment Tool to ensure that any event involving infectious materials was accurately characterized and reported. We are now in the process of updating this reporting requirement in CDC's internal agency-wide policies.

Another key achievement was the creation of the Laboratory Safety Review Board (LSRB) in March 2015. The LSRB is charged with reviewing and approving protocols for the transfer of biological materials out of Biosafety Level 3 (BSL-3) and BSL-4 laboratories to lower levels of containment, a key issue in the 2014 incidents. The LSRB reviews all new and amended protocols for these transfers and conducts annual reviews of existing protocols. The LSRB has authority to suspend any protocol that it finds is not being conducted appropriately and communicates directly to CDC leadership and laboratories about any incidents, protocol lapses, and suspensions. Finally, the LSRB is charged with reviewing and maintaining quarterly summaries of all material transfer certificates.

CDC also established the Laboratory Leadership Service, or LLS, a fellowship program that prepares early career laboratory scientists to become future laboratory leaders. LLS is modeled after the Epidemic Intelligence Service, and it combines competency-based public health laboratory training with practical, applied investigations and service. LLS fellows are deployed to investigate laboratory incidents and near-misses to understand what happened and what steps are needed to prevent safety issues in the future. The inaugural LLS class began in July

2015, and the program will provide CDC and public health laboratories across the country with a cadre of expertly trained laboratory scientists poised to meet the evolving challenges of laboratory science and safety.

Finally, CDC is also committed to advancing what I describe as the science of safety—applying the same rigorous scientific methods to the safety of our laboratories that we use to confront threats to the public's health. To spur the science of safety in CDC laboratories, last month my office launched the Laboratory Safety Science and Innovation Intramural Research Fund. This fund provides one-time awards to laboratories across the agency that propose innovative research or solutions to laboratory safety challenges. This year, we will be funding 13 projects that enhance the science of laboratory safety in diverse ways, from developing a 3D lab risk-assessment training tool to improving virus inactivation techniques and evaluating the efficacy of disinfectants.

Last month, we saw a test of CDC's new laboratory oversight structure when a CDC laboratory worker was diagnosed with a *Salmonella* infection that was likely acquired from their work in a CDC BSL-2 laboratory. *Salmonella* is not a select agent, and the worker has fully recovered and no other people appear to have been exposed. Once DNA fingerprinting conducted at the Georgia Department of Public Health laboratory indicated that the strain of *Salmonella* that caused the infection was the same that the worker had been handling in the laboratory prior to the infection, my office launched an investigation to understand the circumstances that led to the exposure and identify any processes that needed to change to prevent future exposures. While the exposure should not have happened and we are working to reduce the risks involved in working with pathogens in every way possible, CDC responded to this incident with urgency and transparency. Once we received the results of the DNA fingerprinting, we immediately notified Congress, including staff of this Subcommittee, and issued a press statement to notify the public of the likely exposure. We will continue to strive to prevent these incidents from ever happening, but if they do, we will do everything we can to identify and address factors that contributed to the incident and do so swiftly, comprehensively, and openly.

A foundational principle of laboratory safety is having multiple, overlapping layers of protection and containment. GAO's examination of CDC policies in its report on high-containment laboratories, like the internal

and external reviews, provides additional and valuable feedback on areas where CDC is succeeding and where continued improvements are required. GAO's emphasis on the comprehensiveness of laboratory safety policies is especially valuable and reflects CDC's own 360-degree approach of shoring up and strengthening our laboratory safety policies and practices. We are already hard at work to address the issues GAO highlighted. We are finalizing timelines for the completion of all the 148 recommendations included in the Laboratory Safety Improvement Workgroup report and are developing comprehensive policies to address reporting of laboratory incidents, conducting risk assessments, and transporting of specimens at CDC campuses. In addition CDC is working with HHS and our sister agencies on the HHS Biosafety and Biosecurity Coordinating Council, which on behalf of the Secretary provides a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department. The Council's work includes establishing a process to notify HHS leadership about laboratory inspection results and safety incidents.

Supporting U.S. Government Efforts to Strengthen Biosafety and Biosecurity

In addition to the improvements in laboratory safety at CDC, CDC is also participating in U.S. Government efforts to strengthen biosafety and biosecurity. On October 29, 2015, the government released these two sets of recommendations as well as the implementation plans, one from the Federal Experts Security Advisory Panel (FESAP), which conducted an internal U.S. Government review of biosafety and biosecurity practices, and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR), which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories. Recommendations made by both the FESAP and FTAC-SAR address the culture of responsibility, oversight, outreach, and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins.

The U.S. Government has developed a plan to implement the FESAP's and FTAC-SAR's recommended actions and expects that implementing these recommendations will strengthen biosafety and biosecurity practices and oversight.

Conclusion

CDC's laboratories remain an indispensable link in our public health system, from preventing healthcare associated infections at our Clinical and Environmental Microbiology Laboratory in Atlanta; to understanding the spread of the Zika virus in our vector-borne disease laboratories in Ft. Collins, Colorado; to improving the safety of America's workforce at the National Institute for Occupational Safety and Health laboratories in Morgantown, West Virginia. Ensuring that this critical laboratory work is performed with the utmost commitment to the safety of our workers and the public is, and will remain, a vital priority for the agency.

For CDC, laboratory safety is not a singular objective that can be accomplished and checked off. It is an ongoing commitment to a functioning culture of safety that demands constant and vigilant dedication. A healthy and functioning culture of safety is one where monitoring and reporting are valued, where issues are rapidly and openly addressed as they are identified, and efficient systems are in place to prevent a safety issue from becoming a safety incident. Since Dr. Frieden testified before this Subcommittee, CDC has made great progress in advancing this culture of safety at our laboratories across the country. But more work remains to be done. While the risks of working with pathogens and other hazards can never be completely eliminated, we will continue to reduce and mitigate these risks in every possible way. This includes diligently working to address and build upon the recommendations presented by GAO in its report.

Without question, we are in a better and safer place than we were two years ago. We have established a single point of accountability for all laboratory safety and science across the agency; recruited a corps of laboratory safety leaders to champion safety improvements; and created the Laboratory Safety Review Board to review protocols for the transfer of biological materials out of high-containment laboratories. These and other reforms we

have initiated since 2014 have strengthened laboratory safety and science across the agency and ensure that CDC's laboratories are prepared to meet the complex public health challenges of our day.

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. Monroe.

Dr. Pillai, you're recognized for 5 minutes. Turn the microphone on and bring it up very close to you, please. Even closer. Get a lot closer. That's good.

STATEMENT OF SEGARAN PILLAI

Dr. PILLAI. Good morning, Chairman Murphy, Ranking Member Castor and members of the subcommittee. I'm Dr. Segaran Pillai, director of the Office of Laboratory Science and Safety within the Office of the Commissioner at the FDA within the Department of Health and Human Services.

Thank you for the opportunity to appear before you today to discuss FDA's efforts to ensure the safety and security of our laboratories and the people who work in them. FDA's laboratories provide a critical role in fulfilling FDA's regulatory mission.

FDA's laboratories, like all laboratories, must comply with all applicable Federal, State, and local safety requirements.

To ensure this, the agency is deeply committed to ensuring compliance with relevant laws and regulations through a combination of training, issuance of specific policies and procedures, appropriate oversight by the safety offices in the centers and by fostering an agency wide culture of safety and security in our laboratories.

Upon discovery of the vials of Variola at an FDA laboratory located on the NIH campus in July of 2014, the FDA commissioner established the Laboratory Safety Practices and Policy working group.

The goal of the work group was to lead a careful and deliberate review of FDA's biosafety and biosecurity programs and to identify and implement methods to improve laboratory safety practices across the agency.

One of the first key actions of the working group was to complete a clean sweep, a full visual audit of all storage areas and laboratories. The vast majority of the FDA's roughly 670,000 vials of samples were properly stored.

However, there were two instances where select agents were improperly stored in secured locations. In both cases, the CDC's division for select agents and toxins was notified and the materials were destroyed.

In May of 2015 members of the advisory committee to the director of CDC's External Laboratory Safety working group conducted a thorough onsite review of the FDA's laboratory safety policies and procedures.

During this three-day visit, the work group met with key FDA officials to discuss the circumstances surrounding the discovery of the Variola samples on the NIH campus and review the policy elements of biosecurity and inventory control, laboratory safety training programs, laboratory security operations as well as the compliance programs.

The resulting report released in July the 10th, 2015 contained eight observations that included a total of 30 recommendations. We have implemented many of those recommendations and are making steady progress on the remaining recommendations that resulted from the review in order to build and strengthen FDA's comprehensive laboratory safety and security program.

In addition, FDA continues to work diligently to centralize appropriate laboratory safety practices including standardizing policies, procedures and defining inventory policies and audit procedures.

To gauge the cultural safety at FDA, we held a series of 13 focus groups with laboratory staff throughout the agency. The focus of the focus groups was to raise safety awareness and identify trends and risk areas.

Accountability, safety culture, communication and training were identified at critical areas by the focus groups. One of the key findings was in general staff was not afraid of reprisal if they were to report safety-related issues or concerns.

FDA is also planning additional ways to engage laboratory staff in a variety of settings including focus groups, town hall meetings and other forums to provide a positive and productive outlet for employees to communicate their thoughts and ideas for improving safety and security at the FDA laboratories.

An integral way to promote cultural safety and security and ensure compliance with legal and regulatory requirements is through training. FDA is in the process of implementing a core curriculum for biosafety and biosecurity training for all FDA personnel working in the biomedical research laboratories.

This cross cutting agency work safety training program will instill and strengthen a culture of safety and compliance throughout the agency.

In addition to the above, FDA also issued a new agency wide inventory control and management policy for biological agents and toxins.

Using a central electronic inventory control and management system will allow the agency to provide efficient oversight of all biological agents and toxins located at the centers and offices.

The recommendations from both the Laboratory Safety working group and GAO reports further validates our strategic approach and provides essential feedback for FDA as we continue to enhance our laboratory safety and security practices and policies.

The Government Accounting Offices reported that as of December 2015, FDA has met five of the six elements and policies for managing biological agents in the high-containment laboratories.

Although FDA's currently policy did not provide for laboratory incidents to be reported to the senior agency officials, incident reporting does occur within each of the FDA centers and offices and an analysis of the root cause is performed annually.

I'm also working closely with the FDA's safety offices to develop a more comprehensive reporting mechanism to capture laboratory accidents, incidents, near misses and laboratory-acquired infections.

This new reporting mechanism will be implemented in the coming months and will require all centers and offices to report all such events to my office.

The FDA's Office of Laboratory Science and Safety will establish an official FDA wide policy and work with the HHS biosafety and biosecurity coordinating council to recommend appropriate criteria and procedures for reporting incidents to the HHS leadership in a timely manner.

Since the discovery of the vials of Variola, FDA senior officials have taken direct and definitive actions to improve FDA's laboratory safety and security policies, practices and to foster a culture of safety and security across the agency.

I want to assure you that FDA stands fully committed to enhancing the safety and security to protect both our staff and the public. No regulations or guidelines can ensure safe——

Mr. MURPHY. I need you to conclude because you're about a minute and a half over.

Dr. PILLAI [continuing]. Applied toward daily activities. Individuals and organizational commitment to the cultural safety influences all aspects of safe and secure laboratory practices.

This includes a willingness to report incidents and concerns, apply lessons learned and ensure timely communications of potential risk as well as the ability to respond to an incident judiciously.

Mr. MURPHY. Thank you.

Dr. PILLAI. Safety in the laboratory involves experience and knowledge gained over time and how to recognize and minimize risk and control assets. As we share and apply this critical knowledge to our daily activities we are confident that the level of risk will decrease and the goal of reducing risk to the lowest possible level.

Thank you very much for——

Mr. MURPHY. Thank you.

Dr. PILLAI. I'll be happy to answer any questions.

[The statement of Dr. Pillai follows:]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

SEGARAN PILLAI, Ph.D.

DIRECTOR, OFFICE OF LABORATORY SCIENCE AND SAFETY

OFFICE OF THE COMMISSIONER

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HOUSE ENERGY AND COMMERCE COMMITTEE

U.S. HOUSE OF REPRESENTATIVES

"HOW SECURE ARE U.S. BIORESEARCH LABS? PREVENTING THE NEXT SAFETY LAPSE."

APRIL 20, 2016

RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. I am Dr. Segaran Pillai, Director of the Office of Laboratory Science and Safety, within the Office of the Commissioner at the Food and Drug Administration (FDA or the Agency) within the Department of Health and Human Services (HHS). Thank you for the opportunity to appear today to discuss FDA's efforts to ensure the safety and security of our laboratories, and the people who work in them.

FDA's laboratories provide a critical role in fulfilling FDA's regulatory mission. FDA's laboratories, like all laboratories, must comply with all applicable Federal, state, and local safety requirements. To ensure this, the Agency is deeply committed to ensuring compliance with relevant laws and regulations through a combination of training, issuance of specific policies and procedures, appropriate oversight by safety officers in the Centers, and by fostering an Agency-wide culture of safety and security in our laboratories.

Upon discovery of vials of *Variola* at an FDA laboratory located on the National of Institutes of Health's (NIH) campus in July 2014, the FDA Commissioner established the Laboratory Safety Practices and Policies Workgroup (LSPPW). The LSPPW was charged with providing ongoing, structured coordination throughout the Agency and with ensuring implementation of FDA's policies, procedures, and activities for managing all potentially hazardous materials.

One of the first key actions of the LSPPW was to complete a "Clean Sweep" – a full visual audit of all storage areas and laboratories. The vast majority of FDA's roughly 670,000 vials and samples were properly stored; however, there were two instances where select agents were improperly stored in secure locations. In both cases, the Centers for Disease Control and

Prevention's (CDC) Division of Select Agents and Toxins was notified and the materials were destroyed.

The LSPPW continues to lead a careful and deliberate review of FDA's biosafety and biosecurity programs to identify and implement measures to improve laboratory safety practices across the Agency. As part of that review, and to foster a culture of safety, the Agency created a new position, the Director of the Office of Laboratory Science and Safety to provide executive leadership, oversight, and coordination of laboratory policies, practices, and operations.

I joined FDA in October 2015 to lead this newly established Office of Laboratory Science and Safety and serve as the Agency's focal point for laboratory safety and security. In my current capacity, I also serve as the Agency's senior laboratory scientific advisor to the Commissioner of Food and Drugs.

ADVISORY COMMITTEE TO THE DIRECTOR OF CDC, EXTERNAL LABORATORY SAFETY WORKGROUP

In May 2015, members of the Advisory Committee to the Director of CDC's External Laboratory Safety Workgroup (ELSW) conducted a thorough on-site review of FDA's laboratory safety policies and procedures. During this three-day visit, the workgroup met with key FDA officials to discuss the circumstances surrounding the discovery of *Variola* samples on NIH's campus, and reviewed the policy elements of biosecurity and inventory control, laboratory safety training programs, laboratory security operations, as well as compliance programs. The resulting report, released on July 2, 2015, contained eight observations that included a total of 30 recommendations. We have implemented many of those recommendations and are making

steady progress on the remaining recommendations that resulted from that review in order to build and strengthen FDA's comprehensive laboratory safety and security program.

The ELSW recommendation to augment communications throughout the Agency is a top priority. FDA is fully committed to coordinating its Agency-wide laboratory safety training, policies and practices, where feasible. In addition, FDA will continue to work diligently to centralize appropriate laboratory safety practices, including standardizing policies and procedures, and refining inventory policies and audit procedures. Another priority is to provide the communication tools necessary for staff to effectively report problems and solutions to appropriate sources and senior officials. FDA will continue to implement and improve Agency-wide communication and training programs.

CULTURE OF SAFETY AT FDA

FDA is deeply committed to fostering an Agency-wide culture of laboratory safety. To gauge the culture of safety at FDA, we held a series of 13 focus groups with laboratory staff throughout the Agency. The purpose of the focus groups was to raise safety awareness, and identify trends and risk areas. Accountability, safety culture, communication, and training were identified as critical areas by the focus groups. One of the key positive findings was that, in general, staff was not afraid of reprisal if they were to report safety issues.

FDA is in the process of establishing a robust and consistent process for communication of issues and challenges between safety officers and senior leadership. Safety professionals are at the frontline of the FDA safety program. Providing direct lines of communication to senior

leadership will ensure that issues and challenges are identified immediately, and that the root cause will be fully addressed and resolved in a timely manner.

FDA is planning additional ways to engage laboratory staff in a variety of settings, including focus groups, town-hall meetings, and other forums to provide a positive and productive outlet for employees to communicate their thoughts and ideas for improving safety and security at FDA laboratories.

An integral way to promote a culture of safety and security and ensure compliance with legal and regulatory requirements is through training. FDA is in the process of implementing a core-curriculum of biosafety and biosecurity training for all FDA personnel working in biomedical research laboratories. This cross-cutting, Agency-wide safety training program will instill and strengthen a culture of safety and compliance throughout the Agency.

FDA intends to evaluate ways to leverage external safety expertise from industry and elsewhere to bring fresh ideas to the FDA biosafety and biosecurity program.

Through the LSPPW, FDA issued a new Agency-wide inventory control and management policy for hazardous biological agents and toxins. The policy provides for implementation and use of a central electronic inventory control and management system that will allow the Agency to provide efficient oversight of all hazardous biological agents and toxins located at the Centers and Offices. This policy reaffirms FDA's commitment to a culture of security by clearly establishing the roles and responsibilities of FDA safety officers within each of the Centers for scientists, and their managers, who work with hazardous biological agents and toxins.

GAO REPORT

As I have discussed, FDA has already taken steps to enhance laboratory safety and security practices and support the culture of safety. We appreciate the GAO's recommendations as they further validate our strategic approach as we continue to develop a comprehensive and sustainable laboratory safety and security program. The recommendations in both the ELSW and GAO reports provide essential feedback for FDA as we continue to enhance our laboratory safety and security practices and policies. As recommended in the GAO's report, the Agency will continue to build upon its efforts to improve laboratory inventory control, management, and reporting processes.

The GAO reported that, as of December 2015, FDA met five of the six elements key to policies for managing hazardous biological agents in high-containment laboratories. Although FDA's current policies do not provide for laboratory incidents to be reported to senior Agency officials, incident reporting does occur within each of the FDA Centers and Offices and an analysis of the root causes is performed annually.

In addition to following the Occupational Safety and Health Administration's (OSHA) incident reporting policy, FDA policies provide for laboratory managers and principal investigators to report incidents involving significant spills and personnel exposure to hazardous biological agents and toxins to their supervisors, as well as Center or Office leadership. We are working to establish a process for these incidents to be systematically reported to me. I would then communicate these reported concerns with FDA and HHS executive leadership team as frequently and immediately as needed.

Building upon these practices, I am also working closely with FDA Center and Office safety officers to develop a more comprehensive reporting mechanism to capture laboratory accidents, incidents, near-misses, and laboratory-acquired infections. This new reporting mechanism will be implemented in the coming months, and will require all Centers and Offices to report all such events to my office. The FDA's Office of Laboratory Science and Safety will establish an official FDA-wide policy and work with the HHS Biosafety and Biosecurity Coordinating Council to determine appropriate criteria and procedures for reporting incidents to HHS leadership in a timely manner. The HHS Biosafety and Biosecurity Coordinating Council, on behalf of the Secretary, provides a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department. GAO's recommendations specific to FDA are in line with current efforts to improve the culture of safety and security at the Agency and I look forward to integrating them into our overall laboratory safety and security framework.

SUPPORT OF U.S. GOVERNMENT EFFORTS TO STRENGTHEN BIOSAFETY AND BIOSECURITY

In addition to the improvements in laboratory safety at FDA, the Agency is also participating in U.S. Government (USG) efforts to strengthen biosafety and biosecurity. On October 29, 2015, the USG released two sets of recommendations as well as the implementation plans: one from the Federal Experts Security Advisory Panel (FESAP), which conducted an internal USG review of biosafety and biosecurity practices; and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR), which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories. Recommendations made

by both the FESAP and FTAC-SAR address the culture of responsibility, oversight, outreach and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins. The USG has developed a plan to implement the FESAP's and FTAC-SAR's recommended actions. The USG expects that implementing the FESAP and FTAC-SAR recommended actions will strengthen biosafety and biosecurity practices and oversight activities.

CONCLUSION

FDA is fully committed to enhancing laboratory safety and security. Since the discovery of the vials of *Variola*, FDA's senior officials have taken direct and definitive action to improve FDA's laboratory safety and security policies, practices, and to foster a culture of safety and security across the Agency. FDA stands committed to enhancing the safety and security of both our staff and the public.

No regulation or guideline can ensure safe and secure laboratory practices unless applied to daily activities. Individuals and the organizational commitment to the culture of safety influence all aspects of safe and secure laboratory practice. This includes a willingness to report incidents and concerns, apply lessons learned, and ensure timely communication of potential risks, as well as the ability to respond to an incident judiciously. Safety in the laboratory evolves through experience and knowledge gained over time on how to recognize and minimize risk and control

hazards. As we share and apply this critical knowledge to our daily activities, we are confident that the level of risk will decrease, with the goal of reducing risk to the lowest possible level.

Thank you. I am happy to answer your questions.

Mr. MURPHY. General Lein, you're recognized for 5 minutes.

STATEMENT OF BRIAN C. LEIN

MG LEIN. Good morning, Chairman Murphy, Ranking Member Castor, distinguished members of the subcommittee. Thank you for the opportunity to update you on the Department of Defense's actions taken to address the development, implementation and valid oversight policy and procedures for the safe handling and transfer of biologic select agents and toxins.

Eight DoD labs work with these agents with the primary focus on developing medical counter measures, vaccines and drugs as well as diagnostic devices to protect our forces.

I'm the commanding general of the U.S. Army medical research and material command and in support of the surgeon general of the Army as the DoD executive agent and responsible official for the BSAT.

In this role, I am responsible for harmonization of policy, technical review and inspection guidelines throughout the Department of Defense. I will detail the actions that have been taken, the current work and the plan for the future since we first learned of the anthrax shipments incidents in March of 2015.

Immediately after the notification the deputy secretary of defense issued a moratorium on BSAT production and shipments to allow for a thorough investigation, review of potential problems and to ensure the safety of our laboratory personnel.

Additionally, the deputy secretary of defense designated the secretary of the Army as the executive agent for DoD BSAT biosafety program. The director of the Army staff also directed a full accountability review of the life sciences division of Dugway Proving Grounds.

And finally, the secretary of the Army also directed the establishment of a biosafety task force to develop recommendations and implement necessary changes to ensure the long-term safety and security of the Department of Defense BSAT program.

The end result of all of these actions led to a critical reorganization of oversight responsibilities, accountability, inspections and implemented new policies and procedures which are detailed in the written testimony.

In December of 2015 the investigating officer for the incident at the life sciences division of Dugway concluded that the inadvertent shipment of viable bacillus anthracis is a serious breach of regulations. A copy of this report has been previously made available to the committee.

The report included several recommendations including scientific recommendations, institutional recommendations and recommendations to hold individuals accountable for the failure to take action in response to mishaps, failure to execute oversight and ensure compliance with protocols and regulations and failure to exercise care in the performance of their duties.

All personnel actions as a result of the investigation are currently being addressed at the appropriate level of command. I am pleased to report that the biosafety task force capitalized on the best subject matter experts inside and outside the Department of Defense to adopt science-based policies and proven management

procedures for the military services to operate in a safe and secure manner for the foreseeable future.

The task force developed four significant recommendations to ensure the long-term safety and security of the biologic select agents and toxins program.

We anticipate that by March of 2017 all the recommendations will be in place. The anthrax inactivation study will be completed and shared with all other Federal agencies.

The BSAT biosafety program office will be fully staffed and operational. The biosafety scientific peer review panel and the integrated IT solution for tracking and inventorying all BSAT samples will be implemented.

Establishing strong and robust processes that are continually evaluated and improved is our best defense against potential human error or management lapses.

We believe the systems we are developing will provide the necessary checks and balances to prevent or minimize the impacts of future accidental and human or procedural missteps.

We recognize that quality policies and procedures do not stand alone. They must be incorporated with personnel training, evaluation, feedback followed by review, oversight, documentation and reporting in order to have a systematic approach to managing the successful and safe performance of these personnel and institutions.

It is also necessary that we partner with other Federal and private organizations to ensure the transparency and the uniformity of this program.

We are developing a system that incorporates these essential elements to continue the safety performance of this critical research and for the development of detection systems and counter measures.

Finally, both accountability and a standardized inspection process are both critical to the success of this program. Both have undergone significant revision and centralization.

Thank you for the opportunity to share our program with this committee. I look forward to answering any follow-on questions.

[The statement of Major General Lein follows:]

RECORD VERSION

STATEMENT BY
MAJOR GENERAL BRIAN C. LEIN
COMMANDER, US 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

ON MEDICAL LAB SAFETY

APRIL 20, 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 reviews, current actions and future directions to address the development and implementation of valid oversight policy and procedures for the safe handling and transfer of Biological Select Agents and Toxins (BSAT) including, *Bacillus anthracis* spores ("anthrax"), among laboratories and institutions.

The previous incomplete understanding of the science for deactivation, varying DoD protocols for the inactivation of anthrax spores, the failure of procedural checks and balances to certify the killing of all live agent, sub-standard laboratory practices and lack of oversight that allowed for the inadvertent shipments of samples containing live anthrax spores from the Dugway Proving Ground to other facilities was not acceptable. The DoD and the US Army are cooperating and coordinating with other federal agencies including with the proponents of BSAT policy, the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (of the Department of Agriculture), to jointly develop common government policies and procedures to account for the safe use and shipment of BSAT materials across all applicable institutions and specifically those under the command and control of the DoD.

I am here as the Commanding General of the US Army Medical Research and Materiel Command and in support of The Surgeon General of the Army as the DoD Executive Agent Responsible Official (EARO) for BSAT. In this role, I am responsible for harmonization of BSAT policy, technical review, and inspection guidelines across DoD. Today, I will briefly describe why we work with BSAT material, detail several of

the actions that have been taken, ongoing developments, and the plan for future validation procedures, oversight and implementation that have been in progress since May 22, 2015 when we first learned of the anthrax shipment incidents.

Why BSAT?

The public may ask "Why do the various government agencies store, study and ship BSAT materials among various institutions?'" The short answer is because bioterrorism is a serious threat to the US military, our civilian population, and to our allies. The DoD regularly ships inactivated biological materials for research, development, testing and evaluation to industry and academia (on behalf of US Government entities), and other Foreign laboratories of our allies for the development and testing of medical and physical countermeasures to biological threats such as sensors for anthrax. Biological Select Agents and Toxins are designated by the Department of Health and Human Services, CDC/Division of Select Agents and Toxins and the Department of Agriculture, Animal and Plant Health Inspection Services/Agriculture Select Agent Services. They determine which agents present a high bioterrorism risk to national security and have the greatest potential for adverse public health impact with mass casualties of humans and/or animals or that present a severe threat to plant health or to plant products.

The DoD has eight institutions working with BSAT: US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; Naval Medical Research Center, Fort Detrick, MD; Edgewood Chemical and Biological Center (ECBC), Aberdeen Proving Ground, MD; Chemical, Biological and Radiological Defense Division, Naval Surface

Warfare Center, Dahlgren Division, Dahlgren, VA; Air Force 711th Human Performance Wing, Wright Patterson AFB, OH; the Life Sciences Division (LSD), West Desert Test Center (WTDC), Dugway Proving Ground (DPG), UT; and two overseas Navy laboratories: Naval Medical Research Unit (NAMRU)-3 (Cairo, Egypt) and NAMRU-6 (Lima, Peru).

Actions taken

Since the May 2015 notification from the CDC of the discovery of an inadvertent shipment of live anthrax from the LSD at DPG, the DoD has directed comprehensive reviews and inspections of the entire BSAT program. The DoD has done a critical reorganization of oversight responsibilities and implemented new policies and procedures which will be detailed in this statement. As an initial safety step, on July 23, 2015 the Deputy Secretary of Defense instituted a moratorium on BSAT processes and shipments. This action was taken to allow for a thorough investigation and review of the potential problems and to ensure safety of laboratory workers and other personnel.

Many additional steps have been taken starting with the Deputy Secretary of Defense designating the Secretary of the Army as the Executive Agent for the DoD BSAT Biosafety Program. The Director of the Army Staff conducted a full accountability of DPG, including the Chain of Command. Additionally, the Secretary of the Army directed the establishment of the Army Biosafety Task Force (BSTF) to lead the development of recommendations and implement the changes necessary to ensure the long-term safety and security of DoD BSAT programs. A summary of these two critical reviews follows.

Army Regulation 15-6 Investigation

In December 2015, the Investigating Officer for the Army Regulation (AR) 15-6 Investigation Team finalized the "AR 15-6 Investigation Report-Individual and Institutional Accountability for the Shipment of Viable *Bacillus anthracis* from Dugway Proving Ground" which concluded that "The inadvertent shipment of viable *Bacillus anthracis* is a serious breach of regulations, but did not pose a risk to public health." A copy of this report has previously been made available to the Committee.

The preponderance of evidence supports the AR 15-6 finding that no individual or institution was directly responsible for the unauthorized shipment of low concentrations of viable anthrax. Over the years, significant safeguards effectively ensured that the inadvertent shipments were not a threat. However, several findings related to scientific, institutional, and individual failures may have been contributing factors. The report included several recommendations: four specific scientific, several institutional, and the recommendation for twelve individuals to be held accountable for their failures to take action in response to mishaps, failure to execute oversight and ensure compliance with protocols and regulation, and failure to exercise care in performance of duties. For the accountability, all personnel actions as a consequence of the AR 15-6 are currently being addressed at the appropriate level of the chain of command.

I will discuss actions being taken to implement the AR 15-6 recommendations as I present information from the Biosafety Task Force and the development of the BSAT

Biosafety Program Office (BBPO) that will serve to provide continuity to future execution of oversight by the EARO.

Army BSTF

I am pleased to describe the progress of the Army BSTF and the four lines of improvement it has addressed with the completion of its work in January 2016. This Task Force reviewed the recommendations made by the DoD Review Committee and accompanying direction from the Office of the Secretary of Defense and developed implementing tasks and guidance in the form of an Army Directive to ensure the long-term safety and security of BSAT programs. The Army Directive is currently in staffing for Secretary of the Army approval. The Task Force capitalized on the best subject matter experts inside and outside the DoD to adopt science-based policies and proven management procedures for the military Services to operate in a safe and secure manner for the foreseeable future. The four working group specific lines of improvement described above are shown below:

1. Anthrax inactivation studies. This task is the development of a peer reviewed protocol for the inactivation and viability testing of anthrax that incorporates quality assurance. This recommendation was accepted by the Acting Secretary of the Army to approve the draft anthrax inactivation and viability testing Standing Operating Procedure pending the completion of scientific research being performed by ECBC. We have already started the inactivation initiative and a 90- day review will be submitted in May 2016. Emphasis is on validating inactivation and viability testing for a standardized

spore production. The results of this initiative should also answer the concerns raised in the AR 15-6 investigation concerning the potential healing process as well.

2. Understand and Manage Customer Requirements. The Army Joint Program Executive Office Critical Reagents Program has been eliminated and a new program, the Defense Biological Products Assurance Office, has been created to address DoD and non-DoD BSAT needs. Shipments of BSAT materials from the LSD at DPG have ceased. Enhanced tracking systems are being developed to ensure increased accountability and traceability of DoD BSAT material. This initiative involves two tasks, one to identify and develop a centralized Information Technology (IT) system to track and maintain records of material transfers and a second task to develop processes and implement policy to evaluate and approve/disapprove customer requirements to provide BSAT or an appropriate alternative. The first task was approved by the Acting Secretary of the Army and will provide end-to-end tracking, record keeping, and internal movements of BSAT, BSAT derived, and exempt materials. Integration of databases is under development to avoid duplication and provide leadership with visibility. The second task provides for an evaluation of the need for BSAT, BSAT derived, or BSAT exempt material by non-DoD entities, by the EARO.

3. Governance. This BSTF working group had three sub-working groups and made determinations on five important tasks. The first task was to make a recommendation as to who should serve as the Responsible Official to carry out the Army's Executive Agent (EA) responsibilities for the DoD BSAT Biosafety Program. The Secretary of the Army designated the Army Surgeon General, as the Responsible Official to act on his behalf for all EA responsibilities for the DoD BSAT Biosafety

Program. The second task was to establish a standing BSAT biosafety and review anthrax panel which would be subordinate to the lead agent and available to review scientific protocols and procedures; review waiver requests, and provide biosafety and scientific guidance to the EARO. In December 2015, the Acting Secretary of the Army accepted the recommendations of the BSTF and approved the stand-up of the BSAT Biosafety and Scientific Review Panel (BSRP). Five BSRP meetings have already taken place for waiver reviews, and a May 24-25, 2016 meeting is set to initiate the review process for organizational Standing Operating Procedures that involve BSAT. The third task was to develop a strategy to streamline DoD BSAT safety and security policy. The Acting Secretary of the Army approved the strategy to streamline BSAT safety and security policy to eliminate the Army's use of the term "biosurety", and fast track revision and consolidate AR 50-1 (*Biological Surety*). The fourth task was to develop a harmonized inspection regime that balanced oversight and inspection burden. The Acting Secretary of the Army approved the recommendation for an inspection regime conducted by a single DoD joint service inspection team under the supervision of the Department of the Army Inspector General in coordination with the EARO. The fifth and final task was developing the necessary supporting materials to assist the designated Responsible Official to execute this mission and quickly implement the necessary measures in order for the Army to begin serving effectively as the EA. Additional documents for Army Directives and a BSTF final report are in staffing at this time.

4. Organization and Distribution of Research and Production. The first task was to develop recommendations of proposed alternatives to the laboratory missions,

distribution of research, development, and production activities. The Acting Secretary of the Army approved the recommendation to forward the BSTF Research, Development and Acquisition Distribution Study to the Office of the Secretary of Defense with an endorsement that additional study is required, while acknowledging the limitations of the study and the Services' concerns. The second task, to review laboratory missions and chains of command and provide appropriate policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across all laboratories was approved by the Secretary of the Army for the reassignment of WDTC-LSD to ECBC under the Research, Development and Engineering Command. A Memorandum of Agreement and General Order is in staffing for transfer in July 2016.

Other Reviews

The DoD Inspector General (DoDIG) also provided a report for comment with very similar findings and similar recommendations to track results, ensure regular inspections, coordinate external reviews, develop standard training, issue guidance for technical and scientific reviews, and to develop site specific security. The DoD agrees with the DoDIG's findings and recommendations and will act on those in conjunction with other recommended actions.

The Department has also received seven recommendations from the Government Accountability Office (GAO) draft report GAO-16-305, "HIGH-CONTAINMENT LABORATORIES: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," dated January 13, 2016 (GAO Code 291264). The DoD appreciated the opportunity to review the draft report

and concurred with the recommendations of the GAO. We will ensure that the GAO's recommendations are carefully considered and appropriately captured in policy revisions and in the development of associated guidance.

Way ahead

As we look toward the future, we anticipate that within one year, the Inactivation study will be completed, the BBPO office will be at full operating capability, processes and procedures for all BSAT entities will be in review by the BSAT-BSRP, and the integrated IT solution will be implemented.

In conclusion, DoD's goal is to develop a system that incorporates the fundamentals of quality policies and systems. Establishing strong and robust processes that are continually evaluated and improved upon is our best defense against potential human accidental or management lapses. We believe the DoD systems being developed will provide for the necessary checks and balances to prevent or minimize the impacts of future accidental human and procedural missteps. Quality procedures do not stand alone as they must be incorporated along with personnel training, evaluation and encouragement followed by review, oversight, documentation and reporting in order to have a whole systematic approach to manage the successful and safe performance of BSAT personnel and institutions. Finally, it is imperative we partner with other federal and private organizations to ensure transparency of this critical program and ensure the safety of the US and confidence in the responsible execution of this critical program for the DoD.

Mr. MURPHY. Thank you. I recognize myself for 5 minutes.

General, I see you have a parachutist badge on you there. I'm assuming you've jumped a few times. Did you pack your own parachute?

MG LEIN. No, sir.

Mr. MURPHY. Someone just said don't worry about this? A stranger says, "here's your parachute, everything's fine"? Did you doublecheck things?

MG LEIN. Yes, sir.

Mr. MURPHY. Absolutely.

MG LEIN. That's part of the JR—the prejump inspection that's required——

Mr. MURPHY. Exactly.

MG LEIN [continuing]. Not by you, just by you, but by——

Mr. MURPHY. By everybody, right?

MG LEIN [continuing]. By your senior——

Mr. MURPHY. And I'm assuming also it's standard in the military, someone hands you a weapon and says, "Don't worry, it's not loaded," you check it anyways, right?

MG LEIN. Yes, sir.

Mr. MURPHY. So I go back to the thing, because it could be dangerous and you don't want to jump without a parachute that works.

So I go back to this omission, Doctor, and when I asked you to clarify this point of the six vials and two of them were alive they were treated as if they were not and you said oh, it was only later on it was discovered.

That is the core of this hearing and why we keep coming back here, because you treated them as if they weren't. And the fact is the way they were handled too they could have broken. We would have exposure of small pox.

But this is what we mean about the culture of complacency. We just assume, oh, these couldn't possibly be alive. You treat it like it's a loaded gun. You treat it like it's alive, and you didn't.

And even when I asked for a clarification, you once again said, "Oh, we didn't discover that until later." That's the point of this hearing, that you're supposed to treat it as if it is.

Now, let me talk about it, the NIH did not undertake an internal investigation of the root cause and circumstances that led to the boxes containing smallpox being overlooked apparently for decades, even though an international agreement and later Federal law and the regulations required the NIH to account for all smallpox vials in these facilities.

Now, our understanding is that the NIH did not do the internal investigation because of the ongoing CDC and FBI investigation and the subsequent referral to HHS Office of Inspector General. Is that correct?

Dr. TABAK. Yes, sir.

Mr. MURPHY. However, in 2012 the NIH conducted an internal investigation into the improperly stored antibiotic-resistant anthrax incidence while the CDC was investigating. So the pending CDC investigation did not prevent the NIH from conducting an interim investigation into the improperly stored anthrax. Is that correct? You have to turn the microphone on and pull it close to you.

Dr. TABAK. We did conduct and investigation at that time to ascertain where the samples were derived from and who had the samples, and then subsequently reviewed samples from everybody who was a registered user of bacillus anthracis and then following that a survey of all investigators who were registered for select agents.

Mr. MURPHY. We note you led a task force in 2015 to investigate the serious problems with NIH Clinical Center of Pharmaceutical Development section during an ongoing FDA investigation.

So the pending FDA investigation did not prevent the NIH from conducting an internal investigation into the NIH PDS. Is that correct?

Dr. TABAK. Yes, sir.

Mr. MURPHY. Now, the Department of Defense launched their accountability investigation while the CDC and the FBI were still investigating those shipments of live anthrax from Dugway Proving Grounds.

Since the DoD started their internal investigation during this pending investigation, why was it that the current—that NIH could have started all their internal investigations into the root causes back in July of 2014? Why couldn't that be started back then?

Dr. TABAK. It's been our policy not to initiate investigations of this type while there's an ongoing investigation from either the FBI and/or the IG.

Mr. MURPHY. Why not?

Dr. TABAK. We understand that we are not supposed to compromise those investigations in any way.

Mr. MURPHY. DoD managed to do it. DoD said, hey, safety comes first, we're checking into this. We're kicking down doors. And you guys say, hey, let's hold off on this, when you could have been investigating.

Dr. TABAK. We held off on what has been termed the root cause analysis. But we did not stand by idly. We did in fact institute many additional procedures to enhance the safety of what we were doing.

Mr. MURPHY. I don't believe you, because we already established that in moving those smallpox vials you didn't treat them as if they were live and even though you said this morning, well, we didn't discover that until later, you should treat it as if it is alive.

So in August of 2014, CDC Division of Select Agents and Toxins sent a memorandum to NIH detailing the findings of a joint CDC/FBI investigation into the discover of the smallpox vials.

At this point, the joint CDC/FBI investigation was over. So couldn't the NIH have started their internal investigations based on the finding of this report and did you know about this report back in August of 2014? You're still saying you couldn't have done anything?

Dr. TABAK. Again, it was an ongoing IG investigation and in fact we still have not been formally notified by the IG that that investigation is closed.

Mr. MURPHY. Well, I'm out of time. I will turn it over to Ms. Castro for 5 minutes.

Ms. CASTOR. After a number of the incidents involving anthrax and ebola and other dangerous pathogens it was very important for

this committee to ask the GAO to produce a detailed over view and report because when it comes to working with these deadly pathogens there simply is no room for error and rigorous safety policies must be followed.

GAO looked at eight departments and 15 agencies to assess their high-containment lab policies and oversight. GAO's report concludes that the majority of policies were not comprehensive and some were out of date or nonexistent.

Mr. Neumann, could you walk us through this key finding and why having comprehensive and up to date policies is important?

Mr. NEUMANN. Sure, I'd be happy to.

Certainly, we know that there's important research being done and, you know, when there's a safety incidence it interferes with this research.

So when you don't have policies in place or procedures that ensure that those are being carried out it puts that research at risk and also puts personnel at risk. And what we found is that this comprehensive oversight was not in place.

Some policies that would really help the foundation of the lab safety culture were not in place and furthermore there weren't the oversight mechanisms that can ensure that these policies are being carried out.

And then, finally, leadership was not informed of some key incidents and the inspection result was all important for ensuring that these labs are being overseen properly.

Ms. CASTOR. OK. So let's get more specific. Your report concluded that the departments and agencies are using inspections as their primary activity to oversee the management of hazardous biological materials.

However, as you testified, some agencies do not routinely report the results of these inspections to senior officials. What issues are presented by this finding of incomplete information sharing?

Mr. NEUMANN. Well, certainly, without having those inspection results or incident reports, leadership can't determine if there's systemic issues that need to be addressed across the labs.

Ms. CASTOR. During your oversight and interviews, were all of the agencies forthcoming? Did they provide the materials you requested? Was there any resistance to providing any information to GAO?

Mr. NEUMANN. No, all the agencies and departments complied with our request and we worked very closely with them to identify the policies and procedures.

So we got great cooperation from the agencies.

Ms. CASTOR. OK. General Lein, many think that in addition to all of these inspections and oversight and policies that one of the greatest risks we face is from theft or misuse of a deadly pathogen and we certainly had an incident of that at Fort Derrick in 2001.

Tell us, since 2001 what have you done to strengthen all of your oversight and your ability to root out potential theft or misuse of deadly pathogens.

MG LEIN. Ma'am, thank you.

We've done several things in inventory management process with 100 percent review of what's in each one of the labs on an annual basis at the Research Institute of Infectious Disease.

Everybody that works in the lab has got to be vetted for security processes, coming to the lab and to work into the lab, and then recently we are completely redoing who it is and where it is that we ship all of our agents.

So we used to have the critical re-agent program which was the process whereby external labs would get the information from us or get the samples from us. It did not have full accountability of all the systems and there were often labs that were able to—because of a direct contract were able to send.

We have since shut that down, and after the moratorium was lifted everything will have to get requested through this new office with the requirement of a peer review before it even gets shipped out of ensuring that they need the highest level of toxin and why can't we substitute a lesser level of toxin that can never be moved into a BSAT program.

And so associated with that there will also be a use-by date like the carton of milk and that that specimen that we send out must be used by and then we must get a message back from the lab that we sent it to that it's either used or they destroyed it or they're returning the specimen back to us.

So we maintain full accountability of all of the specimens that we've got within our program.

Ms. CASTOR. I'd like to ask this—the CDC, Dr. Monroe, what policies and procedures are newly in place to prevent theft or misuse of deadly pathogen?

Dr. MONROE. Thank you. First, I would emphasize that our laboratory safety review board, which reviews all the policies for inactivation and transfer of materials from our highest containment biosafety level three and four labs.

Has looked at those policies both initially when they were initially released from the moratorium imposed by Dr. Frieden and then on an annual basis. And so we've come up now on having annual review of some of those procedures.

Importantly, all of those procedures include a step that we we refer to as secondary verification. So as has been pointed out, it's not only important to have the right policies but you have to show that there's adherence to those policies.

And by having the secondary verification step of either a second person watching or a time stamp or something that verifies that an activation procedure was done as described in the policy is a critical part of our inactivation policies for anything that's brought out from high-containment to lower levels of containment.

In terms of the personnel, we also, along with others, have instituted a so-called personnel suitability program for those that have access to the highest risk pathogens—the so-called tier one pathogens.

Ms. CASTOR. Thank you.

Mr. MURPHY. I have to follow up with you, Dr. Tabak, on just on that line of questioning about the timing of your own investigation.

We were informed that CDC was recently notified by the HHS Office of Inspector General to close out all the NIH referrals, given that there's no known pending potential investigation will the NIH now commit to conducting an internal investigation?

Dr. TABAK. Absolutely.

Mr. MURPHY. Thank you. I now recognize Mr. McKinley, vice chairman of the committee.

Mr. MCKINLEY. I thank you, Mr. Chairman.

Mr. Neumann, if I could spend a little time on your report. You've got a chart on Page 5 of the six elements that you were referring to in compliance.

I know that they're not all the same in weight. So I don't know which ones are more important than others in compliance. Would you suggest to us which are the ones that we should be spending more attention to of those six elements?

Unless you're going to tell me they're all equal, which I doubt.

Mr. NEUMANN. Well, I think we determined that there were 60 elements. We didn't weight them. But incident reporting is certainly one that has more immediate impact. If incidents are reported to senior leadership they can take action on the systemic issues that are identified.

Mr. MCKINLEY. OK. If that's number one, what would number two be?

Mr. NEUMANN. Like I said, inventory control also is very important——

Mr. MCKINLEY. I understand.

Mr. NEUMANN [continuing]. Because keeping track of the specimens. Each of these have their importance. Training, for example.

Mr. MCKINLEY. Inventory control might be number two?

Mr. NEUMANN. Excuse me?

Mr. MCKINLEY. Inventory control might be number two?

Mr. NEUMANN. In my mind, yes. Definitely there's an important step.

Mr. MCKINLEY. I'm just trying to understand not everything is going to be equal. So I'm trying to—for example, in your report you say that two of the agencies wouldn't cooperate or said they didn't think anything more was necessary—Department of Energy and the EPA. And I looked at your chart and I see the EPA under their pesticide program those are the two—number one and number two—in your mind that they're not complying with and yet they think everything is copasetic.

Mr. NEUMANN. Yes, and we disagreed with their position.

Mr. MCKINLEY. Thank you.

Do you disagree then with DoE as well? Because Doe also has numbers of violations as well in that. The others seem to think that they're in compliance.

Mr. NEUMANN. Yes, I think that we believe that these recommendations are important in establishing the foundation for the lab safety.

Mr. MCKINLEY. Well, I think that if—what I've heard here a little bit is it sounds like everyone at the panel all thinks they're in compliance, that everything is just fine.

But I know in 2009 your department put together a report that said that there needs to be an oversight, someone to look over all the agencies.

But that was rejected as being cumbersome and overly broad. Do you still think it's cumbersome, overly broad? Or is it something that's necessary, because you just heard the testimony. Everyone

thinks they're in control. But there's a real question in America whether they are. So what do you think?

Mr. NEUMANN. Well, our recommendation still stands open. The one we made in 2009 was looking more broadly at all high-containment labs, not just the Federal labs.

This report we focused on the Federal high-containment labs. But that recommendation we still openly stand by that. But there could be better oversight with a single entity to oversee all these labs given the fragmentated——

Mr. MCKINLEY. One of them that might help but I'm afraid of a software type thing is IV&V. Do you see how IV&V might have an impact here whereas the IV&V—I don't want to suggest what I—you're familiar with IV&V?

Mr. NEUMANN. I'm not familiar with that, no.

Mr. MCKINLEY. Independent verification and validation?

Mr. NEUMANN. Oh, yes. Yes. Uh-huh.

Mr. MCKINLEY. OK. NASA has been using it successfully ever since the rocket explosion. Others have used it. Unfortunately, the Obama administration chose not to use IV&V when they put out the registration and, you know, the computer system all collapsed under the registration.

I don't know whether that would help out. Would IV&V be of any help to these or is that just going to be checking the box?

Mr. NEUMANN. Well, certainly, any type of verification is going to be useful. There needs to be a system of independent verification, inventory control, all these different steps to ensure that you have——

Mr. MCKINLEY. But would they just check the box, or if there's no one overlooking their shoulder, who's going to know that they've actually done something as a result of checking the box?

Mr. NEUMANN. Well, that's why the oversight mechanisms are so important that leadership be paying attention to the labs and ensuring that they're being inspected and they're reviewing the results of those inspections to see where there might be lapses.

Mr. MCKINLEY. So in the time, is that something that perhaps you would—the GAO would look at as a recommendation that maybe IV&V should be implemented under each of these labs?

Mr. NEUMANN. We didn't look specifically at that but I think the leadership oversight is going to be really important to ensure that these mechanisms are actually operating, not just policies.

Mr. MCKINLEY. My question is would you consider that in the future in looking at that to see whether or not there might—other agencies have found it to be very useful and I'm just wondering whether or not you see it from your perspective with the lab will they simply just use it to check the box and not do anything about it?

Mr. NEUMANN. Well, I definitely would like to take some time to think that over. Perhaps we can provide a response for the record.

Mr. MCKINLEY. If you would, please. And my time has expired so I thank you, Mr. Chairman. I yield back my time.

Mr. MURPHY. Thank you. I now recognize Mr. Griffith of Virginia for 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Thank you all for participating in this hearing today.

Dr. Tabak, I understand that the historical collection that contains the smallpox vials where there was a problem that had been previously discussed is not the only historical collection at NIH.

In fact, in 2002 or 2003, NIH registered a historical collection that included plague and Burkholderia samples using the information listed on labels for sealed envelopes. Isn't that correct?

Dr. TABAK. Yes, sir.

Mr. GRIFFITH. And did anyone at NIH open the envelopes at the time to check not only the accuracy of the samples but also to ensure that the samples were intact?

Dr. TABAK. To my knowledge, they did not.

Mr. GRIFFITH. And I also understand that in 2007 the NIH office responsible for overseeing compliance with select agent regulations reregistered these select agents again without opening the sealed envelopes. Isn't that correct?

Dr. TABAK. It is. The reason they did not open them at the time is that they were not registered to work with that particular agent in the laboratory where they were brought.

Mr. GRIFFITH. So the individuals who were looking at it weren't registered to deal with the plague or Burkholderia?

Dr. TABAK. The laboratory was not registered and so they needed to file an amendment so that they could in fact work with those agents.

Mr. GRIFFITH. OK. So they did that and then from my understanding in 2008 they finally opened the envelopes up and the materials contained were not the same as what had been registered back in 2002, 2003 with the select agent program twice earlier.

They weren't the same as had been previously registered and that one of the envelopes contained more vials of Burkholderia than was listed. Isn't that accurate?

Dr. TABAK. That is correct. It has been described to me as a clerical error that indeed they did know that there were 39 vials but unfortunately it was transcribed inaccurately, and so that's my understanding of it.

Mr. GRIFFITH. So there were 39 vials, but they had it written down as 32?

Dr. TABAK. I may be misspeaking but, yes, there was a difference of, I believe, seven vials.

Mr. GRIFFITH. Now, I was not—obviously, I'm familiar with the plague. I was not familiar with Burkholderia, and so I looked it up online. So my sources are Internet sources. They may or may not be accurate.

So you get me straight if I've got it wrong. But it looks like it depicts mostly horses but there are a couple of species or subspecies of the bacteria that affect human beings.

Do you know whether the samples that were discovered in 2008 were the type of species of Burkholderia that affect horses or were they the type that affect humans?

Dr. TABAK. I do not know the answer to that.

Mr. GRIFFITH. And could you please find that out for us because in my research it indicated that at least two of the species not only affect humans but are considered possible agents for biological warfare?

Dr. TABAK. Indeed, and this is why they were treated as select agents and contained. But I will find out the answer for the record, sir.

Mr. GRIFFITH. If you could let me know I would greatly appreciate that. Dr. Pillai—did I say it right? All right.

And you're now with the Office of Laboratory Science and Safety at the FDA and it's a fairly new office. What is the budget for your office and how many staff do you have?

Dr. PILLAI. So as you mentioned, it's fairly a new office that we are trying to stand up at the current time. We have actually worked out this for the division and planned a mission for the office and have actually pulled together a budget and we have put in the budget request to our senior leadership, the Office of Operations, to the Office of the Commissioner, and both of those offices are working diligently to ensure that we get the necessary budget support needed to stand up the office.

The request that we have proposed was $2.8 million to basically staff with 14 members to ensure that we can address all the safety and security-related issues at FDA.

Mr. GRIFFITH. All right. And can you get us that once it's been approved by the other folks? Can you get us a copy of that budget?

Dr. PILLAI. Absolutely.

Mr. GRIFFITH. I would appreciate that, and who is it that you report to?

Dr. PILLAI. At the current time I report to the Office of the Chief Scientist and to the Commissioner through the Office of the chief scientist. The external laboratory safety working group's recommendation was for this position to be a direct report to the commissioner.

As you are fully aware, that we have a new commissioner on deck at the current time, Dr. Robert Califf. Dr. Califf is taking a look at all of the organizational structures at the current time and you'll make a final call and decision as to what the department structure should be.

Mr. GRIFFITH. All right. I do appreciate that. I see my time is up and I yield back. Thank you, sir.

Mr. MURPHY. Thank you. I now recognize Mrs. Brooks for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman.

As the panelists might know, yesterday both NATO and the European Union intelligence officials indicated that there are, quote, "justified concerns," end quote, that ISIS is working on obtaining biological material needed to carry out an attack.

With persistent analysis like this supporting the notion that terrorists are actively looking to acquire a weapon of mass destruction, I certainly hope that our Government will redouble our efforts in protecting sensitive materials from getting into the wrong hands.

We also know that in October it was revealed that a 26-year-old Moroccan-born man who had worked in a sensitive area in a nuclear power plant in Belgium died in the spring while fighting for ISIS.

This terrorist had passed a background check and had access to a secure area where the nuclear reactor is located. Obviously, it

can happen in the biological space as well. We shouldn't forget that the perpetrator of the '01 anthrax incident was a scientist who worked at the Government's biodefense labs at Fort Derrick.

I bring that up because we can have all the policies and procedures in place and we can have taken corrective actions and so forth. But I'm curious, Mr. Neumann, did you and GAO look at the security level of personnel in your report?

Mr. NEUMANN. We did not. We looked at the policies we had in place to ensure that they had all these key elements. We looked at the oversight mechanisms to make sure they were checking them and we looked at——

Mrs. BROOKS. I understand that. But what about security and background checks? Why did you not look at security and background when it has to do with personnel actually following or not following these procedures?

Mr. NEUMANN. This was a broad look at all the Federal departments and agencies or the eight departments and 50 agencies. So just getting a sense of their policy and procedures they have in place and the oversight mechanisms was quite a large volume of work.

So we didn't drill down in specific aspects of this. But that's definitely an area that we could, you know, potentially follow up on if there's interest in that.

But it's part of making sure that you have the checks and balances with the policies and the oversight mechanisms to make sure that all the policies are being followed.

Mrs. BROOKS. And I certainly appreciate it and don't want to take away from your work. But I do think that is of critical importance and I'm going to ask very briefly, because I have a different line of questioning for Dr. Tabak, but if you could please each agency indicate, and I may ask for the record, we may submit questions for the record with respect to what level of security clearances do your personnel have who have access to these deadly pathogens, how often are they cleared, because it's very common for many agencies to have that clearance process when an individual comes in to an agency, but often maybe not checked on routinely every few years, and I'm curious about that, as well as what is the level of security clearance that the personnel must have.

So I will be submitting those questions for the record for each of your agencies. I believe that Major General indicated that certainly people are vetted, and I assume that people are vetted within your agencies.

But having been a former U.S. attorney and going through security background checks I'm very interested in knowing what level of security clearances all of the personnel that have any access.

I'm not just talking about the scientists. I'm talking about all levels of personnel. I'm curious to know what level of background checks are performed.

Dr. Tabak, I'm very curious to know because the majority staff investigation found that the National Cancer Institute of Frederick does not report to the NIH Safety Office on the main campus. Who does the safety officer at NCI Frederick report to?

Dr. TABAK. Ultimately, to the director of the NCI.

Mrs. BROOKS. Who do they directly report to?

Dr. TABAK. They report up to the scientific director of the NCI Frederick and then in turn that individual reports up to the director of the NCI who, of course, reports up to the director of NIH.

Mrs. BROOKS. So is the NIH management of safety—is it centralized or is it decentralized across the various campuses? I've just visited your incredible campus. It's a very, very large place. Is it decentralized or is it centralized?

Dr. TABAK. In the case of the NCI Frederick they have this separate reporting chain. Everything else is centralized in one place.

Mrs. BROOKS. And we heard from Mr. Neumann that—do you receive reports of select agent inspection results now?

Dr. TABAK. I do indeed.

Mrs. BROOKS. OK. Does Dr. Collins?

Dr. TABAK. I notify Dr. Collins when there are variations—if there are issues that are problematic.

Mrs. BROOKS. And we've heard that according to HHS comments and response to the GAO's report, the associate director of research services is the designated agency safety and health official. Does this individual report to your or Dr. Collins about lab safety issues?

Dr. TABAK. The responsible official reports through a chain of the director of division of occupational health services who reports to our director of the Office of Research Services who reports to our Deputy Director for Management, who in turn, you know, works through me to Dr. Collins.

But each individual is required to move up the chain if the next person up does not respond for some reason and indeed when there are serious issues we are all immediately notified simultaneously.

Mrs. BROOKS. OK. Thank you. I yield back.

Mr. MURPHY. Just clarifying, Dr. Monroe, who do you report to?

Dr. MONROE. I report directly to Dr. Tom Frieden, the CDC Director.

Mr. MURPHY. OK. Thank you.

I recognize Mr. Hudson for 5 minutes.

Mr. HUDSON. Thank you, Mr. Chairman, and thank you to the panel for being here.

Dr. Pillai, the NIH office that had the smallpox boxes was reassigned to the FDA in 1972. Why didn't the FDA do any sort of inventory over the room when it was transferred to control at that point or at any time from 1972 to 2014.

It seems to me that one simple inventory, something that businesses back in my district do every year, would have caught this mistake.

Dr. PILLAI. I agree with you totally. I think this is one of the failure points that we have encountered for this incident. You know, one of the key points that I'd like to make is that by nature laboratory scientists, right, they tend to attend to the materials that belongs to them and they don't really look into other people's properties or materials and this is one of those areas where it was a shared laboratory storage cold room, basically.

So there was no one single individual assigned to be responsible for the inventory or whatever was contained in that cold storage facility.

Mr. HUDSON. Has that been changed now?

Dr. PILLAI. That's been changed. What they've done is ever since this incidence has taken place we have actually assigned a single individual to be responsible for any cold storage areas that's been shared by multiple scientists and all the materials in the cold storage must be labelled with the PI's name along with the content and the date so that you can actually do a very simple easy inventory control process as to who it belongs to and what the contents are.

Mr. HUDSON. Appreciate that answer. When we asked FDA why it failed to utilize proper inventory controls in the cold storage room we were told that this room is apparently not subject to inventory controls since there was no accountable Government property inside the cold storage room.

Accountable Government property is a term that's defined as all computers and pieces of equipment with a value of more than $5,000. But how could FDA know there's no accountable Government property if they hadn't done an inventory?

Dr. PILLAI. That's a very good point. In most cases, cold storage facilities actually are used to store reagents and supplies and things of that nature, which usually doesn't amount to greater than $5,000.

As such, there's usually not a custodial individual assigned to the cold storage areas where you're basically storing medias and things of that nature. This is one of those incidents that we do not anticipate such a problem to take place.

We would have put in appropriate safety protocols and policies in place to address that. But this was a valuable lesson learned and we are looking forward to implementing the appropriate policies and procedures and managers can ensure that this doesn't happen again.

Mr. HUDSON. So your opinion now—any kind of critical reagent programs, they have a value of some $500 to $1,000 apiece. I mean, would, in your opinion, they now be considered this Government property that needs to be inventoried? I mean, has there been a change of mind set in terms of—instead of just making $5,000 and up we need to have an inventory of everything?

Dr. PILLAI. I mean, talk about equipments and things of that nature—if you're talking about an instrument and equipment and anything to the nature that is a custodial individual assigned to ensure the responsible—to ensure and be responsible for that particular property.

When in the case of the cold room the situation is different whereby what we are doing is we are getting a full inventory control of what the contents are.

This is where you usually store biological materials as well as freezes and things of that nature. So we have implemented a policy at FDA to have a full inventory control of all the biological agents, not just the BSL–3 agents but also the risk two agents as well as the risk three agents.

So now we have a full account of every materials where they are stored, the location, who it belongs to and every time an individual takes the material for work to work on it or to add a new agent to the list, they update that information on a daily basis.

So this will allow us to control this select agents and high consequence pathogens in a much more efficient manner.

Mr. HUDSON. So just to clarify, so going forward, vials of biological pathogens are no longer not considered important enough to be inventoried or as an accountable Government property there's no discrepancy now?

Is that what you're telling me in terms of having a dollar amount? If it's a pathogen, it's going to be inventoried?

Dr. PILLAI. That's right. If it's a high-consequence pathogen or it is a hazardous biological agents and toxins it will be in the inventoried.

Mr. HUDSON. OK. Thank you for that.

Mr. Chairman, I see I'm running out of time. I'll go ahead and yield back.

Mr. MURPHY. If I could just take the last few seconds, let me ask the panel here, except for DoD: So within this, given all the sweeps that you've done are there any more orphan pathogens of any kind that are not identified who they're with?

Dr. Tabak, are there any more? You've done all these sweeps. Everything has been checked. Is there any more vial samples, anything that you don't know where it's come from, who it belongs to?

Dr. TABAK. Not to our knowledge.

Mr. MURPHY. Dr. Monroe.

Dr. MONROE. Everything has been inventoried.

Mr. MURPHY. Dr. Pillai.

Dr. PILLAI. Yes, every agent has been inventoried and accounted for by the FDA.

Mr. MURPHY. Thank you. Mr. Mullin, you're recognized for 5 minutes.

Mr. MULLIN. Thank you, Mr. Chairman. I'm going to follow up on your questions, too.

Even after we got the information that anthrax had been basically not kept good records on and it had been shipped around, being used for experiments, people not knowing where they're at.

Once you discovered this you decided to do an inventory and look for anthrax, if any more had taken place. And specifically, NIH limited the search to only anthrax. Why was this?

Dr. TABAK. If I may clarify, this was done in two steps. The initial search indeed was limited to those investigators working with bacillus anthracis. But after we discovered additional issues, we expanded that to include all principal investigators working with any select agent.

Mr. MULLIN. When did you expand that?

Dr. TABAK. During that same year, sir. And so——

Mr. MULLIN. What was the discovery of that?

Dr. TABAK. I'm sorry?

Mr. MULLIN. What did you discover in that? Because when you started searching for anthrax you found other cases even after it was revealed that it wasn't properly followed and the procedures wasn't followed. You found other issues with anthrax. So what else did you find?

Dr. TABAK. So subsequently we searched cold storage areas with any principal investigator working with select agents.

We searched over 6 million vials, vial by vial. And so that was a very comprehensive search that was undertaken. So it was a two-step process. I know——

Mr. MULLIN. But what else did you discover? Other than anthrax what else was being improperly labeled and shipped around without the knowledge of NIH?

Dr. TABAK. The search only revealed, to my knowledge, things related to different forms of anthrax.

Mr. MULLIN. Mr. Tabak, just please help me here with your knowledge. We're talking about very serious consequences if this gets out, and to your knowledge you can't give me a definite answer?

We're talking about serious diseases. We're talking about things that could be used against us. We're talking about if they leaked out it could have serious consequences throughout areas of contact.

And you're telling me your knowledge. I'm asking for specifics.

Dr. TABAK. Sir, I understand the gravity of the situation. I'm giving you the response that I can give you. I will provide for the record additional details so that I can——

Mr. MULLIN. Is it classified? Is that why you can't give me——

Dr. TABAK. No, sir. It is not.

Mr. MULLIN. OK. So the response—that's what I'm trying to get to. And, sir, I mean absolutely no disrespect. But as something as this serious I would think you would have definite answers for.

Dr. TABAK. And I am trying not to misspeak and so I'm giving you the best answer I can.

Mr. MULLIN. I apologize with that.

Dr. TABAK. And for the record, I will give you with certainty if any additional agents besides those related to anthrax were found in this 2008 time frame.

Mr. MULLIN. So what caused you guys to open the research and search for further information. After you had simply opened it up for anthrax, what led you to decide, hey, let's look farther into this?

Dr. TABAK. When we discovered additional vials of anthrax that were unaccounted for and anthrax spores that were unaccounted for in laboratories and it was at that point that we decided that we needed to broaden the search and do a vial by vial for everybody who had the use of select agents.

Mr. MULLIN. Do you have any additional cases showed up with anthrax?

Dr. TABAK. So we found 30 vials in one laboratory——

Mr. MULLIN. That were unaccounted for, 30? Thirty in one laboratory?

Dr. TABAK. These were unaccounted for. These were findings that we made. Thirty vials in one laboratory that had not been entered properly.

Four vials in a second laboratory that had not been entered properly and in six vials a third laboratory that had not been entered properly.

Mr. MULLIN. Was this due to procedures not being followed or procedures not in place?

Dr. TABAK. I believe in one instance procedures were not followed and I would say in the other two instances I believe it was really due to human error.

Mr. MULLIN. Thank you. I look forward to your response on the other one too. Thank you for getting back to me and Mr. Chairman, I'll yield back.

Mr. MURPHY. Thank you. I don't know if Ms. Castor has any more questions. I want to ask a couple more quick ones. Mrs. Brooks, did you want to be recognized for a quick question?

Mrs. BROOKS. Thank you, Mr. Chairman.

Very briefly, and this would be to Major General Lein.

In its report, GAO recommended to DoD that it require all high-containment labs including those not registered with the select agent program to report the results of any agency inspections to DoD.

DoD told GAO that it had no plans to implement such a requirement. Why does the department disagree with GAO on this issue and why not require reporting inspections of all high-containment labs and not just the select agent registered labs?

MG LEIN. Ma'am, I have to get back to you on that. We should be reporting all of the—not just the labs but all of our high-containment labs. So I owe you a response to that.

Mrs. BROOKS. Thank you. We agree.

MG LEIN. So just follow on the recommendations from the GAO report.

Mrs. BROOKS. OK. We'll look forward to your response, or changes and procedures. Thank you. I yield back.

Mr. MURPHY. Thank you. I have a couple more questions. I think we're waiting for Dr. Burgess. But Dr. Tabak, has the NIH ever taken any personnel actions related to not complying with select agent regulations?

Dr. TABAK. Because of the sensitivity of personnel actions, sir, I would hope that we could discuss that with you and the committee in another venue.

Mr. MURPHY. Can you tell us numbers?

Dr. TABAK. Again, because of the numbers involved, sir, I would—because of the——

Mr. MURPHY. Is that a yes, that something has happened?

Dr. TABAK. I'm sorry, sir?

Mr. MURPHY. So is it a yes that some personnel action has happened, but you would talk about the other things privately?

Dr. TABAK. I would prefer to, sir, we discuss that in another venue with you.

Mr. MURPHY. Well, we're trying to get the answer to this. So Government employees? They're Government employees?

Dr. TABAK. Yes, sir.

Mr. MURPHY. Generally, are they Government employees, and I—wasn't some personnel action taken among people who mishandled the procedures for the anthrax?

MG LEIN. Yes, sir. Twelve recommendations for 12 personnel at Life Sciences.

Mr. MURPHY. OK. And I don't need to know their names or anything, but action took place. So you are taking some action, yes?

I'd be willing to talk about some other things with—I mean, I think both sides would like assurance on that.

Dr. TABAK. Again, sir, because of the relatively small numbers of individuals I think we would be breaching confidentiality to have a conversation publicly.

Mr. MURPHY. Yes or no? Actions taken place?

Dr. TABAK. Actions were initiated.

Mr. MURPHY. OK. That helps us. We can proceed. Has the FDA began an interim investigation to the root cause or facts and circumstances surrounding the discovery of smallpox vials in an FDA laboratory on the NIH campus—into root cause?

Dr. PILLAI. So like my colleague, Dr. Tabak, given the fact that there was an FBI investigation complemented with a CDC select agent followed by an OIG inspection that is ongoing we have decided not to interfere with the process and have laid back. My understanding is that the OIG investigation is coming to an end and given the fact that that report is going to be available to us in the near term we are initiating a process to understand the root cause for the event that took place in 2014 and understand what the failure points are and then we plan to mitigate those failure points through implementation of appropriate policies and procedures.

Mr. MURPHY. OK. So it's the OIG inspection is over?

Dr. PILLAI. That's my understanding. My understanding is——

Mr. MURPHY. Yes, it's true? And so did you have a plan in place saying hey, as soon as this investigation is over we're ready to move forward?

Dr. PILLAI. Right.

Mr. MURPHY. So you do have a plan ready?

Dr. PILLAI. We have a plan.

Mr. MURPHY. So when you said—but now you're discussing it. It should be the moment you were told you said now let's roll with ours. So it is happening now?

Dr. PILLAI. Yes.

Mr. MURPHY. And after FDA personnel found a smallpox vials they transferred them to the NIH responsible official apparently without taking any steps to package and transfer the vials in a safe manner.

In fact, the FBI and CDC highlighted that the individuals who carried the boxes to NIH responsible officer heard the vials clinking together. What steps should this individual have taken in transporting the vials?

Dr. PILLAI. This is one of those situations where we had not anticipated to take place. So there were no appropriate safety procedures and protocols for the transfer of such materials from one——

Mr. MURPHY. I'm stopping you there. That's why we're having this hearing.

Dr. PILLAI. Right.

Mr. MURPHY. So how long has FDA been involved with diseases? Since your beginning.

Dr. PILLAI. Right.

Mr. MURPHY. So you ought to have some—for you to tell me you had not anticipated that you'd be transporting something that's a viable pathogen with deadly results—you had not anticipated that? I'm sorry, that's just not acceptable, Doctor. That's why we keep having these hearings.

How many personnel from the FDA have been involved in investigating this problem?

Dr. PILLAI. I totally agree with you.

Mr. MURPHY. How many personnel from the FDA have been involved in investigating this problem?

Dr. PILLAI. There is a large group of individuals involved.

Mr. MURPHY. Five? A hundred?

Dr. PILLAI. I would say not as much as a hundred but a significant number of folks.

Mr. MURPHY. How many hours have been spent on this?

Dr. PILLAI. I would say probably many hours, to be honest.

Mr. MURPHY. I don't know what many means.

Dr. PILLAI. I don't have the exact number of hours.

Mr. MURPHY. Hundreds of hours?

Dr. PILLAI. Probably.

Mr. MURPHY. Dr. Monroe, how many hours involved with CDC in investigating these things?

Dr. MONROE. Investigating——

Mr. MURPHY. Investigating these problems with pathogens and transport and some of these difficulties? Any idea?

Dr. MONROE. I would have to, you know, get back with an estimate of the number of hours. But, for each of the incidents that CDC was directly involved with, we had an internal team plus the external select team.

Mr. MURPHY. Quite a few, Dr. Tabak, I'm assuming? You may not know the numbers, but quite a few hours were involved?

Dr. TABAK. Yes, indeed.

Mr. MURPHY. So I think we'd rather have your scientists involved with science in identifying causes of diseases and cures for them. But the fact that we have had multiple hearings on this and Mr. Neumann, you were involved with hours of work in this, too, and there's lots of things your office has been doing, as well.

And then to say—Dr. Tabak, to go back to the point, you didn't even mention to this committee again that some of those pathogens were alive. Dr. Pillai, you're saying we didn't have a procedure in place for transporting these things.

Dr. PILLAI. But we do have procedures.

Mr. MURPHY. But you had said——

Dr. PILLAI. But not for pathogens of this nature. This event was unusual in the sense that when the discovery was made, it was made by scientists who are not familiar with the policies and procedures of dealing with select agents.

Mr. MURPHY. Whoa, whoa, whoa. This is an office that deals with select agents. They didn't know how to transport them? I just find this astonishing.

So here's where I'm getting to with this.

Dr. PILLAI. Right.

Mr. MURPHY. We've also been informed in the past—I'm not sure if it was CDC or someone—we have to understand these are scientists, and sometimes they get a little absent-minded and you have to—I don't accept that.

The American public doesn't accept that. Someone had salmonella. Thank goodness that person recovered, right?

But this can have deadly consequences. These are offensive weapons. I'm pleased that DoD has taken definitive action on this. This was a tragic mistake—unfortunate mistake. Luckily caught it, taken definitive action. I just don't find it acceptable the scientific community kind of gives it the shrug.

Now, we've seen that shrug before when GM was here and someone, you know, decided we're going to shrink a spring in a steering

column and, you know, save a few cents on each car and some people died. Oh, well. No one spoke up.

When Volkswagen was here someone mysteriously came up with some sort of a software formula and—suddenly, in the morning we didn't know how to pass the EPA tests, in the afternoon we suddenly did, and no one said, "How'd you do that?"

And so now they're facing so many billions of dollars worth of suits and other fines. I don't know if that company is going to survive.

But those are cars, and here we're talking about diseases, and I would hope the lesson you take from this committee—and I'm tired of going over this because we keep having this conversation.

But if your scientists are saying, "Gee, we never thought about how to transport something that's deadly—never really thought about that"—then find a new job.

Look, we all make mistakes. I mean, we're human. We make mistakes, that's what it is. I get that. I have no problem with that.

I just want to make sure we have some sense of learning, and if someone says well, yes, never had a protocol of how to transport deadly diseases from one place to another, and the bottles are clinking together—gee, what do I do about that?

They weren't transporting bottles to return—a Coke for deposits and they're clinking together. I hope that you're going to do a lot more with training as this proceeds.

Well, it looks like other members are not going to be here. So I ask unanimous consent that the document binder be introduced into the record and to authorize staff to make any appropriate redactions.

Without objection, the documents will be entered into the record with any redactions the staff determines are appropriate.

[The information has been retained in committee files and also is available at *http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=104823.*]

Mr. MURPHY. In conclusion, I thank all the witnesses and members that participated in today's hearing. I remind members they have 10 business days to submit questions for the record. I ask the witnesses to all agree to respond promptly to the questions, and with that this committee is adjourned.

[Whereupon, at 11:43 a.m., the hearing was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Mr. Chairman, thank you for holding this hearing. The subcommittee meets again as in previous years about the challenge of improving safety at the Federal Government's high-containment laboratories. During 2014 and 2015 several lapses in safety at HHS agency and Defense Department labs could have exposed Federal personnel and other individuals to hazardous biological agents.

In response to these concerns, there have been executive-branch wide efforts and internal agency efforts to improve lab safety. At the request of the bipartisan leadership of the committee, the GAO will present its report on oversight at Federal high-containment labs. The GAO will tell us that much work still needs to be done. Most of the Federal agencies need more comprehensive or up-to-date policies.

However, to really stop this troubling pattern of safety lapses at our bioterrorism labs, changes on paper will not be enough if the agencies are not addressing cultural and behavioral factors. To its credit, the Department of Defense and the Centers for Disease Control have conducted internal, soul-searching reviews into the root

causes of incidents. These internal investigations revealed various failures at both the systemic and individual level. As noted in the CDC testimony, these deep and critical internal reviews are essential to reforming lab safety.

With regard to the lapse involving the discovery of the smallpox vials in an FDA lab on the NIH campus, both the NIH and the FDA have yet to conduct the necessary self-examination and introspection to fully understand the weaknesses and failures that led to smallpox being unknowingly stored in an unregistered, and improperly secured conditions. I hope this hearing helps the NIH and the FDA to undertake such reviews. We want NIH, FDA, and all our Federal laboratories to be successful in implementing lab safety improvements. These labs conduct vital research that can lead to the development of treatments, diagnostic, and vaccines to address public health needs. This research is also important to our defense efforts against bioterrorism, a serious threat to our troops, our nation, and our allies.

Finally, it is disappointing that the CDC produced blacked-out documents in response to my confidential request letter on behalf of the committee to obtain key investigative information about improperly stored anthrax at the NIH and the FDA in 2012. There is no legal basis for the CDC to withhold such information from its authorizing committee in Congress. I would urge the CDC to live up to its claims of transparency and accountability, and to work cooperatively with this committee, as has occurred in the past.

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

April 18, 2016

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse."

The Subcommittee on Oversight and Investigations will hold a hearing on Wednesday, April 20, 2016, at 10:15 a.m. in 2322 Rayburn House Office Building, entitled "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse." The Subcommittee will hear testimony on the Government Accountability Office's (GAO) recent report on the need for comprehensive policies and stronger oversight at high-containment laboratories,[1] as well as the steps taken by the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Department of Defense (DOD) to strengthen their policies. In recent years, the Subcommittee has examined numerous safety lapses at high-containment laboratories.

I. WITNESSES

- John Neumann, Director, Natural Resources and Environment, Government Accountability Office;
- Lawrence A. Tabak, D.D.S., Ph.D., Principal Deputy Director, National Institutes of Health;
- Steve Monroe, Ph.D., Associate Director for Laboratory Science and Safety, Centers for Disease Control and Prevention;
- Segaran Pillai, Ph.D., Director, Office of Laboratory Science and Safety, Office of Commissioner, Office of Chief Scientist, U.S. Food and Drug Administration; and
- MG Brian C. Lein, Commanding General, U.S. Army Medical Research and Material Command and Fort Detrick and Deputy for Medical Systems to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, Department of the Army, U.S. Department of Defense.

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 high-containment

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

laboratories.[2] The Committee requested this report in July 2014 after several incidents involving the mishandling of hazardous biological agents raised questions about Federal policies for managing hazardous biological agents in high-containment laboratories. In this bipartisan request, the Committee asked GAO to analyze the policies and procedures in place at Federal agencies to ensure the proper management of pathogens and the steps taken to improve their inventory management of pathogens. The Committee also requested GAO assess how the agencies evaluate the effectiveness of their policies and procedures relating to pathogen management.[3]

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 84 CDC employees were exposed to live anthrax, because established safety practices were not followed.[4] 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.[5] The hearing also examined other incidents, including a spring 2014 cross-contamination involving H5N1 influenza virus at the CDC influenza laboratory and the discovery of decades-old vials of smallpox in a FDA lab on the NIH campus that were only discovered while employees were preparing for the lab's move to the FDA's main campus in White Oak, Maryland.

In July 2015, the Subcommittee held a hearing on the Department of Defense's 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.[6] These shipments revealed that Dugway's process for inactivating anthrax with radiation was unreliable, and that sterility testing used to validate and ensure that the inactivation process was working had failed to detect the live anthrax spores.

a. <u>Federal Select Agent Program</u>

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

---

[2] GAO, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," GAO-16-305 (March 2016).
[3] Letter from Hon. Fred Upton, Chairman, Hon. Tim Murphy, Hon. Joseph Pitts, Hon. Henry Waxman, Ranking Member, Hon. Diana DeGette, and Hon. Frank Pallone, Jr., H. Comm. on Energy & Commerce, to Hon. Gene Dodaro, Comptroller Gen., U.S. Gov't Accountability Office (July 31, 2014).
[4] *Review of CDC Anthrax Lab Incident: Hearing before the Subcomm. on Oversight and Investigations, H. Comm. on Energy & Commerce*, 113th Cong. (2014).
[5] On June 8, 2015, the BRRAT Laboratory received approval from CDC's internal Laboratory Safety Improvement Workgroup and CDC leadership to reopen. The lab is currently conducting laboratory training and validation of new laboratory procedures in preparation of resuming fall operations.
[6] *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).

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 to or deleted from the list.[7] 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.[8] The USA Patriot Act also made it a criminal offense for any individual knowingly to possess any biological agent, toxin, or delivery system in type or quantity not justified by a peaceful purpose.[9]

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.[10] The 2002 Act also establishes civil money penalties for persons violating the regulations and additional criminal penalties for knowingly possessing a select agent or toxin without registering it or knowingly transferring a select agent or toxin to an unregistered person.[11]

b. <u>High Containment Laboratories</u>

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 infected 17 others.[12] 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.[13] GAO had recommended in 2009[14] that the National Security Advisor make a single Federal agency responsible for assessing lab standards, but in its 2013 report, GAO noted that

---

[7] Federal Select Agent Program, About Us, http://www.selectagents.gov/about.html.
[8] USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).
[9] *Id.*
[10] 42 U.S.C. § 262a.
[11] *Id.*
[12] 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.
[13] 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.
[14] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.

the National Security Staff and the Office of Science and Technology Policy (OSTP) rejected the recommendation as "unnecessarily broad and cumbersome."[15]

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.[16] Each biosafety level is associated with specific physical and procedural protections. In general, the more dangerous the pathogen is to public health, the higher its recommended biosafety level. Procedures deemed unlikely to produce disease in healthy humans should be conducted at BSL-1. Those that may cause disease in healthy humans, but for which immunization or antibiotic treatment is available, should be conducted at BSL-2. Procedures that may cause serious or potentially lethal diseases as a result of pathogen inhalation should be conducted at BSL-3. Procedures that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease should be conducted at BSL-4. Generally, the term "high-containment laboratory" refers to BSL-3 and BSL-4 laboratories.

The GAO has conducted comprehensive work on the oversight of high-containment laboratories. In 2009, GAO noted that the number of high-containment laboratories was increasing in different sectors throughout the United States.[17] The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.[18] And since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.[19] GAO has continued to recommend a government-wide strategy for the requirements of high-containment laboratories and the need for national standards for designing, constructing, commissioning, and maintaining such laboratories.[20]

c. GAO Report on High-Containment Laboratories

In the wake of the recent safety lapses, DOD, HHS, and other agencies undertook multiple reviews to strengthen the policies surrounding and oversight of high-containment laboratories. Last year, the Committee requested that GAO review biosafety and biosecurity policies for the eight departments and fifteen component agencies that own and operate the Federal government's high-containment laboratories. GAO also examined any oversight policies at each department and component agency. GAO found a number of deficiencies in the policies for high-containment laboratories.

---

[15] 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.
[16] 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/
[17] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.
[18] *Id.*
[19] *Id.*
[20] *Id.*

GAO found that most of the departments and agencies did not have comprehensive policies for managing hazardous biological agents.[21] That is, the policies lacked at least one of six elements identified by GAO as critical to safely manage high-containment laboratories:

- Establishing appropriate lines of reporting for incidents involving hazardous biological agents;
- Defining roles and responsibilities of department, agency, or laboratory personnel;
- Establishing training for personnel handling hazardous biological agents;
- Ongoing monitoring during normal laboratory operations; and
- Requiring adherence to, or referencing, the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) guidance.[22]

GAO determined DOD's policies not to be comprehensive because some elements only applied to DOD's select agent-registered laboratories and not all high-containment laboratories. DOD's component agencies, including the Army, had policies that were missing one or more elements or applied only to select agent-registered laboratories. GAO specifically noted that DOD and its component agencies only had inventory control policies for select agent-registered laboratories, and that requirements for training and inspections in the Air Force's and Navy's policies only applied to select agent-registered laboratories.[23] GAO further found that the Army and Navy did not routinely report the results of internal inspections to either senior agency or senior department officials.[24] The Air Force reported to GAO that they routinely report the results of inspections to senior agency officials, but not senior department officials.[25] DOD officials told GAO that they did not require high-containment laboratories not registered with the select agent program to report the results of any agency inspections to DOD, and had no plans to implement such a requirement.[26]

GAO found that HHS did not have comprehensive policies because HHS did not have department-level policies for managing hazardous biological agents, and neither the CDC nor the FDA had all six elements in their agency-level policies. Specifically, CDC's policies for training and inspection only applied to select agent-registered laboratories, and CDC and FDA policies did not contain requirements for incident reporting to senior department officials. GAO found that NIH's policies for laboratory management to be comprehensive.[27] GAO further found that CDC, FDA, and NIH did not routinely report the results of internal inspections to either senior

---

[21] GAO, "High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety," GAO-16-305 (March 2016) at 12.
[22] *Id.*
[23] *Id.* at 15.
[24] *Id.* at 31.
[25] *Id.*
[26] *Id.*
[27] *Id.* at 16.

agency or senior department officials.[28] CDC and NIH did inform GAO that the results of select agent inspections are reported to senior agency officials, but not senior department officials.[29] CDC reported that, beginning in January 2016, following the creation of a laboratory safety oversight office, laboratories would begin reporting the results of inspections to senior agency officials.[30] FDA told GAO that it is contemplating whether to create an ongoing oversight role for the Laboratory Safety Practices and Policies Workgroup, which was established to conduct the laboratory sweeps for the White House's August 2014 safety stand-down.[31]

GAO detailed recent policy changes taken by the relevant departments to strengthen inventory control management controls. DOD is working with its component agency laboratories to establish a database to centralize the select agent inventory of all DOD laboratories into one system.[32] At HHS, each relevant component agency strengthened its inventory management controls in the last year in the wake of numerous select agent lapses:

- CDC developed a new procedure for scientists separating from the agency to account for biological research specimens in February 2015. CDC also launched a centralized electronic system to manage hazardous biological agents in all infectious disease laboratories, and expects to expand the system to all labs within two years.[33]

- FDA introduced electronic inventory control and management system to track the agency's biological, radiological, and chemical materials in October 2015. FDA plans to fully implement this system in the first quarter of fiscal year 2017.[34]

- NIH revised its safety audit inspection checklists to include documentation of inventory spot-checks during annual inventory audits in March 2015. NIH also established a database to record all hazardous biological agents in long-term storage in September 2014.[35]

GAO also analyzed the progress made by HHS and DOD to implement recommendations from laboratory safety reviews conducted after the 2014 and 2015 safety lapses. CDC reported implementing 91 recommendations from 209 total recommendations across all internal and external reviews. FDA reported implementing six of thirty recommendations from its external laboratory safety review. NIH reported implementing nine of ten recommendations from its external laboratory safety review.[36] DOD reported implementing one recommendation from its July 2015 report on the anthrax safety lapse, and was taking steps to implement the remaining 21 recommendations. DOD also convened a committee to review the May 2015 anthrax incident,

---

[28] *Id.* at 31.
[29] *Id.* at 32.
[30] *Id.* at 31.
[31] *Id.*
[32] *Id.* at 28.
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.* at 36.

which issued a report in July 2015 with 19 recommendations. Further, CDC, DOD, and the Army lack some time frames for implementing each of the recommendations. This is inconsistent with Federal internal control standards that departments and agencies should establish policies and procedures for ensuring that the findings of audits and other reviews are promptly resolved.[37]

GAO made a number of recommendations to each department or agency that has high-containment laboratories. With respect to the Department of Defense, GAO recommended, in part, that the Secretary:

- Revise existing department policies to contain specific requirements for inventory control for all high-containment laboratories, not just for select agent-registered laboratories;
- Routinely analyze agencies' inspection results and incident reports to identify potential trends that may highlight recurring laboratory safety or security issues, and share the lessons learned with relevant personnel;
- Require routine reporting of the results of inspections and laboratory incidents at non-select agent registered laboratories to senior department officials; and
- Develop timeframes for the remaining recommendations from the July 2015 review.

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

- Develop department policies for managing high-containment laboratories that contain requirements for reporting laboratory incidents to senior department officials;
- Develop department policies with specific requirements for training and inspections for all high-containment laboratories, not just the select agent registered laboratories;
- Direct the Director of NIH to review and update the agency's policies for high-containment laboratories; and
- Require routine reporting of the results of inspections to senior department and agency officials.

III. ISSUES

The following issues may be examined at the hearing:

- GAO's findings that HHS and DOD must create more comprehensive policies and enhance oversight to improve safety at high-containment laboratories;

[37] *Id.* at 40-41.

- Steps taken by DOD and HHS component agencies in the wake of recent safety lapses to enhance laboratory safety at high-containment laboratories; and

- How to improve oversight of select agents, and the Federal Select Agent Program.

IV. STAFF CONTACTS

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

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

TO: Members, Subcommittee on Oversight and Investigations

FROM: Majority Staff

RE: Supplemental Memorandum: Committee Investigation on the 2014 Discovery of Smallpox Vials at the National Institutes of Health, Bethesda, Maryland Campus

I. Introduction

On April 20, 2016, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "How Secure are U.S. Bioresearch Labs? Preventing the Next Safety Lapse." At the hearing, the Government Accountability Office (GAO) will present its report on agency policies on Federal laboratories working with hazardous biological agents, as well as policies related to the oversight of the labs. In addition to the GAO report, the Committee's majority staff has been investigating issues arising from the Food and Drug Administration's (FDA) discovery of twelve "overlooked" cardboard boxes containing 327 vials of laboratory samples – including six vials of *Variola*, the agent of smallpox – in an National Institutes of Health (NIH) building in July 2014. The discovery of the smallpox vials was one of three incidents that led the White House in August 2014 to urge Federal agencies handling select agents to conduct a "safety stand-down" to search their laboratories for unregistered or improperly stored select agents and establish a Federal review to identify improvements in lab safety.

This supplemental memorandum summarizes the majority Committee staff's preliminary observations from additional information obtained in its investigation into the facts and circumstances pertinent to the discovery of the smallpox vials in July 2014. The purpose of the supplemental memorandum is to identify additional issues that should be further investigated by agencies of the Department of Health and Human Services (HHS), and to highlight systemic, cultural, and behavioral factors that may need to be addressed in addition to the policy changes and oversight efforts being implemented by Federal agencies. Over the last decade, the Subcommittee has held several hearings on Federal lab incidents and biosafety. In addition, both the GAO and the HHS Office of Inspector General (OIG) have issued reports highlighting concerns and deficiencies with oversight and compliance of Federal select agent regulations. The hearings and reports show a pattern of recurring issues, of complacency, and a lax culture of safety. The lesson learned from past reviews is that Federal agencies must address cultural factors in addition to its policy and management efforts to ensure the effectiveness of its lab safety programs.

II. Background of the Discovery of Vials Containing Smallpox

On July 1, 2014, in an effort to clean out and organize material in preparation for the move of FDA's laboratories from the NIH campus in Bethesda, Maryland, to the FDA's White Oak, Maryland, campus, an FDA researcher working in Building 29A discovered twelve "overlooked" cardboard boxes in a common cold storage room.[1] The FDA researcher who found the material immediately reported the discovery to the Associate Director for Research at the FDA Center for Biologics Evaluation and Research. The FDA Associate Director for Research then notified the Responsible Official (RO) for the NIH Select Agent Program. The boxes were transferred to the NIH RO, who secured the materials until

[1] In an interview with Committee staff, the FDA researcher stated that he was in the cold room on a daily basis. He said that he first saw the twelve cardboard boxes in question sitting at the end of a shelf when he came to work at Building 29A in 1992 and never opened the boxes until July 1, 2014. The boxes were not hidden behind anything, but the FDA researcher said that the boxes were at the end of a shelf in a corner and could have been overlooked.

the Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation (FBI) removed the contents.

A. The CDC and FBI Joint Investigation

From July 7 to 9, 2014, the CDC and FBI conducted a joint investigation into the discovery of the smallpox vials, reporting their findings to the NIH on August 8, 2014.[2] Although the cold room had the capability of being locked, FDA personnel reported that the room had never been locked to their knowledge. Further, there were no access logs or inventory records for any material or equipment in the cold room where the vials were found. In addition to the vials of smallpox, labels on the other vials indicated other potential select agents such as Q fever and certain Encephalitis viruses. The CDC and FBI concluded that the location of the materials found did not meet the requirements of the select agent regulations, and that there were "significant vulnerabilities with access control and accountably [sic]."[3]

The twelve boxes contained 327 vials of laboratory samples, including six vials of *Variola*, the agent of smallpox. The twelve boxes were marked on the outside with a series of Roman numerals and letters. Based upon the numbering system, CDC and FBI surmised that there may be at least two boxes not accounted for. All other lettering on the outside of the boxes had been previously marked through, but some of the marked out lettering was legible (e.g., "Measles," "Enders strain"). None of the boxes contained information on the source of the material, but dates on the labels ranged from 1946 to 1964. Some of the labels contained possible names or potential sources. FDA researchers told the CDC and FBI that no one was aware of the owner or source of the material.[4]

The FBI and CDC highlighted that FDA personnel did not take any steps to package and transport the vials in a manner sufficient to prevent their release when they moved the vials from building 29A to the NIH RO. The report states:

> [H]ad any of the six glass vials containing the Variola virus been breached, there would have been nothing to contain the agent and prevent its release to the surrounding environment. During the initial inspection of the vials on July 7, 2014 it was noted that one vial labeled *NOR.SPL.ANT* (presumably Normal Spleen Antigen) had been breached. It was not known when this breach occurred, but this could have occurred during the move on July 1, 2014.[5]

The report further noted that the individual who carried the boxes to the NIH RO indicated that she heard the vials clink together as she transported them from building 29A. Subsequent testing of the samples by the CDC showed that the smallpox virus was still viable in two of the six vials.

---

[2] Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention to Deborah Wilson, Responsible Official, National Institutes of Health (Aug. 8, 2014).
[3] *Id.*
[4] The policy regarding unlabeled cardboard boxes in cold storage rooms at the National Cancer Institute—Frederick was explicit and apparently different from the policy at NIH's Bethesda campus. According to a biosafety technical bulletin on cold rooms and mold issued by NCI-Frederick in November 2011, personnel were advised that "at a minimum," "DO NOT store cardboard, . . . in cold rooms." National Cancer Institute—Frederick, *Biosafety Technical Bulletin: Cold Rooms and Mold* (Nov. 2011) (emphasis in original). Further, the bulletin stated, "Label equipment and any on-going experiments with name, date and responsible Principle[sic] Investigator (PI). **Note: Any unlabeled samples should be discarded by laboratory managers.**" *Id.* (emphasis in original).
[5] Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention to Deborah Wilson, Responsible Official, National Institutes of Health 2 (Aug. 8, 2014).

Federal officials familiar with this case believe that no one detected the cardboard boxes since at least 1972 when the FDA became an NIH tenant of Building 29A. In an interview with Committee staff,[6] the FDA researcher who reported the twelve cardboard boxes, and who had worked in the corridor and cold storage room since 1992, stated that he worked in the cold room on a daily basis. He first saw the twelve cardboard boxes in the cold storage room when he began working in Building 29A in 1992. He did not open the boxes until July 1, 2014. The boxes were not hidden behind anything, but the FDA researcher stated that the boxes were at the end of a shelf in a corner, and could have been overlooked. The CDC and FBI identified the following root cause assessment for the incident:

> Failure of past NIH and FDA actions to fully identify and account for material labeled as potentially select agents and toxins on the NIH Bethesda campus, specifically the failure to have oversight and accountability for material in a shared storage space (e.g. walk in cooler) where ownership of the material is not clear or unknown.[7]

On September 8, 2014, the CDC made a referral to the HHS Office of Inspector General (OIG) regarding the smallpox discovery. In the referral, the CDC noted that this referral supplemented other information provided in an April 2012 referral CDC made to the OIG, which was still pending.

As a result, in contravention of the Public Health Security and Bioterrorism Preparedness and Response Act, neither the FDA nor the NIH accounted for the select agents, nor did NIH ever register these select agents as required by the 2002 law.[8] In addition, the United States had committed in a 1979 international agreement that any remaining stock of smallpox vials would be accounted for and stored only at the CDC or at the Vector Institute in Russia. As a result of this discovery, the World Health Organization was notified and invited to come to the U.S. to confirm that the smallpox vials were secured and then destroyed.

In 1995, NIH safety officers received an anonymous tip that a top-ranking official at an NIH lab in a casual conversation years earlier had said there was smallpox in the freezers.[9] The allegation was not substantiated with the particular lab. However, an NIH spokeswoman said, that if smallpox were found, "that would be regarded as a very serious transgression against science," and "it would be taken very seriously."[10]

B. Subsequent Actions

The 2014 smallpox discovery at NIH was one of a series of high-profile mishandlings involving dangerous pathogens at Federal laboratories. The CDC reported three incidents of inadvertent shipments containing highly pathogenic biological agents such as anthrax, Ebola, and H5N1 influenza, in one year alone.[11] In 2015, the Department of Defense (DoD) acknowledged that the Dugway Proving Ground, an

---

[6] Interview with [FDA Researcher] conducted by H. Comm. on Energy & Commerce staff, April 6, 2014.
[7] Letter from Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention to Deborah Wilson, Responsible Official, National Institutes of Health 2 (Aug. 8, 2014).
[8] 42 U.S.C. § 262a.
[9] Justin Gillis, *NIH Denies It Has Smallpox Sample*, WAS. POST, Sept. 25, 1995.
[10] *Id.*
[11] In June 2014, CDC inadvertently transferred live anthrax between CDC labs, resulting in the potential exposure of 81 CDC staff and the closure of a bioterrorism rapid response lab. In the spring of 2014, CDC inadvertently shipped highly pathogenic H5N1 influenza to a USDA lab. CDC staff further did not inform CDC leadership of the incident for two months. In December 2014, CDC inadvertently transferred potentially live Ebola virus from a biosafety level 4 lab to a lower biosafety level 2 lab.

Army facility in Utah, inadvertently shipped live anthrax to a several laboratories. The CDC[12] and DoD conducted internal reviews on each one of these events.[13] In contrast, neither the NIH nor the FDA have conducted an internal review on the discovery of the smallpox vials in 2014.[14]

The smallpox discovery, along with other incidents, led to a sweep of Federal laboratories in the summer and fall of 2014. As a result of the lab sweep at NIH, other select agents, including botulinum, plague, and ricin were found to be improperly stored. On January 15, 2015, CDC made a referral to the OIG about these additional discoveries.

III. Additional Information Discovered during the Committee's Investigation

The Committee launched its investigation into the smallpox discovery at NIH more than two years ago, after examining the series of incidents involving Federal laboratories mishandling dangerous pathogens. On July 28, 2014, the Committee sent requests to the CDC, NIH, and FDA for documents and information relating to the handling of select agents by Federal laboratories and compliance with the Federal Select Agent Program (FSAP).[15] These requests included questions about the smallpox vials and other dangerous pathogens discussed above. To date, the Committee has obtained documents from the NIH, FDA, CDC, and involving safety inspections and external investigations into the smallpox discovery at NIH. Additionally, the Committee has conducted several interviews with FDA and NIH staff directly involved with the 2014 smallpox findings, and has also spoken with senior officials for both FDA and NIH.

In recent months, after learning of a CDC investigation report into the smallpox discovery, the majority Committee staff looked at other elements of the discovery to understand whether the NIH or FDA could have discovered the smallpox vials earlier, and more broadly, what systemic weaknesses in the NIH and FDA lab safety programs indicated by this lapse may remain unaddressed. The Committee has learned that NIH experienced major events in 2011, when it discovered unregistered, antibiotic resistant plague specimens, and in 2012, when it discovered unregistered, antibiotic resistant anthrax, including at an FDA lab in Building 29A. At least one of these specimens was found improperly stored in a hallway freezer in a building on the NIH Bethesda campus. The Committee believes that these discoveries should have spurred NIH and FDA to conduct a comprehensive sweep of all laboratories to ensure that all select agents were properly accounted for and registered. Unfortunately, neither NIH nor

---

[12] CDC, *Report on the Potential Exposure to Anthrax* (July 11, 2014); CDC, *Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1* (August 15, 2014); and CDC, *Report on the Potential Exposure to Ebola Virus* (Feb. 4, 2015).

[13] DOD conducted a particularly robust review of the inadvertent shipment of anthrax from the Dugway Proving Ground that identified the root causes of the incomplete inactivation of anthrax, found other systemic problems in the management of DoD's high-containment laboratories, and proposed steps necessary to fix those problems. The findings were produced in an Army Regulation (AR) 15-6 Investigation Report entitled, *Individual and Institutional Accountability for the Shipment of Viable Bacillus Anthracis From Dugway Proving Ground*. DoD assigned ten staff members to conduct an internal investigation, during which staff conducted interviews with over eighty individuals, obtained sixty-nine sworn statements, and produced fifty documents classified as evidence to support findings.

[14] NIH and FDA senior officials have informed the Committee via interviews that an internal review has yet to be conducted to avoid interference with the CDC and FBI investigation, and the HHS-OIG pending FSAP investigation. These investigations have been closed. Both agencies have expressed a willingness to conduct internal reviews once notified that external investigations are closed.

[15] The FSAP oversees the possession, use, and transfer of biological select agents and toxins. The program requires that HHS identify a list of organisms and toxins (known as select agents) that potentially could be used for bioterrorist attacks, and currently regulates sixty-five select agents, including smallpox. CDC's Division of Select Agents and Toxins (DSAT) regulates the possession, use, and transfer of biological agents and toxins that could pose a severe threat to public health and safety.

FDA undertook such a sweep until 2014—after the public disclosure of the discovery of the smallpox vials.

A. 2012 Anthrax Discoveries

In 2014, the NIH reported to the Committee that, in February 2012, the NIH found vials of *Bacillus anthracis* spores in an unregistered space in Building 33 on the Bethesda, MD campus during an inspection of a registered laboratory.[16] NIH described the materials discovered:

> The materials were not secured; personnel in the laboratory were not registered to possess this strain of *B. anthracis*; and the material had not been identified to the NIH Select Agent Program. The vials were immediately removed from the freezer and transported to the registered NIH Select Agent Program laboratory. The spores found were from a non-infectious strain, but were still regulated under the Select Agent Regulations.[17]

After this discovery, the NIH initiated a search of all laboratories known to work with any form of anthrax, regulated or unregulated, to ensure that no further anthrax was stored inappropriately. This inspection found regulated anthrax in three other unregistered locations on campus.[18]

The Committee's investigation has recently uncovered additional facts about NIH's prior violations of Federal select agent regulations. The Committee has learned that the discovery of unreported, unregistered anthrax during a laboratory inspection actually resulted from two principal investigators (PIs) self-disclosing their unauthorized work involving antibiotic resistant *Bacillus anthracis* to the NIH Select Agent Program (SAP) on January 26, 2012, during a Select Agent Program retraining.[19] NIH surrendered these vials of *B. anthracis* spores to the FBI Weapons of Mass Destruction Coordinator shortly after they were identified.[20] As a result of this disclosure, NIH SAP conducted a search of twenty-two refrigerators, freezers, and a cold room used by the laboratory of these researchers.[21] It was during this search that NIH discovered the additional vials of anthrax in three unregistered locations. Recent interviews with NIH staff acknowledged that the 2012 laboratory searches only searched registered spaces for anthrax because NIH believed it had no reason to suspect that there was inappropriate storage of other materials.

The Committee further learned that the Select Agent retraining effort in January 2012, in which two NIH PIs self-disclosed select agent material, occurred because of a previous discovery of unauthorized select agent material. While preparing for an inspection of the Rocky Mountain Laboratories[22] in October 2011, the lead DSAT (Division of Select Agents and Toxins) inspector identified publications that indicated a NIH researcher may have conducted experiments using antibiotic resistant *Yersinia pestis* (plague).[23] After further review, DSAT determined that the NIH researcher did conduct these experiments, and failed to comply with the FSAP in 2007 when he received an unauthorized transfer of the *Y. pestis* without obtaining prior approval from DSAT. This matter was

---

[16] Letter from Hon. Dr. Francis Collins, Director, NIH, to Hon. Fred Upton, Chairman, H. Comm. on Energy & Commerce (Sept. 17, 2014).
[17] *Id.*
[18] *Id.*
[19] NIH, Select Agent Investigative Report, Findings, Actions, Bethesda, MD, (June 5, 2012).
[20] *Id.*
[21] *Id.*
[22] Rocky Mountain Laboratories is an NIH facility located in Hamilton, Montana.
[23] Letter from Robin Weyant, Director, CDC Division of Select Agents and Toxins, to Tony Maida, Senior Counsel, HHS-OIG, (December 9, 2011).

referred to HHS-OIG on December 9, 2011, from DSAT.[24] After this discovery, the NIH retrained all Select Agent PIs by the NIH SAP, and it was during this retraining effort that the two NIH PIs self-disclosed possession of the *B. anthracis*.

After NIH reported the discovery of anthrax in 2012, DSAT conducted an onsite visit of NIH. In a letter addressed to the NIH RO, DSAT informed NIH that it "[h]ad significant concerns regarding the compliance of the NIH with the requirements of 42 CFR Part 73 Section 73.8 of the select agent regulations."[25] The following concerns were identified by DSAT's site visit:

- NIH failed to ensure that the biosafety and containment procedures were sufficient to contain the select agents;
- NIH failed to implement provisions of the NIH security plan to safeguard select agents against unauthorized access, theft, loss, or release in violation of section 11of the select agent regulations;
- NIH conducted work with the select agents that had not been approved by DSAT and failed to restrict access to select agents to personnel approved by HHS;
- The RO failed to ensure compliance with the select agent regulations during annual inspections of select agent registered laboratories; and
- The RO failed to ensure an accurate, current inventory for each select agent held in long-term storage.

As a result of these observations, DSAT asked NIH to "[s]how cause why the registration of the NIH (Registration #C20110919-1265) should not be suspended or revoked."[26] DSAT ultimately placed NIH on a Performance Improvement Plan Program (PIPP).[27]

The FDA was also involved in the 2012 anthrax discovery because six vials of A-34 (a strain of *Bacillus anthracis*) was found in an FDA laboratory freezer in Building 29A on the NIH campus in Bethesda, Maryland.[28] After this discovery, all PIs on NIH's campus completed written attestation forms, attesting to the fact that each PI surveyed their laboratory spaces for select agent materials and that none were found. FDA staff on campus also submitted attestation forms.[29] The Committee interviewed the FDA PI that worked in Building 29A on NIH's campus, and he explained that he only checked his own materials for select agents, and did not check other materials. As a result of FDA's failure to require researchers to conduct inventories of all items maintain in shared spaces, the discovery of the smallpox vials was delayed until 2014.

B. 2009 – NIH Inventory Discrepancy

A 2009 HHS OIG audit report about NIH's compliance with Federal select agent regulations reported concerns about inventory management stemming from an unexplained inventory discrepancy. The discrepancy stemmed from the NIH's handling of sealed envelopes, unopened since 1960, containing historical specimen select agents. The select agents included plague and Burkholderia. Apparently, the

---

[24] *Id.*
[25] Letter from Robbin Weyant, Director, CDC Division of Select Agents and Toxins, to Deborah Wilson, Responsible Official, NIH, (June 4, 2012).
[26] *Id.*
[27] *Id.*
[28] Letter from Thomas Kraus, Associate Commissioner for Legislation, FDA to the Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce (Sept. 18, 2014).
[29] *Id.*

NIH clinical laboratory registered the sealed envelopes in the Federal Select Agent Program around 2002 or 2003 based on the labels on the envelopes, but did not actually open the envelopes to inspect the materials within. Because of a flood in 2007, these envelopes were transferred to the NIH OSH office (the office responsible for overseeing NIH compliance with select agent regulations), and were re-registered with FSAP, but again without opening the envelopes. In 2008, while preparing for an HHS OIG on-site audit, a lab in the NIH clinical laboratory performed a hand count inventory and opened the sealed envelopes. One of the envelopes contained seven more vials of the select agent Burkholderia than was listed.[30]

Interviews with NIH staff advised that the materials were registered using information on the envelopes' labels. This practice raises several concerns. Since the envelope was not opened until at least five years after registration, the NIH could not and did not confirm the number of vials and materials on the label to assure the accuracy of the registration information submitted to CDC both in 2003 and in 2007. Further, without opening the envelopes, the NIH could not and did not ensure that a breach did not occur, or that the select agents were secured properly in the vials.

The NIH also told the OIG that envelopes are considered acceptable containers for storage,[31] and cited 42 CFR 73.17 several times.[32] Not only was the citation provided by NIH incorrect, but even the correct citation did not show that envelopes are acceptable for storage under the FSAP. The NIH did not report any information to the OIG about the circumstances surrounding the envelopes containing the select agents. At the time of the writing of this memorandum, the NIH had not provided an explanation of how envelopes could qualify as containers for storing select agents.

IV. Findings

Question: **With respect to the vials of smallpox virus discovered in July 2014, did the NIH and the FDA fail to account for all select agent materials in its possession as required?**

Finding: Yes. Both the NIH and FDA failed to include the smallpox discovered in Building 29A in the registration application to the Federal Select Agent Program in 2003.

Discussion:

Per 42 U.S.C. § 262a, the NIH is responsible for ensuring compliance with the Federal select agent regulations for all select agent materials in its possession.[33] Thus, even if the FDA was using NIH space, NIH's RO was responsible for the space.[34]

The CDC reported to the Committee that NIH submitted the required "notification of possession" of select agent forms[35] to HHS in 2002, but did not indicate possession of any smallpox virus.

---

[30] HHS-OIG, "Review of the National Institutes of Health Bethesda, Maryland, Laboratories' Compliance with Select Agent Regulations," A-03-09-00350, December 2009.
[31] *Id.*
[32] Email from Anne Tatem, NIH to Committee staff, April 13, 2016.
[33] Letter from Dr. Thomas Frieden, Director, CDC to the Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce (August 22, 2014).
[34] *Id.* at 6.
[35] Pursuant to 42 CFR §73.9 (a)(6), the Responsible Official required to register select agents must ensure that annual inspections are conducted for each laboratory where select agents or toxins are stored or used in order to determine compliance with these requirements. The results of each inspection must be documented, and any deficiencies identified during an inspection must be

Notably, the form explicitly listed Variola major (smallpox virus) as a select agent requiring notification. The registration application submitted to the Federal Select Agent Program by NIH, as required under the select agent regulations, likewise did not acknowledge possession of Variola viruses.

Further, the CDC reported that neither the FDA nor the NIH identified the possession of smallpox.[36] While NIH registered the building with the Federal Select Agent Program, it failed to register the space where the vials were found and the vials themselves. The individual who served as NIH's Responsible Official in 2003, the Director of the NIH Division of Occupational Health and Safety, is still the current NIH RO.

The NIH reported that it had no records of the transfer of smallpox and other pathogen samples when the office that had custody over the vials was transferred from NIH to the FDA in 1972.[37] During a November 21, 2014 bipartisan Committee staff briefing, the NIH RO acknowledged that the agency did not comply with Federal select agent regulations because it did not identify the smallpox vials.

Question: **Was the smallpox incident the only occasion on which the NIH apparently violated the Federal select agent regulations for lack of accountability and improper storage of a previously unidentified select agent?**

Finding: No. The NIH previously failed to account for vials of *Bacillus anthracis* spores in an unregistered space in February 2012.

Discussion:

As discussed above, with respect to the 2012 discovery of *B. anthracis* spores, the Committee's investigation determined that the discovery of unreported, unregistered anthrax during a laboratory inspection resulted from two principal investigators self-disclosing to the NIH Select Agent Program on January 26, 2012, during a Select Agent Program retraining, about their unauthorized work involving antibiotic resistant *Bacillus anthracis*. The Committee further learned that the Select Agent retraining effort in January 2012 occurred because of a previous discovery of unauthorized select agent material.

Recent interviews with NIH staff acknowledged that the 2012 laboratory searches only searched registered spaces for anthrax because NIH believed it had no reason to suspect that there was inappropriate storage of other materials. Yet, NIH learned about the unreported, unregistered anthrax after its discovery the prior year that an NIH researcher received an unauthorized transfer of plague. Had NIH undertaken a more extensive review in response to these problems with two different select agents, the smallpox vials could have been discovered years earlier.

---

corrected. In addition, under 42 CFR §73.9 (c)(1), the Responsible Official must immediately report the identification and final disposition of certain enumerated select agents or toxins, including the smallpox virus.

[36] *Id.* On July 12, 2002, the CDC published a notice stating that facilities should complete a "notification of possession" form by September 10, 2002, based on an inventory of its facility and consulting with others (e.g., principal investigators), as necessary, to obtain information required for the form. The "notification of possession" form was to be submitted to HHS under the Public Health Security and Bioterrorism Act. In addition, the HHS Federal select agent regulation (42 CFR § Part 73.9 (c)(1)) became effective on February 7, 2003, and required the registration of the possession, use, and transfer of select agents and toxins, including Variola major and Variola minor viruses.

[37] Letter from Hon. Dr. Francis Collins, Director, NIH, to Hon. Fred Upton, Chairman, H. Comm. on Energy & Commerce (Sept. 17, 2014).

Question: **Prior to the July 2014 discovery of undeclared smallpox, had the NIH previously engaged in checking inventories or conducting surveys for undeclared and unregistered Federal select agents, including cold storage rooms?**

Finding: Yes. These efforts, however, assumed that any potential select agents would be attributed to a researcher and did not include searches or surveys to cover select agents that were not "owned" or under the control by any current researcher.

Discussion:

After the 2012 anthrax discovery, the NIH initiated a search of all laboratories known to work with any form of anthrax, regulated or unregulated, to ensure that no further anthrax was stored inappropriately. This inspection found regulated anthrax in three other unregistered locations on campus, including in Building 29A, where the smallpox vials were ultimately discovered.[38] The NIH focused only on anthrax despite learning of an unauthorized transfer of plague by an NIH researcher in 2007 the year before.

Notably, the NIH did not engage in any effort to account for materials in all spaces in NIH laboratories—searches and inventory checks were limited to researchers, materials, or spaces already registered to the FSAP. For example, while the lab sweep focused on anthrax vials, all NIH Principal Investigators and FDA PIs in NIH buildings registered with FSAP had to sign written attestations that they had no other unregistered select agents. Had the NIH focused its lab sweep on all select agents or had the NIH investigated the possibility of unregistered locations improperly storing select agents, it may have discovered the 327 vials of dangerous pathogens, including smallpox, years earlier. In an April 8, 2016 meeting with Committee staff, the NIH Principal Deputy Director acknowledged that the scope of NIH's investigation was flawed because it assumed that the universe for possible improperly stored select agents would be limited to researchers and locations already registered in the Federal select agent program.

Question: **Did the NIH inspect the cold storage room containing the smallpox vials, and did the scope of these inspections include issues that related to the cardboard boxes containing the smallpox vials?**

Finding: Yes. The NIH conducted annual inspections of the cold storage room in question. The smallpox vials were stored in cardboard boxes in the cold room. The NIH's safety inspection program drew attention to the presence of cardboard storage in the very room in which the smallpox vials were ultimately discovered. The NIH safety survey used from 2011 to 2013 included a checklist to confirm that there was no cardboard storage in the cold room. During two 2011 inspections, NIH safety inspectors found cardboard in the cold room, and one of the inspectors wrote "remove all cardboard from the cold storage room." In 2012, the NIH inspectors returned and reported no cardboard in the cold room. Contradicting her earlier interview with Committee staff, the NIH RO told the Washington Post that inspectors were not actually concerned about cardboard boxes on shelves, the preponderance of evidence from documents and interviews shows the concern over cardboard mold in Building 29A cold rooms at that time was very broad and included cardboard sitting on shelves.

---

[38] *Id.*

Discussion:

Documents produced by NIH to the Committee show that NIH safety inspectors inspected cold storage room 3C16 as part of NIH inspections of nearby FDA labs.[39] Building 29A, which contains cold storage room 3C16, was built in 1968. In an interview with FDA staff that worked in room 3C16, staff described the building as "quite moldy" and mentioned that the cold room failed on a regular basis. The temperature in the cold room warmed to almost room temperature at times, and an FDA PI confirmed the rooms had contamination issues due to mold growth.

The NIH conducted two different safety inspections on October 11, 2011, both of which indicated the presence of cardboard storage in cold room 3C16. The first inspection completed on October 21, 2011, was for the FDA laboratory located in Building 29A, Room 3C22 (a lab on the 3rd floor C corridor permitted access to the cold storage room 3C16). The NIH inspector wrote the following comment regarding the cold room: "Please remove all cardboard from the cold room."[40] The second inspection, conducted by a different NIH inspector, also found cardboard in the cold storage room. This inspection was conducted for the laboratory located in Building 29A, Room 3C12. The NIH inspector checked "No" on "No cardboard storage" in the cold room, indicating the presence of cardboard in the cold storage room. The same PI supervised both of these labs.

In May 2015, the NIH RO told *The Washington Post* that the removal of cardboard in cold room storage referred to "Cardboard that is abandoned on floors, or in wet piles."[41] The NIH RO further remarked that "it has nothing to do with cardboard boxes on shelves in which research materials may be stored."[42] The NIH RO did not provide this interpretation to Committee staff in November 2014 when the NIH safety surveys of the cold room and cardboard storage were specifically discussed. The NIH RO did not correct or question Committee staff's view that NIH inspectors were looking at all cardboard generally in cold storage rooms, not certain categories of cardboard. These statements are also inconsistent with the Committee's recent interviews with NIH and FDA staff. In these interviews, NIH and FDA staff confirmed that the purpose of removing cardboard boxes in the storage room was to prevent mold growth. NIH and FDA staff explained that comments directing the removal of cardboard were not limited to cardboard only on floors or in wet piles, as the NIH RO stated in *The Washington Post* article. NIH and FDA staff further explained that while cardboard on the floor or wet cardboard posed the greatest risk for mold, it was an ideal best practice and recommendation to remove all cardboard for mold growth prevention. Finally, multiple safety surveys for Building 29A showed that in 2011, NIH inspectors were requesting removal of all cardboard boxes from cold rooms and in some cases specifically requesting that the cardboard boxes be replaced with plastic bins. This would be consistent with the reported maintenance problems with the aging Building 29A facility, multiple closures of cold storage rooms in Building 29A because of mold growth, four to five failures a year of the cold storage room in question as told by the FDA researcher, and the more hard-line approach toward cardboard in cold rooms that occurred in the 2011 NIH inspections in response to cold room problems in Building 29A.

The Committee also learned that each NIH campus has different safety protocols and procedures. For example, the National Cancer Institute-Frederick Fact Sheet, "Biosafety Technical Bulletin: Cold Rooms and Mold," dated November 2011, states that "[s]ince cold rooms are typically shared spaces, an

---

[39] *Id.*
[40] A subsequent 2012 NIH inspection confirmed that the cold room associated with the 3C22 lab was the cold storage room 3C16. Previous NIH inspections of this lab indicated that the "cold room storage" category was not applicable to this lab.
[41] Lena Sun, *House Panel Seeks Expanded GAO Review of Smallpox Incident at NIH*, WASH. POST (May 19, 2015).
[42] *Id.*

established protocol should be adopted by all users to reduce the chance of mold growth in the space. At a minimum, . . . DO NOT store cardboard, . . . in cold rooms."[43] However, other NIH campuses did not implement similar standards in their safety policies. The Committee questions whether NIH should have consistent safety and policy standards across their campuses. If so, under what circumstances would it be appropriate for campuses to have different policies?

Since the 2014 smallpox discovery, the NIH has recently revised their safety inspection form. The new form requires inspectors to limit its search of cardboard in cold room storage if the cardboard is, "free of unused, discarded, or damaged." This raises the question of whether future inspections will properly detect mold growth of cardboard inside boxes, since new inspections will be limited to external factors.

Question: **Was there a previous instance of questionable NIH handling of unopened historical collections of select agents?**

Finding: Yes. Both the laboratory at the NIH Clinical Center and the NIH Safety Office registered materials contained in sealed envelopes in the FSAP that were labeled as containing various select agents, including plague, without opening up the envelopes to verify the contents and the amounts.

Discussion:

As described above, a 2009 HHS OIG audit report about NIH's compliance with Federal select agent regulations reported concerns about inventory management stemming from an unexplained inventory discrepancy in a historical collection of specimens, including select agents, contained in sealed envelopes and unopened between 1960 and 2008.

The Committee is concerned about NIH's registration of the select agents contained in the sealed envelopes based only on the labels of the envelopes, and without confirming the actual pathogens contained within. Since the envelope was not opened until at least five years after registration, the NIH could not and did not confirm the number of vials and materials on the label to assure the accuracy of the registration information submitted to CDC both in 2003 and in 2007. Further, without opening the envelopes, the NIH could not and did not ensure that a breach did not occur, or that the select agents were secured properly in the vials. The Committee is further concerned about the use of envelopes as acceptable containers for the storage for select agents. Not only was the citation provided by NIH incorrect, but even the correct citation did not support NIH's assertion that envelopes are acceptable for storage under the FSAP. The NIH did not report any information to the OIG about the circumstances surrounding the envelopes containing the select agents. At the time of the writing of this memorandum, the NIH had not provided an explanation of how envelopes could qualify as containers for storing select agents.

The NIH has stated that "it is routine in the conduct of infectious disease or vaccine research and for quality control purposes to maintain collections of pathogens in laboratories. The maintenance of pathogen collections by laboratory is a common practice."[44] Given this practice, historical collections were known to NIH safety officials and subject to inventory control and Federal select agent regulation, where applicable. At other departments, such as the Department of Defense, there were written policies

[43] NCI, Frederick Campus, Biosafety Technical Bulletin, November 2011.
[44] Letter from Hon. Dr. Francis Collins, Director, NIH, to Hon. Fred Upton, Chairman, H. Comm. on Energy & Commerce (Sept. 17, 2014).

governing the accountability of abandoned or remnant research materials or materials such as historical collections without identifiable ownership. Had the NIH undertaken a search for other historical collections when it found and registered this historical collection in 2002 or 2003, the agency could have discovered the smallpox vials contained in another historical collection over a decade earlier.

Question: **Did FDA have sufficient policies and protocols in place in 2014 to ensure safety in its laboratories?**

Finding: No. FDA policies and protocols in place at the time did not ensure safety in its laboratories. For example, FDA did not require researchers to conduct inventories of all items maintained in storage rooms. Further, FDA did not enforce relevant policies that it did have in place at the time. These insufficient and unclear policies, in part, delayed the discovery of the smallpox vials.

Discussion:

The FDA acknowledged to the Committee its responsibility for complying with applicable Federal requirements governing the possession, use, and transfer of all select agents stored in FDA lab facilities on the NIH campus.[45] FDA explained its failure to account for all select agent material:

> Because FDA's internal procedures did not clearly assign responsibility for inventorying the contents of common cold storage areas in Building 29A, the vials were not discovered until July 1, 2014, when a thorough search was conducted in preparation for the relocation of FDA's Building 29A laboratories from Bethesda to FDA's main campus in Silver Spring, Maryland.[46]

The Committee interviewed the FDA PI who found the smallpox vials, and he confirmed that the agency did not implement a formal inventory protocol until 2014—after the discovery of the smallpox vials. The FDA PI also stated to the Committee that, prior to 2014, PIs managed their inventory by keeping a "running list" of materials in their possession.

The Committee asked the FDA about the inventory control responsibilities for the cold storage room. The FDA responded that it had no inventory control responsibilities for this room because "the cold storage room, 3C16, is not part of a custodial area since there was not any accountable government property stored in this space . . . . Accountable property is defined as computers and all pieces of equipment with a value of more than $5,000."[47] Furthermore, when the Committee asked the FDA to identify the cold storage property custodian, the FDA identified "[n]o one, for the reasons described above. There was a Point of Contact who had limited responsibilities with respect to the cold room. These limited responsibilities did not include maintaining an inventory of the contents of the cold room."[48]

The Committee also learned that while the FDA had a policy specifically for Cold Rooms, no one held staff accountable for complying with policy. FDA's Cold Room Policy issued in 2011 required that "[a]ll materials in the cold room should be properly labeled, including owner's name and work phone

---

[45] Letter from Thomas Kraus, Associate Commissioner for Legislation, FDA to the Hon. Fred Upton, Chairman, H. Comm. on Energy and Commerce (Sept. 18, 2014).
[46] *Id.*
[47] Email from FDA counsel, to Committee staff (Dec. 11, 2014).
[48] *Id.*

number."[49] The boxes containing smallpox vials were unlabeled despite this policy issuance, and FDA never at any time prior to 2014, required that an individual be identified as a contact for its contents. The Committee's interviews with FDA staff confirmed that each PI who used the cold storage room was responsible for taking inventory of his or her own specimens. Interviews with FDA staff also confirmed that FDA had an unwritten policy on handling the abandonment or transfer of research materials.

The Committee has learned about recent changes to FDA's safety and oversight for laboratories. Recently, the FDA hired a Director for the Office of Laboratory Science and Safety. FDA has communicated their intentions to assign a Responsible Official to each cold storage room, and to implement an electronic inventory mechanism that allows researchers to upload materials in real-time. The inventory documentation will identify a description and quantity of the materials, where the materials are located, and who is responsible for the materials. In addition, FDA has informed the Committee that they plan to implement an official policy on the transfer or abandonment of materials. Furthermore, FDA relayed that it plans to hire staff for the Office of Laboratory Science and Safety to oversee these forthcoming implications. The Committee acknowledges that these new procedures sound promising; however, it is unclear when the Office for Laboratory Safety will expand due to budget.

Question: **Are there concerns with CDC's oversight of NIH compliance with the Federal Select Agent Program?**

Finding: Yes. The CDC's Division of Select Agents and Toxins did not examine NIH's response to earlier incidents upon discovering new violations, and, until recently, narrowly construed requirements so that reports to Congress on notifications, thefts, losses, or releases of select agents did not include discoveries of select agents not previously accounted for and reported to the Federal Select Agent Program.

Discussion:

The CDC's Division of Select Agents and Toxins is responsible for assessing FSAP violations. DSAT has the authority to deny, suspend, or revoke an entity's registration, and may require an entity to enter into a Performance Improvement Plan. In July 2011, HHS OIG audited FSAP compliance, specifically evaluating DSAT. OIG found that DSAT did not effectively monitor and enforce certain FSAP regulatory provisions. OIG also found a high incidence of access to select agents by unapproved persons during select agent transfers. The CDC concurred with OIG's recommendations for improvements to its FSAP oversight; however, the Committee continues to observe inadequacies with the DSAT enforcement.

On September 8, 2014, the CDC DSAT referred NIH's 2014 discovery of smallpox to the HHS-OIG for potential FSAP violations. In the referral letter, the CDC DSAT mentions that the 2014 smallpox referral "supplements the information provided in April 2012 of NIH's discovery of *Bacillus anthracis* in areas not listed on NIH registration application."[50] Although the CDC DSAT recognized a connection between the 2012 and 2014 incidents, there was no further examination of why previous efforts, such as past performance improvement plans, were ineffective at detecting unregistered vials of smallpox. Nor is there any evidence that CDC asked NIH for a stronger performance improvement plan in light of the smallpox discovery.

---

[49] FDA,CBER Cold Room Policy (2011).
[50] Letter from Robbin Weyant, Director, CDC Division of Select Agents & Toxins, to David Blank, Senior Counsel, HHS-OIG, (Sept. 8, 2014).

After the 2014 NIH laboratory clean sweeps, DSAT learned that the sweep identified additional select agent material.[51] As a result, DSAT Director instructed staff to "prepare a package for consideration of compliance penalties by the HHS IG. Although NIH is being admirably responsive and transparent in their reporting these discoveries, the retention of multiple samples if Tier 1 BSAT outside of secure registered space is a serious compliance matter."[52] The Committee has learned that DSAT took no additional action, despite DSAT explicitly stating that NIH's FSAP violations were a serious compliance matter. DSAT did not revoke or suspend NIH's registration in the FSAP. The Committee is disappointed in the lack of enforcement by DSAT.

Lastly, for more than a decade, the CDC failed to implement a policy for the reporting of discovered select agents and toxins in unregistered areas. Prior to 2015, the CDC's "Form 3" required entities to report only instances of theft, loss, and release of a select agent or toxin. The form did not include discoveries of unregistered select agent materials since the inception of the FSAP program. In a response to the Committee regarding the use of the Form, CDC explained that "NIH did not submit a Form 3 to the Federal Select Agent Program (FSAP) reporting the discovery of the vials as a loss, and FSAP did not treat the discovery of these vials as a loss in the 2014 Annual Report to Congress."[53] As Congress relies on the Form 3 to identify the number of inadvertent lapses in the FSAP, the CDC's failure to report unregistered discoveries is misleading.

Question: **Did the Office of Inspector General take timely action with respect to the CDC referrals concerning the NIH?**

Finding: No. After receiving the CDC referrals concerning NIH's FSAP violations, OIG took years to resolve the referrals.

Discussion:

HHS receives FSAP referrals from the CDC DSAT if an investigation determines that a civil violation may have occurred. Once HHS receives the referral, the Office of Inspector General evaluates the case and, if OIG concludes there is a violation, OIG determines the appropriate disposition of the case. OIG has three options to resolve a DSAT referral: (1) imposing a Civil Monetary Penalty (CMP), (2) issue a Notice of Violation letter, or (3) close the case. During the Committee's July 2015 hearing on anthrax shipments, Chief Counsel to the Inspector General for HHS OIG testified that the OIG has not imposed a CMP on a Federal entity for FSAP referral violations.

DSAT referred a total of four FSAP violations on NIH to HHS OIG, with the oldest referral dating to 2011. Until this month, all four NIH referrals had remained open by OIG. OIG recently informed the Committee and CDC that it plans to close all four referrals without imposing any monetary fines. Officials at NIH and FDA informed Committee staff that the HHS OIG's open investigations of the DSAT referrals was a factor in each agency's decision to refrain from conducting any internal and retrospective review on the systemic factors contributing to the 2014 smallpox incident. The HHS OIG's recent reaffirmation of an earlier decision not to impose civil monetary fines on Federal laboratories as a practical matter now limits enforcement over civil violations to the CDC. Those potential CDC enforcement actions are limited to performance improvement plans, or revocation/suspension of Federal select agent registration.

---

[51] Email from Robbin Weyant, Director, CDC Division of Select Agents & Toxins, to Sonja Rasmussen, Joanne Andreadis, & Roberto Ruiz, CDC Division of Select Agents & Toxins (Aug. 20, 2014).
[52] *Id.*
[53] Email from Barbara Rogers, CDC, to Committee staff (April 8, 2016).

V. Conclusion

The majority Committee staff's preliminary investigation uncovered several issues related to the discovery of the smallpox vials that require further investigation by the HHS agencies. These issues include: the failure to account for regulated select agents; the failure to conduct comprehensive inventory of all select agent material; and the failure to restrict unauthorized access to select agents. Concerns are also raised about current FSAP enforcement as applied to Federal laboratories since neither the FDA nor the NIH received sanctions or penalties from the Office of Investigations for FSAP violations.

To date, neither the FDA nor NIH has conducted an internal investigation (along the lines of CDC and Army internal investigations) on the events leading to the discovery of smallpox. While senior officials from the NIH and FDA have recently indicated a willingness to conduct an internal review, neither has informed the Committee that they are, in fact, initiating such a review. This much needed internal review is in addition to the policy changes and oversight efforts currently under review and implementation at HHS agencies.

Dr. Lawrence Tabak, the Principal Deputy Director for the National Institutes of Health, and Dr. Segaran Pillai, Director of the Office of Laboratory Science and Safety for the FDA, will be testifying at the Committee's April 20 hearing. Members will have an opportunity to question these witnesses about issues arising from the information presented in this memorandum.