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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, D.C.

The subcommittee met, pursuant to call, at 10:15 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, O&I; Rebecca Card, Assistant Press Secretary; Ryan Coble, Detailee, O&I; Paige Decker, Executive Assistant; Giulia Giannangeli, Legislative

This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the final, official transcript will be posted on the Committee's website as soon as it is available.

Clerk, Commerce, Manufacturing, and Trade Brittany Havens, Oversight Associate, Oversight and Investigations; Charles Ingebretson, Chief Counsel, Oversight and Investigations; Chris Santini, Policy Coordinator, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Ryan Gottschall, Minority GAO Detailee; Chris Knauer, Minority Oversight Staff Director; Una Lee, Minority Chief Oversight Counsel; Elizabeth Letter, Minority Professional Staff Member.

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 two 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 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 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.

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

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 don't think -- I may stay here for the whole thing because I want to hear. This so 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 -- did I say that right? 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 Bryan Lein -- is that correct?

General Lein. It's Lein.

Mr. Murphy. Lein. Commanding general, U.S. Army medical research and material command at -- 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 as 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 were 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 five-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 five minutes is up.

Can I just have yourself about two or three 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, GOVERNMENT ACCOUNTABILITY OFFICE; DR. LAWRENCE A. TABAK, DDS, PH.D., PRINCIPAL DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH; STEPHEN MONROE, PH.D., ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE AND SAFETY, CENTERS FOR DISEASE CONTROL AND PREVENTION; DR. SEGARAN PILLAI, DIRECTOR, U.S. FOOD AND DRUG ADMINISTRATION; MAJOR GENERAL BRIAN C. LEIN, COMMANDING GENERAL, U.S. DEPARTMENT OF DEFENCE

STATEMENT OF MR. 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 two 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 ten 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 ten 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:]

**********INSERT 1**********

Mr. Murphy. Thank you, Mr. Neumann.

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

STATEMENT OF DR. 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:]

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

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. Okay. 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 five minutes, please.

STATEMENT OF MR. MONROE

Mr. 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 Mr. Monroe follows:]

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

Mr. Murphy. Thank you, Dr. Monroe.

Dr. Pillai, you're recognized for five 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 DR. PILLAI

Mr. 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, states 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.

Mr. Pillai. -- - 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.

Mr. 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.

Mr. Pillai. I'll be happy to answer any questions.

[The statement of Dr. Pillai follows:]

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

Mr. Murphy. General Lein, you're recognized for five minutes.

STATEMENT OF GEN. LEIN

General 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 Gen. Lein follows:]

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

Mr. Murphy. Thank you. I recognize myself for five 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?

General 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 double check things?

General Lein. Yes, sir.

Mr. Murphy. Absolutely.

General Lein. That's part of the JR -- the prejump inspection that's required --

Mr. Murphy. Exactly.

General Lein. -- not by you -- just by you but by --

Mr. Murphy. By everybody, right?

General Lein. -- 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?

General 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 you already said -- 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 five 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, the -- we know that there's important research being done and, you know, this -- 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 our findings -- 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. Okay. 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 that -- 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. Okay. 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.

General 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 was -- 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 there are -- there will be -- and 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?

Mr. 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.

Looks at those -- 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 recently notified -- the HHS Office of Inspector General was recently notified by the HHS Office of Inspector General that all the NIH referrals -- 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. There were several -- 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?

I don't think -- 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. Okay. 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. -- 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 not -- 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 you put together a report -- 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 given the -- 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. Okay. 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 there -- 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 is there -- who's -- 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 five 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 did the -- who were looking at it weren't registered to deal with that particular -- with the plague or Burkholderia?

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

Mr. Griffith. Okay. 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 but -- I mean, 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 samples -- 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?

Mr. 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?

Mr. Pillai. Absolutely.

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

Mr. 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 five 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 that's -- it's part of having -- 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 personnel are -- what level of security clearances do your personnel have who have access to these deadly pathogens, how often are they -- 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 does the principal deputy director receive -- do you receive reports of select agent inspection results now?

Dr. Tabak. I do indeed.

Mrs. Brooks. Okay. 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 director of -- 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. Okay. Thank you. I yield back.

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

Mr. Monroe. I report directly to Dr. Tom Frieden, the CDC director.

Mr. Murphy. Okay. Thank you.

I recognize Mr. Hudson for five 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.

Mr. 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?

Mr. 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?

Mr. 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.

There's easily -- 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 these -- 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?

Mr. 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 highly -- 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?

Mr. 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. Okay. Thank you for that.

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

Mr. Murphy. I think I -- 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.

Mr. Monroe. Everything has been inventoried.

Mr. Murphy. Dr. Pillai.

Mr. Pillai. Yes, every agent has been inventoried and accounted for by the FDA.

Mr. Murphy. Thank you. Mr. Mullin, you're recognized for five 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 -- 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 labelled and shipped around without the knowledge of NIH?

Dr. Tabak. That -- 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 -- 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. Okay. 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 -- 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?

General 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.

General Lein. So just follow on the recommendations of -- from the GAO report.

Mrs. Brooks. Okay. We'll look forward to your response and -- 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 respect -- 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 handled -- mishandled the procedures for the anthrax?

General Lein. Yes, sir. Twelve recommendations for 12 personnel at Life Sciences.

Mr. Murphy. Okay. 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, we just want -- 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. Okay. 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?

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

Mr. 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?

Mr. Pillai. Right.

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

Mr. 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?

Mr. 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?

Mr. 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.

Mr. Pillai. Right.

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

Mr. 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?

Mr. Pillai. I totally agree with you.

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

Mr. Pillai. There is a large group of individuals involved.

Mr. Murphy. Five? A hundred?

Mr. 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?

Mr. Pillai. I would say probably many hours, to be honest.

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

Mr. Pillai. I don't have the exact number of hours.

Mr. Murphy. Hundreds of hours?

Mr. Pillai. Probably.

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

Mr. Monroe. Investigating --

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

Mr. Monroe. I would have to, you know, get back with an estimate of the number of hours. But there were -- 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 finding -- 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.

Mr. Pillai. But we do have procedures.

Mr. Murphy. But you had said --

Mr. 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.

Mr. 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 say I can -- 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, yeah, never had a protocol of how to -- 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 of the documents -- 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 follows:]

**********COMMITTEE INSERT 6**********

Mr. Murphy. In conclusion, I thank all the witnesses and members that participated in today's hearing. I remind members they have ten 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.]