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CONTINUING CONCERNS WITH THE FEDERAL SELECT AGENT PROGRAM: DEPARTMENT OF DEFENSE SHIPMENTS OF LIVE ANTHRAX

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

JULY 28, 2015

Serial No. 114–69

Printed for the use of the Committee on Energy and Commerce

energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

97–913 PDF WASHINGTON : 2016

For sale by the Superintendent of Documents, U.S. Government Publishing Office
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C O N T E N T S

	Page
Hon. Tim Murphy, a Representative in Congress from the Commonwealth of Pennsylvania, opening statement	1
Prepared statement	3
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement	4
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	6
Prepared statement	7
Hon. Fred Upton, a Representative in Congress from the State of Michigan, prepared statement	97
WITNESSES	
D. Christian Hassell, Ph.D., Deputy Assistant Secretary of Defense for Chemical and Biological Defense, Department of Defense	8
Prepared statement	11
Answers to submitted questions	114
Daniel M. Sosin, M.D., Deputy Director and Chief Medical Officer, Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention, Department of Health and Human Services	22
Prepared statement	24
Answers to submitted questions	124
Gregory E. Demske, Chief Counsel to the Inspector General, Office of Inspector General, Department of Health and Human Services	37
Prepared statement	39
Answers to submitted questions	132
Marcia Crosse, Ph.D., Director, Health Care, Government Accountability Office	46
Prepared statement	48
Answers to submitted questions	139
SUBMITTED MATERIAL	
Slide, "Irradiation of *Bacillus anthracis* Spores (Ames Strain)," submitted by Mr. Murphy	67
Subcommittee memorandum	98
Article of July 27, 2015, "CDC lacked key lab incident reporting policy despite scrutiny, promises," by Alison Young, USA Today, submitted by Mr. Murphy	110

CONTINUING CONCERNS WITH THE FEDERAL SELECT AGENT PROGRAM: DEPARTMENT OF DEFENSE SHIPMENTS OF LIVE ANTHRAX

TUESDAY, JULY 28, 2015

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

The subcommittee met, pursuant to call, at 10:04 a.m., in room 2123 of the Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Members present: Representatives Murphy, McKinley, Burgess, Blackburn, Griffith, Bucshon, Flores, Brooks, Mullin, Hudson, Collins, DeGette, Schakowsky, Castor, Tonko, Kennedy, Green, Welch, and Pallone (ex officio).

Staff present: Noelle Clemente, Press Secretary; Jessica Donlon, Counsel, Oversight and Investigations; Brittany Havens, Oversight Associate, Oversight and Investigations; Alan Slobodin, Deputy Chief Counsel, Oversight; Jessica Wilkerson, Oversight Associate, Oversight and Investigations; Christine Brennan, Democratic Press Secretary; Jeff Carroll, Democratic Staff Director; Ryan Gottschall, Democratic GAO Detailee; Christopher Knauer, Democratic Oversight Staff Director; Una Lee, Democratic Chief Oversight Counsel; and 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. Welcome to our hearing once again dealing with anthrax. The subcommittee today examines continuing concerns over the Federal Select Agent Program. This time our focus is on shipments of live anthrax from a Department of Defense laboratory at the Dugway Proving Grounds that occurred over a nearly 10-year period.

And as Yogi Berra said, it is like déjà vu all over again.

Last year, we held a similar hearing on a CDC anthrax incident that potentially exposed dozens of CDC researchers to live anthrax, due to the fact that established safety procedures were not followed. During the hearing CDC Director Frieden testified, "We will take every step possible to prevent any future incident that could put our laboratory scientists and the public at risk." Yet here we are again today.

We also examined CDC's mistaken shipment of highly pathogenic avian flu and the FDA's discovery of vials of smallpox in an NIH building. Months after our hearing and after a White House-ordered safety stand-down and a laboratory sweep of all Federal labs, the CDC revealed there had been a transfer of Ebola from a CDC Level 4 lab to a CDC Level 2 lab. This is all deeply troubling. And despite the growing number of red flags, these incidents keep happening.

Now we have learned that the Dugway Proving Grounds, an Army lab in Utah, has inadvertently shipped live anthrax to facilities across the globe. At last count, at least 192 labs have received shipments of live anthrax. Apparently, Dugway's process to inactivate anthrax spores was not fully effective. And the sterility testing used to validate and ensure that the anthrax spores were inactivated failed to detect the live anthrax spores. What is most troubling, however, is that Dugway used this potentially deadly process for years.

As I said at last year's hearing, this is completely unacceptable. These dangerous safety lapses at our high-containment labs are threatening our Nation's security and public health. The committee hopes to learn today what is being done this time to prevent future safety lapses. And will this be any different?

Last week, the Department of Defense released a report following its internal review of the circumstances surrounding the live shipments of anthrax, and according to its report, the DoD was unable to definitively determine the root causes for how and why Dugway shipped live anthrax. Yet, in the report, the Department acknowledged that all its labs "routinely operate outside validated experimental data for kill curves."

So in other words, it seems that Department of Defense labs have been irradiating larger numbers of spores than recommended. And the labs should have known that they could not guarantee inactivation of all the anthrax spores at those numbers, especially at the dosage of radiation given.

This revelation begs a lot of questions, beginning with why? And why for so long? Who was responsible for making the decisions about which inactivation process to use, including how many spores and at what levels of radiation? Are these decisions evaluated and then ever re-evaluated? And what is the CDC's role in developing and evaluating these processes?

According to a recent and all-too-familiar headline, CDC has also announced that it will be conducting yet another comprehensive review of how it regulates safety and security at bioterror labs. I think it is important to review current regulations to improve processes and procedures. But past reviews have not brought about the change necessary to truly improve safety and standardize processes and procedures. Maybe—we hope—this review will actually bring about different results.

As I said a year ago, what we have here is a pattern of recurring issues, of complacency, and a lax culture of safety. Last year, CDC Director Frieden stated that this was a wake-up call. However, it appears that critical Government agencies have hit the snooze button once again. What is it going to take to change things this time, and when?

None of us want to be here again a year from now, discussing another set of safety lapses, and heaven forbid, a loss of life.

The U.S. Government Accountability Office has conducted comprehensive work on the oversight of high-containment labs. In fact, GAO has been issuing recommendations for years calling for a Government-wide strategy for the requirements for high-containment labs and the need for national standards for designing, constructing, commissioning, and maintaining such labs. Yet, these recommendations have not been implemented, which is one of the reasons we are here again today discussing another safety lapse that threatens national security and the public health.

Today I would like to thank our witnesses for testifying here. I look forward to hearing your testimony and learning from you. Please be candid and straightforward with us as we try to find ways to improve the safety and procedures in our bioterrorism labs. This subcommittee will not relent in its oversight of Federal laboratories' compliance with select agent regulations, and will further explore the possibility of an independent agency to oversee these labs.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

The subcommittee today examines continuing concerns over the Federal Select Agent Program. This time our focus is on shipments of live anthrax from a Department of Defense laboratory at the Dugway Proving Grounds that occurred over a nearly 10-year period.

As Yogi Berra said, it's like déjà vu all over again.

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And despite the growing number of red flags, these incidents keep happening.

Now, we have learned that the Dugway Proving Grounds, an Army lab in Utah, has "inadvertently" shipped live anthrax to facilities across the globe. At last count, at least 192 labs have received shipments of live anthrax. Apparently, Dugway's process to inactivate anthrax spores was not fully effective. And the sterility testing-used to validate and ensure that the anthrax spores were inactivated-failed to detect the live anthrax spores. What's most troubling, however, is that Dugway used this potentially deadly process for years.

As I said at last year's hearing, this is completely unacceptable. These dangerous safety lapses at our high-containment labs are threatening our Nation's security and public health. The committee hopes to learn today what is being done this time to prevent future safety lapses. Will this time be different? Last week, the Department of Defense released a report following its internal review of the circumstances surrounding the live shipments of anthrax. According to its report, the DoD was unable to definitively determine the root cause for how and why Dugway shipped live anthrax. Yet, in the report, the Department acknowledged that all its labs "routinely operate outside validated experimental data for kill curves." So in other words, it seems that Defense Department labs have been irradiating larger numbers of spores than recommended. And the labs should have known that they could not guarantee inactivation of all the anthrax spores at those numbers, especially at the dosage of radiation given.

This revelation begs a lot of questions, beginning with why? And why for so long? Who is responsible for making the decisions about which inactivation process to use, including how many spores and at what levels of radiation? Are these decisions

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As I said a year ago, what we have here is a pattern of recurring issues, of complacency, and a lax culture of safety. Last year, CDC Director Frieden stated that this was a "wake-up" call. However, it appears that critical Government agencies have hit the snooze button. What is going to change this time? And when? None of us want to be here again a year from now, discussing another set of safety lapses, that may have actually caused loss of life.

The U.S Government Accountability Office has conducted comprehensive work on the oversight of high-containment labs. In fact, GAO has been issuing recommendations for years calling for a Government-wide strategy for the requirements for high-containment labs and the need for national standards for designing, constructing, commissioning, and maintaining such labs. Yet, these recommendations have not been implemented, which is one of the reasons we are here again today discussing another safety lapse that threatens national security and the public health.

I would like to thank the witnesses for testifying here today, and I look forward to hearing your testimony about what needs to be done to improve the safety, and procedures in our bioterrorism labs. This subcommittee will not relent in its oversight of Federal laboratories' compliance with select agent regulations and will further explore the possibility of an independent agency to oversee these labs.

Mr. MURPHY. I now recognize the ranking member, Ms. DeGette of Colorado, for 5 minutes.

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

Ms. DEGETTE. Thank you, Mr. Chairman. Mr. Chairman, you say you don't want to be back here in a year like we were last year, but we have been here in 2007, 2009, 2014, and now 2015. So might as well mark your calendar now. And part of that is because it is really important that the Federal Government work on identifying and containing public health risks. But the work itself inherently contains risk. And that is why we do have to continue our oversight.

At last year's hearing on the anthrax transfer I talked about the high-containment lab that we have in Fort Collins at which some years ago we identified terrible lapses, and I was able to work with my former Republican colleague, Bob Schaffer, from that district to get a new lab built. I am proud of that work, but we have to continue to be able to assure our constituents that similar facilities across the country provide no risk to workers or to the broader community.

Now Mr. Chairman, as you said, frankly the details of the Dugway incident do not inspire confidence. We are talking about a long-term series of inadvertent shipments of live anthrax from the Dugway Proving Ground in Utah which is supposedly one of the most sophisticated facilities in the world. This incident only came to light in May because a private company contacted CDC after discovering what it thought was inactivated anthrax was actually live anthrax.

Since then we have learned that 86 laboratories in 20 States and the District of Columbia and seven foreign countries received live

anthrax spores from Dugway over the last 12 years. Those labs then transferred the live spores to an additional 106 labs. So we are talking about almost 200 labs in all 50 States accidentally receiving live anthrax for over a decade. Miraculously, nobody seems to have fallen ill as a result of this series of incidents. Still, like you, Mr. Chairman, I am concerned that this activity was going on for so long before one lab finally raised questions that spurred the Department to action.

I am eager to hear answers from DoD about how this was allowed to happen in the first place and what they are doing to ensure it never happens again.

I understand that the Department's review of the Dugway incident released last week found there is insufficient scientific literature to develop effective protocols for the inactivation of anthrax spores. The Dugway lab was therefore relying on procedures that did not permanently or completely sterilize the anthrax spores.

Now, this is not my area of expertise, but it seems troubling on its face. How have we conducted research on this dangerous pathogen for the past decade without thoroughly understanding how to inactivate it? We need to conduct a serious examination of whether we use similarly questionable protocols for other select agents, and if so, I think we can all agree that we should immediately cease those operations to ensure we are not putting public health at risk.

For now, appropriately, DoD has issued a moratorium on shipping inactivated anthrax from its labs. This seems like an important first step, but I do want to know how that affects the research the lab was doing. Furthermore, I want clarification, as how do we have 200 separate labs all across the country working with anthrax? Do we need to have 200 labs working with anthrax or is it possible that we could limit the number of labs and therefore limit the risk while still being able to do this important research?

I also want to hear today about whether the breakdowns at Dugway are indicative of broader problems at this site or even across the high-containment lab system. The labs that handle these pathogens must be held to the highest standards. Yet, the incidents that we have seen recently raise questions about whether we can trust high-containment labs to safely handle select agents.

Now in the last year, we have seen an anthrax exposure incident at CDC—this is what you said—improper shipments of avian flu, and even a potential Ebola exposure at a CDC lab. I feel really lucky that we haven't had anybody infected, but it could happen and I think we have just been going on borrowed time here.

So I hope all of you have answers today about what we are really doing to make serious changes to the system and include recommendations that GAO has made.

I also want to hear from our witnesses about the role Congress should play in making sure the program operates safely. And with that, Mr. Chairman, I yield back. Thank you.

Mr. MURPHY. Thank you. Does anybody else on this side wish to make any opening statement or comments? If not, I would ask—and I don't know if you have seen this yet, Ms. DeGette and Mr. Pallone. An article appeared in last night's USA Today. I would like to have you look at it and see if you would have unanimous consent to submit that to the record. With no objection? This is ti-

tled, "CDC lacked key lab incident reporting policy despite scrutiny, promises," and I think it is going to be relevant to today's hearing.

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

Mr. MURPHY. I now recognize Mr. Pallone for 5 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman. I hope today we can get to the bottom of what happened at Dugway Proving Ground that resulted in live anthrax being shipped to 192 labs in all 50 States and at least seven foreign countries.

Deputy Defense Secretary Robert Work described these lapses as a "massive institutional failure." I hope Dr. Hassell can explain to us today how these failures could possibly have occurred as well as what DoD is doing to strengthen and standardize safety protocols across all DoD labs as we move forward.

I am deeply relieved that no one has fallen ill as a result of these lapses, and I am hopeful that this will remain the case as DoD and CDC continue to track all the labs that receive these samples and the personnel that handle them. But this incident also raises broader questions about the safety of high-containment laboratories across the country.

Every day hundreds of labs in the Federal Government as well as academic institutions and private companies handle dangerous pathogens and toxins under the Federal Select Agent Program. Make no mistake, these labs perform important work. High-containment labs play a critical role in biodefense by conducting research to improve our defenses against biological attacks and strengthening our public health response capabilities.

Laboratories that handle select agents are required to abide by a set of regulations commensurate with the risk that these agents pose. They are required to restrict access to select agents to individuals who have undergone a security risk assessment by the FBI and implements physical security safeguards, lab safety measure, and incident response plans. They must also ensure that laboratory workers are properly trained on biosafety and security measures.

Labs that participate in the program are also subject to registration and inspections by the CDC's Division of Select Agents and Toxins. There are civil penalties associated with lapses in safety protocols. Unauthorized possession or misuse of select agents is subject to severe criminal penalties. However, incidents in the past year involving anthrax, Ebola, and highly pathogenic avian flu raise questions about whether we need to strengthen our Federal oversight of labs that are working with dangerous pathogens. Is the current regulatory framework sufficient? Do the enforcement agencies have sufficient resources to ensure that oversight is robust? What is CDC doing to improve the Federal Select Agent program and prevent similar situations from occurring in the future?

I understand that CDC and DoD have conducted reviews of these incidents and have promised several more. I look forward to hearing about the findings and recommendations from those reviews and how they can be used to enhance safety and security at all of

our Nation's high-containment laboratories. I also want to note that GAO has an important body of work that can inform this discussion. I look forward to hearing from GAO about its recommendations to strengthen safety measures across high-containment labs.

I am glad that nobody appears to have suffered any injuries because of this latest incident out of Dugway. The next time, however, the mishap may be from something more dangerous than liquid anthrax such as a highly infectious pathogen. So I hope we can all learn from this latest incident and will take seriously the important recommendations made by recent and ongoing investigations by GAO and others to make this program safer. Obviously we look forward to a productive discussion today on how we can improve oversight and what this committee can do to facilitate that process and again thank our chairman and our ranking member as we proceed. I yield back.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Thank you, Mr. Chairman, for convening this important hearing. I hope today we can get to the bottom of what happened at Dugway Proving Ground that resulted in live anthrax being shipped to 192 labs in all 50 States and at least seven foreign countries.

Deputy Defense Secretary Robert Work described these lapses as a quote "massive institutional failure." I hope Dr. Hassell can explain to us today how these failures could possibly have occurred, as well as what DoD is doing to strengthen and standardize safety protocols across all DoD labs moving forward.

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I look forward to a productive discussion today on how we can improve oversight of these labs, and what this committee can do to facilitate this process.

Thank you to all of our witnesses for your testimony.

Mr. MURPHY. The gentleman yields back, and if no further comments from here, then we are going to go to our witnesses.

So as you are aware, when the committee is holding an investigative hearing, when doing so, it has had the practice of taking testimony under oath. Do any of our witnesses today 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? No. No one is asking for that.

In that case, would you please rise, raise your right hand, and I will swear you in?

[Witnesses sworn.]

Mr. MURPHY. All of our witnesses have answered in the affirmative, and so now you are under oath and subject to the penalties set forth in Title 18, Section 1001, of the United States Code.

You may now each give a 5-minute summary of your written statement. Please pay attention to the lights there, and we will start with you, Dr. Hassell, 5 minutes.

STATEMENTS OF D. CHRISTIAN HASSELL,PH.D., DEPUTY ASSISTANT SECRETARY OF DEFENSE FOR CHEMICAL AND BIOLOGICAL DEFENSE, DEPARTMENT OF DEFENSE; DANIEL M. SOSIN, M.D., DEPUTY DIRECTOR AND CHIEF MEDICAL OFFICER, OFFICE OF PUBLIC HEALTH PREPAREDNESS AND RESPONSE, CENTERS FOR DISEASE CONTROL AND PREVENTION, DEPARTMENT OF HEALTH AND HUMAN SERVICES; GREGORY E. DEMSKE, CHIEF COUNSEL TO THE INSPECTOR GENERAL, OFFICE OF INSPECTOR GENERAL, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND MARCIA CROSSE, PH.D., DIRECTOR, HEALTH CARE, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF D. CHRISTIAN HASSELL

Dr. HASSELL. Chairman Murphy, Ranking Member DeGette, and distinguished members of the subcommittee, I appreciate the opportunity to brief you today on the Department of Defense's inadvertent shipments of samples containing live Bacillus anthracis spores or anthrax. My name is David Hassell. I am the Deputy Assistant Secretary of Defense for Chemical and Biological Defense.

The Use of inactivated or dead anthrax is an important element of longstanding DoD programs to develop ways to protect warfighters and the public from known biological threats, doing this with the development and testing of detection systems, protection equipment, diagnostics, and decontamination capabilities.

We first learned of the incidents under consideration today on May 22 of 2015 when the Centers for Disease Control and Prevention was alerted by a private company regarding the growth of live anthrax in a sample that was inactivated by a laboratory at the Army's Dugway Proving Ground in Utah. The CDC immediately began an investigation, working with DoD laboratories, State officials, and the FBI.

By May 25, all known laboratories that received inactivated anthrax samples from that same batch had been notified and instructed to stop working with the samples. Also on May 25th the four DoD laboratories that produce inactivated anthrax were directed to stop producing, shipping, and working with any inactivated anthrax other than for purposes related to this current matter.

Subsequent tests by Dugway identified other batches of inactivated anthrax as containing live spores, and on June 2nd the Department of Defense notified all known recipients of inactivated anthrax from Dugway to stop working with the material, whether it was confirmed to contain live anthrax or not.

There's no known or suspected cases of anthrax infection among workers at any of the laboratories that produced or received inactivated anthrax, and there is no known risk to the general health and very little risk to laboratory workers themselves. However, as a precaution, 31 U.S. citizens, 8 non-DoD, 23 DoD, were placed on postexposure prophylaxis treatment, and this was completed yesterday.

Returning to the subject of the four DoD Laboratories that produce inactivated anthrax, on May 29th the Deputy Secretary directed that those four DoD laboratories test all previously inactivated anthrax that was in their inventory to identify the presence of any live spores. That testing is now complete, and the results are as follows: Since 2003, the four DoD laboratories irradiated a total of 149 batches of live anthrax spores. Of the 96 samples that were available to test, 17 tested positive for the presence of live anthrax. All of these originated from Dugway.

We now know that over the past 12 years, 86 laboratories in 20 States, DC, and seven foreign countries received directly from Dugway inactivated samples that contained live spores. In addition, the CDC has informed us that an additional 106 labs received secondary transfers from some of the original 86 direct recipient labs. This brings the total to 192 labs in all 50 States, DC, and the three Territories of Guam, Puerto Rico, the U.S. Virgin Islands.

A recently completed Comprehensive Review of the root causes of the incident resulted in several key findings including that the primary systemic issue is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures, and the resulting recommendations are grouped into three broad categories being enhance quality control programs, establish testing protocols that are based on relevant scientific data, and improve program management.

The Department is committed to ensuring that this doesn't occur again and will implement the recommendations that were in the report and the further directives outlined by Deputy Secretary Work on 23rd of July. In the interim, the aforementioned morato-

rium will continue. Our top priority is the safety of all involved, and we remain committed to complete transparency of information as we go forward. Thank you for the opportunity to testify today, and I'll welcome your questions.

[The prepared statement of Dr. Hassell follows:]

Opening Statement

Dr. David C. Hassell, Deputy Assistant Secretary of Defense
for Chemical, and Biological Defense Programs

Hearing of the

House Energy and Commerce Oversight and Investigations Subcommittee

On

Shipment of Inactivated *Bacillus anthracis* (Anthrax)

July 28, 2015

Not for Public Release until Approved by the

House Energy and Commerce Oversight and Investigations Subcommittee

Chairman Murphy, Ranking Member DeGette, Distinguished Members of the Subcommittee, thank you for this opportunity to brief you on the Department of Defense's inadvertent shipments of samples containing live *Bacillus anthracis* spores ("anthrax").

Use of inactivated anthrax remains an important element of longstanding Department of Defense (DoD) programs to develop ways to protect warfighters and the public from known biological threats. Inactivated (or dead) anthrax has been used to develop detection systems, protection equipment, diagnostics, and decontamination capabilities. It is also used for training, validation and testing of existing biodetection and diagnostic systems throughout the country. To ensure that the Department obtains the best technologies for national security, those development efforts, including research projects, involve partnerships with many other government organizations, industry, academic institutions and Allies.

We first learned of these incidents on May 22, 2015, when the Centers for Disease Control and Prevention (CDC) received a call from a private company regarding the growth of live anthrax in a sample that was inactivated by a laboratory at the Army's Dugway Proving Ground, Utah. The company was involved in a competitive procurement for new detection systems, and decided to test their sample before using it to ensure it had been inactivated. The CDC immediately

began an investigation, working with DoD laboratories, state officials, and the Federal Bureau of Investigation.

By May 25, 2015, all known laboratories that received inactivated anthrax samples from that same batch had been notified and instructed to stop working with the samples and to follow CDC instructions. Also on May 25, 2015, the four DoD laboratories that produce inactivated anthrax in support of defensive research and development (i.e., Dugway Proving Ground, U.S. Army Medical Research Institute of Infectious Diseases, Naval Medical Research Center and the Edgewood Chemical Biological Center) were directed to stop producing, shipping and working with any inactivated anthrax, other than for purposes related to this current matter.

Subsequent tests by Dugway of other batches of inactivated anthrax identified as containing live anthrax. Recipients of samples from those batches were notified and instructed to stop working with the samples and to follow CDC instructions. As a further precaution, beginning on June 2, 2015, the Department of Defense notified all known recipients of inactivated anthrax from Dugway to stop working with the material, whether it was confirmed to contain live anthrax or not.

There are no known or suspected cases of anthrax infection among workers at any of the laboratories that produced or received inactivated anthrax, and there is no

known risk to the general public and very little risk to laboratory workers. This is due to the low concentration of live anthrax in the samples, the samples were in liquid, and the sample vials were securely packed and transported in accordance with the Department of Transportation and International Air Transport Association requirements. As a precaution, 31 U.S. citizens (8 non-DoD and 23 DoD) were initially placed on post-exposure prophylaxis after an evaluation of their use of biosafety practices, which were appropriate for inactivated anthrax but not for live anthrax; 2 non-DoD citizens subsequently discontinued treatment. All personnel are expected to have completed post-exposure prophylaxis by July 31, 2015. Personnel from other countries did not require post-exposure prophylaxis.

Returning to the subject of the four DoD Laboratories that produce inactivated anthrax, on May 29, 2015, the Deputy Secretary directed that those four DoD laboratories test previously inactivated anthrax in inventory to identify the presence of live spores. Testing of the samples is now complete, and the results are as follows:

Since 2003, the four DoD laboratories irradiated a total of 149 batches of live anthrax spores and reported them as inactivated and safe for subsequent testing. Every one of those batches have been accounted for and either tested or destroyed.

Fifty three of the 149 batches are no longer in DoD inventory. Of the remaining 96 samples available to test, 17 of those 96 tested positive for the regrowth or presence of live anthrax, and every one originated from Dugway Proving Ground.

In other words, of the total batches in Dugway's inventory, 17 of 33 batches tested positive, which is over 50%.

We now know that over the last 12 years, 86 laboratories in 20 states, the District of Columbia, and seven foreign countries ultimately received inactivated spores that were live, all directly from Dugway. In addition, the CDC has informed us that an additional 106 labs received "secondary transfers" from some of the original 86 recipient labs. This brings the total to 192 labs in all 50 States, the District of Columbia, and 3 Territories (Guam, Puerto Rico, The U.S. Virgin Islands).

Also on May 29, Deputy Secretary of Defense Work directed the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L) to oversee a Comprehensive Review, focusing on:

- The root causes of the incomplete inactivation of anthrax;
- DoD laboratory biosafety procedures and protocols relating to the inactivation of anthrax;
- Laboratory adherence to established procedures and protocols; and

- Identification of systemic problems and the steps necessary to fix those problems.

The DoD Comprehensive Review was completed on June 30. The key findings are:

- In certain cases, DoD procedures to irradiate and kill live anthrax spores, and to test the viability of irradiated (and presumed inactivated) samples, are ineffective.
- The primary systemic issue responsible for failures in the preparation of inactivated anthrax spores is the lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures.
- The development and implementation of ineffective irradiation and viability testing procedures took place over the last decade; this represents an institutional problem particularly at Dugway Proving Ground (DPG).
- Inactivated anthrax originating from DPG are the only samples that have tested positive for live anthrax.
- The confluence of large production quantities associated with DPG, low sampling volume of the inactivated material for viability testing,

and a very short time period between the completed irradiation cycle and start of the viability testing may have exacerbated the likelihood of not properly identifying live anthrax spores in inactivated samples.

- Laboratory biosafety protocols and procedures are not standardized amongst the DoD laboratories; this is potentially due to the fact that the laboratories are managed under multiple chains of command.

The Comprehensive Review Committee's recommendations are grouped into three broad areas. The Review Committee recommends DoD laboratories that work with hazardous select agents and other pathogens:

- Enhance quality control programs, particularly regarding inactivation and viability testing protocols.
- Establish anthrax spore inactivation and viability testing protocols that are based on relevant scientific data, standards, and studies conducted to fill knowledge gaps.
- Improve program management to ensure adequate laboratory space, equipment, and time to conduct relevant research for select agents and other pathogens.

In a memorandum dated 23 July, 2015, the Deputy Secretary of Defense directed the following:

- The Under Secretary of Defense for Acquisition, Technology and Logistics (USD(AT&L)) will:
  - Work with DoD stakeholders, the CDC, and other relevant departments and agencies to develop a plan for research related to the development of standardized irradiation and viability testing protocols;
  - Establish standards, in coordination with DoD stakeholders, the CDC, and other relevant departments and agencies, for irradiation and viability testing using the results of research conducted;
  - Ensure sufficient funding is available through the Chemical and Biological Defense Program for research related to the development of standardized irradiation and viability testing protocols;
  - Review, and revise as necessary, DoD biosafety and biosecurity policy and ensure consistent application across DoD laboratories; and
  - Oversee Military Department and Service implementation of the Review Committee's recommendations.
- The Secretary of the Army will:

- Conduct a full accountability assessment of the responsible institutions and individuals at DPG, including the chain of command, to include initiating a formal investigation by an appropriate investigative organization, of the specific actions at DPG that contributed to the unintended and unacknowledged shipment of viable anthrax spores to a large number of recipients;
- In coordination with the Secretary of the Navy, develop an implementation plan for addressing the specific recommendations in the Report on quality assurance, peer review, and program management;
- Provide the implementation plan to me for review in 30 days, with quarterly updates on progress thereafter;
- Review laboratory missions and chains of command and provide policy and organizational recommendations to ensure consistent application of biosafety and biosecurity policies across the laboratories; and
- Assess the optimal distribution of research, development, and production activities at the laboratories that support the Chemical and Biological Defense Program mission to develop countermeasures for the warfighter against chemical and biological threats.

- In addition:

- The Secretary of the Army is designated as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program.
- Continuation of the moratorium on the production, handling, testing, and shipment of inactivated anthrax, except as required for the development of standardized, peer-reviewed, validated protocols for inactivation and viability testing, until all the recommendations in the Report are addressed.
- USD(AT&L) will work with all DoD and interagency stakeholders to mitigate the impacts of the continuing moratorium on important research, development, and production activities related to the development of countermeasures to protect the warfighter and the Nation from biological threats.

The Department is committed to putting in place the systems so that ensure that this does not occur again, and will implement the recommendations of the Report and the further directives outlined by Deputy Secretary Work on July 23. DoD and CDC continue to work closely to understand the issues relating to the inactivation of anthrax and necessary changes to the viability testing protocol in order to respond to the findings of the investigation and review. In the interim, the DoD

moratorium on producing, shipping and working with any inactivated anthrax, other than for purposes related to developing the science basis for irradiation and viability testing, will remain in effect.

Our top priority is the safety of all involved, and we remain fully committed to complete transparency of information. Thank you for the opportunity to testify today and I welcome your questions.

Mr. MURPHY. Thank you, Dr. Hassell. Dr. Sosin, before you speak, I just want to note that we haven't really had the chance to review a lot of your testimony because it wasn't in until 9:00 last night, and the committee rules, we ask for 48 hours. So we really didn't have time to review that. So when we get the testimony at the last minute, it is difficult for us to review it. I don't want to think that CDC is trying to frustrate our purposes here, but I do want to indicate to you and if you could pass the word onto CDC department that for future testimony, we want that 48-hour limit adhered to.

So at this point, we would like to hear from you for 5 minutes. Thank you.

STATEMENT OF DANIEL M. SOSIN

Dr. SOSIN. Thank you. Chairman Murphy, Ranking Member DeGette, distinguished members of the subcommittee, I want to thank you for this opportunity to testify before you today. I would like to share with you what CDC has done to respond to the inadvertent release of live Bacillus anthracis spores, or anthrax, from Dugway Proving Ground and to provide perspective on the Select Agent Program that CDC supports.

CDC works 24/7 to save lives and protect people. We activated our emergency operation center in face of uncertainty about the scope and severity of this release. We understand how concerning this incident has been, and our primary focus continues to be making certain people are safe and that anthrax materials are secured and ultimately disposed of.

This incident raises serious and challenging issues. It is important to note, however, that scientific research in laboratories is a vital component of our Nation's defense against naturally occurring diseases and bioterrorism. This research is complex and sometimes dangerous. While it is not possible to eliminate all risk, those of us working in this field across the country and around the world must do all we can to minimize risk.

Here's what we know about today about the Dugway incident. There have been no suspected or confirmed cases of anthrax infection associated with these samples. Persons that CDC has assessed is at some risk and who have accepted treatment will have completed antibiotic and vaccine prophylaxis yesterday, and no complications have been reported.

The facilities that received these samples have appropriately secured or destroyed them, and those needing decontamination have completed the procedures or are well under way.

Highlighting this positive news is not meant to downplay the seriousness of the situation. On multiple occasions over more than a decade the production methods at Dugway failed to inactive anthrax spores. The failure of inactivation was evident because growth was being detected on multiple production runs. These runs were routinely sent back for additional irradiation. This should have been seen for what it was, an indication that the margin of safety with the method was not sufficient. Additionally, sterility testing at Dugway to confirm the inactivation was successful at killing the organism failed to detect live spores.

We have looked and found no evidence of a similar problem at other facilities that inactivate anthrax spores. The existing rules and regulations on anthrax spore inactivation are under review.

Here's what we don't know. The Federal Select Agent Program relies primarily on sterility testing to assure that a select agent can no longer grow. We remain unsure whether there was a problem with the execution of this testing at Dugway or if the biology of spores was not sufficiently understood to make the procedure reliable.

And here's what we are doing moving forward. We are maintaining a moratorium on the use and transfer of inactivated anthrax spores until we have an acceptable and credible approach to increasing safety and security. And we are developing a research agenda on spore biology to answer questions about inactivation and sterility, and we will help to conduct some of that research.

At Dr. Frieden's direction, we are initiating a review of the CDC Federal Select Agent Program. The review will complement ongoing work to improve laboratory safety at CDC this past year. The time is right with new leadership over the CDC Federal Select Agent Program for a thorough review of our program to ensure it's meeting its mandate, especially in light of recent lab incidents.

The world benefits from discoveries made working with dangerous pathogens, and the scientists who work with these organisms also have a commitment to protecting public health and safety. We must achieve a balance to protect workers and the communities around them while encouraging and supporting scientific advancement. But safety comes first.

One characteristic of CDC's stewardship of the Federal Select Agent Program is a commitment to improvement. The regulations have been refined with advice from many including numerous Federal advisory and review bodies and the public. This input has led to revisions to the select agent regulations concerning personnel reliability, incident reporting, coordination of inspections with Federal partners, and tracking shipments of select agents.

Although much work has been done to enhance the effectiveness of CDC's regulatory oversight of select agents and toxins, more work remains to be done. Where improvements can be made to better the program, we will make them. Whether there is disagreement on the best path forward, we will contribute our scientific and programmatic expertise to the debate. We will work diligently and thoughtfully with anyone sharing our commitment to protect Americans from biological threats. Thank you.

[The prepared statement of Mr. Sosin follows:]

Testimony before the
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives

Review of Department of Defense Anthrax Shipments

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For Release upon Delivery
Expected at 10:00 a.m.
July 28, 2015

Thank you, Mr. Chairman, Ranking Member DeGette, and Members of the Subcommittee. I am Dr. Daniel M. Sosin, Deputy Director and Chief Medical Officer with the Office of Public Health Preparedness and Response at the Centers for Disease Control and Prevention (CDC). The Committee on Energy and Commerce has played an instrumental role in ensuring that CDC and other components of the Department of Health and Human Services (HHS) have the needed authorities to prepare for, respond to, and recover from threats to the nation's health -- whether they are the result of terrorism or naturally occurring events -- and to appropriately address biosafety and biosecurity. I appreciate the Committee's continued leadership on these important issues and the opportunity to appear before you to discuss CDC's role in the investigation of and response to the inadvertent shipments of live anthrax from a laboratory at the Department of Defense (DoD) Dugway Proving Ground (Dugway) in Utah.

As CDC's Incident Manager for this response, I oversaw all aspects of CDC's involvement. Today I am going to talk with you about CDC's investigation under the authority of the Federal Select Agent Program (FSAP), and about other aspects of CDC's response in its traditional role of protecting peoples' health. I also want to mention briefly the FSAP's contributions to efforts over the past year to strengthen safety and security around Federal select agent laboratories in the United States, and participation in ongoing comprehensive reviews of FSAP and biosafety more generally, led by the White House.

CDC's Highest Priority is to Save Lives and Protect People

CDC's commitment to saving lives and protecting people applies to all aspects of our work, including responding to health threats, and -- with the U.S. Department of Agriculture -- jointly regulating laboratories that work with select agents.

CDC responded to shipments of live anthrax from Dugway to achieve several goals:

- Ensure that people were safe, by working with state health departments to identify potentially exposed workers, asses their health risk, and offer treatment when appropriate;
- Develop recommendations for effective decontamination of laboratories, in collaboration with the Environmental Protection Agency (EPA);
- Secure the samples of live anthrax inadvertently sent to many places not approved to have anthrax or any select agent, to prevent any further potential exposures; and
- Importantly, to understand what happened so that we can take additional steps to prevent this from happening again.

On May 22, 2015, after being advised by a laboratory that live anthrax was detected in a sample from Dugway that was supposed to have been inactivated, CDC initiated outreach to what has amounted to 183 domestic laboratories (164 of which are not DoD labs) to track 575 shipments of presumed inactivated anthrax material (that turned out to include live anthrax) coming from Dugway. (There were an additional nine labs in seven foreign countries that received lots from Dugway, making for a total of 192 labs that received hot lots, but CDC's outreach was only to

domestic labs). In the last two months, CDC has reached out to each laboratory to identify potential exposure to this material within the past year – with most outreach coming within hours of learning that the laboratory might hold incompletely inactivated material. If a potential exposure was encountered, CDC doctors and scientists, in collaboration with state health departments, assessed workers and the laboratory environment for any possible aerosol spore exposure (inhalation anthrax is considered to be the most deadly form of anthrax). CDC laboratory scientists tested samples shipped from Dugway to confirm our understanding of low concentrations of spores in the positive results, and CDC environmental microbiologists and hygienists worked with EPA to develop recommendations for decontamination of the laboratories to allow them to be back up and running again and ensure the safety of the people that work there.

CDC assessed the risk to workers in all 164 domestic civilian laboratories that received the live DoD anthrax specimens, and only eight individuals, working in three different civilian laboratories, were identified as potentially exposed. (DoD managed assessment and follow-up of additional individuals who worked in DoD labs). Out of an abundance of caution, given that our assessment concluded low exposure and disease risk, post-exposure prophylaxis was recommended for these eight individuals. Of those eight, two began but later discontinued post-exposure prophylaxis. The other six individuals will have completed their 60-day post-exposure prophylaxis regimen of antibiotics and vaccine by July 27. As of submitting this testimony, none have experienced complications. In fact, in over more than a decade (since 2004) of working in laboratories with these presumed inactivated

samples from Dugway, no laboratory researcher has been diagnosed with anthrax infection.

CDC and EPA have supported all seven states where laboratory decontamination has been recommended, and supported all states to effectively decontaminate these laboratories.

On May 24, in its role under the Federal Select Agent Program, CDC's Division of Select Agents and Toxins (DSAT) sent email to DoD officials (Dugway) advising to them to stop further production and shipment of anthrax samples. Dugway stopped further production and shipment of anthrax samples. Using the National Select Agent Registry database maintained by the Federal Select Agent Program, CDC identified six additional institutions in the United States, including two additional DoD facilities, that produce and ship inactivated anthrax spores or vegetative cells for research purposes. CDC requested that each of the six additional institutions also agree to a moratorium on the use and shipping of the materials pending further evaluation of the methods for killing anthrax spores and validating that the spores have been killed. All six of these institutions also agreed to honor the moratorium.

On May 26 – 28, DSAT conducted an on-site investigation of Dugway. Based on our investigation into the incident, CDC has determined that inactivation procedures used at Dugway failed to kill the anthrax spores, and its validation methods to confirm the success of the inactivation procedures (sterility testing) failed to detect growth of the live material prior to Dugway sending out the presumed inactivated material. CDC's investigation has not identified any similar problems at any of the other six institutions.

However, CDC will maintain the moratorium on use and transfers of these materials to lower biosafety level laboratories until more well-defined standards for inactivation and sterility testing have been identified.

CDC's DSAT gained new insights in three areas that will lead to stronger safeguards to prevent a similar incident from occurring. Until we finalize these safeguards, the moratorium on the production, use and shipment of inactivated anthrax spore preparations will remain in place.

First, the requirements for inactivation procedures require more oversight to increase assurance that the procedure is successful. Of necessity, there are several different methods of inactivating anthrax, depending on the type of study being conducted. These methods include heat, gaseous sterilization, non-gaseous chemical sterilization, and radiation (such as gamma irradiation; the process used by Dugway). For example, if the inactivated material will be used to measure the performance of a diagnostic test (as DoD was doing when preparing its *B. anthracis* samples), then radiation would be an appropriate method because the procedure neutralizes/kills the cells without altering their structure. For these types of experiments, chemical sterilization would not be appropriate because the cell structure would be altered, and would not be detected with a simple diagnostic test that is looking for intact cells. We are actively considering improvements to inactivation requirements to ensure procedures are successful and to enhance oversight.

Second, there is uncertainty about whether Dugway failed to conduct proper inactivation and sterility testing or, alternatively, whether there is something previously

unrecognized about anthrax spores recovering from irradiation damage. Additional studies could help us understand whether spores that do not grow immediately after irradiation will grow at a later time or if something about the method inhibits growth until further processed, such as by dilution. Increasing the rigor of sterility testing and the frequency of testing will further protect against inadvertently sending live anthrax spores.

Third, better record keeping and record systems are needed for inactivated agents to ensure that we can quickly and efficiently contact those who receive these materials. CDC has convened a working group of experts to further examine the first two areas (inactivation and sterility testing) to inform recommendations for the methods that are used. To address the third area, CDC is working with our partner at the U.S. Department of Agriculture to update the select agent requirements to strengthen those pertaining to record keeping for inactivated select agents.

In summary, CDC reacted promptly to the incident at Dugway. CDC's response included the proactive steps to contain and reduce potential risk by: issuing a call for a moratorium on transfer and use of the inactivated anthrax samples; assessing worker exposures and initiating prophylactic treatment when indicated; closing laboratories where exposures may have occurred until they could be cleaned; securing and ensuring the disposal of all Dugway production lots; and testing of inactivated materials made by other facilities to ensure that the problem was isolated to Dugway.

CDC's Role in the Federal Select Agent Program

Laboratory research is a critical component in our defense against naturally-occurring disease and bioterrorism, and the scientists who work with these organisms are dedicated to protecting Americans through improving the ways we detect and respond to health threats from infectious disease and from agents that have the potential to pose severe threats to health. All research on select agents and toxins has some risk, and our goal is to minimize that risk. We are committed to do all we can to protect workers and the communities around them while encouraging and supporting scientific advancement.

Understanding *Bacillus anthracis,* the bacteria that causes anthrax, is critical in protecting the health security of the American people. As the nation experienced in October 2001 (when letters containing anthrax were mailed, killed five people, and sickened 17 people), this organism can be used as a weapon. Research with anthrax is needed to create new tests for rapid identification and to develop vaccines, drugs, and therapeutics that can save lives of those infected. It should be noted that the DoD laboratory was working as part of a DoD effort to develop a field-based test to identify biological threats in the environment.

The regulation of select agents and toxins is a shared federal responsibility involving the HHS, USDA, and the Department of Justice (DOJ). Through the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188), Congress gave HHS the responsibility and authority to regulate the possession, use, and transfer of biological agents and toxins that have the potential to pose a severe threat to public health and safety (i.e., select agents and toxins). The authority has

been delegated to CDC. Congress gave USDA similar authority to regulate select agents that pose a severe threat to animal and plant health and/or animal and plant products. DOJ is responsible for conducting electronic database checks of any entities and individuals that want to possess, use, or transfer select agents. By regulating the possession, use, and transfer of select agents, HHS, USDA, and DOJ -- otherwise known as the "Federal Select Agent Program" -- contribute to the Nation's overall terrorism deterrence strategy.

The Federal Select Agent Program promotes laboratory biosafety and biosecurity by developing, implementing, and enforcing the select agent regulations (42 CFR Part 73, 9 CFR Part 121, and 7 CFR 331), providing guidance to the regulated community, and inspecting facilities that work with select agents. Since 2003, CDC has focused effort on reducing the risks for thefts, losses, and releases of select agents through monitoring of facilities and enforcement of regulations. Since implementing the select agent regulations, the Federal Select Agent Program has provided:

- A comprehensive, real-time database containing information on all entities possessing select agents, including the location of the agents, the individuals who work with them, and the associated activities;
- Standard safety and security regulatory requirements for all entities working with select agents, including the development and execution of site-specific security, biosafety, and incident response plans, which are supported by training programs and annual drills or exercises;
- A national system for reporting the theft, loss, or release of select agents;

- An electronic database check for all individuals accessing select agents, performed by the Federal Bureau of Investigation (FBI), to determine whether they are "restricted persons";
- A system to provide eligible state emergency preparedness and response planners with information on facilities registered for select agents within their jurisdictions;
- A surveillance system to track the identification of select agents by front line laboratories;
- A confidential system for reporting safety and security concerns regarding select agents;
- A tracking mechanism to monitor shipments containing select agents and ensure that senders and recipients are adequately registered for select agents (the actual shipment of the select agent is done under Department of Transportation regulations); and
- An outreach and training program that includes a library of over 14 guidance documents and a collection of answers to 75 frequently asked questions, an inspection video, a security risk assessment tool and a training webinar series that has educated over 2000 participants. This information is available on the Federal Select Agent Program website, and we log over 25,000 visits each month.

One characteristic of CDC's stewardship of the Federal Select Agent Program is a commitment to continuous improvement. CDC works with its federal partners within

HHS, and at USDA, DOJ, the Department of Homeland Security, and DoD to ensure that the list of select agents reflects those agents of greatest risk to public health or agriculture through misuse. Since the establishment of the Federal Select Agent Program in 2003, the list of select agents and toxins has been updated on four occasions, including adding four new agents to the list (e.g., reconstructed 1918 Influenza virus) and removing twenty-three agents and toxins. The biosafety, security, and incident response requirements of the select agent regulations have been refined over the years with advice from many stakeholders within and outside the government including the Federal Experts Security Advisory Panel, the National Science Advisory Board for Biosecurity, the Office of Public Health Preparedness and Response Board of Scientific Counselors, the Intragovernmental Select Agents and Toxins Technical Advisory Committee, the Government Accountability Office (GAO), HHS's Office of Inspector General (OIG), and the public through our rulemaking process. In addition, the CDC component of the Federal Select Agent Program has received recommendations from reviews of the program by GAO, the HHS OIG, and the Homeland Security Institute. These reviews have led to revisions to the select agent regulations to include Tier 1 (a subset of regulated select agents that are deemed to pose the greatest threat) requirements such as personnel reliability, updates to our guidance regarding incident reporting, coordination of inspections with federal partners, and tracking shipments of select agents. The Federal Select Agent Program has also made improvements in accordance with White House directives through Executive Orders 13486 and 13546. In executing these Orders, the Federal Select Agent Program revised regulations to concentrate our resources on a reduced list of the

highest agents of concern and focus additional security requirements (e.g., enhanced physical security standards, suitability assessments of lab workers before they can work with Tier 1 agents, and ongoing monitoring of personnel suitability for those with access to agents or toxins on the Tier 1 list) on Tier 1 select agents, those that have the greatest risk for deliberate misuse and the most significant potential for mass casualties, or devastating effects on the economy or critical infrastructure.

Although much work has been done to enhance the effectiveness of CDC's regulatory oversight of select agents and toxins, more work remains to be done. In the wake of recent incidents, the Federal Select Agent Program has revised the inspection process and now places more emphasis on observing the implementation of the biosafety plan (i.e., are they doing what they said they are doing) and whether they doing it correctly (e.g., observing employees donning and doffing of personal protective equipment. In response to the biosafety and biosecurity incidents last summer, CDC's FSAP program supported other U.S. departments and agencies in their laboratory sweeps as part of the Safety Stand-Down urged by the White House, by providing information on what to do if they find a BSAT in unregistered space, and working with labs that reported findings to us to secure the materials and then either transfer or destroy them on site.

For nearly 70 years, CDC has been a leader in scientific research and practice committed to protecting the American people and keeping Americans healthy, safe, and secure. The CDC Director, Dr. Thomas Frieden, recently ordered a review of CDC's

Federal Select Agent Program to identify additional areas where procedures and regulations can be improved to increase our effectiveness while balancing the requirements on those in the research community. In addition, the FSAP program is actively participating in an ongoing review led by the White House of recommendations to enhance biosafety and biosecurity in the United States. We stand ready to address recommendations from that process when they are released.

Where improvements can be made to better the program, we will make them. Where there is disagreement on the best path forward, we will contribute our scientific and programmatic expertise to the debate. We will work diligently and thoughtfully with all of our federal partners and anyone sharing our commitment to protect Americans from biological threats. We welcome the Committee's input as we undertake this important review, and we look forward to continuing to work with you to achieve our shared goal of enhancing the nation's oversight of the safety and security of select agents.

Mr. MURPHY. Thank you. Dr. Demske, you are recognized for 5 minutes.

STATEMENT OF GREGORY E. DEMSKE

Mr. DEMSKE. Good morning, Chairman Murphy, Ranking Member DeGette, members of the subcommittee, I'm Greg Demske, Chief Counsel to the Inspector General at the Department of Health and Human Services. I appreciate the opportunity to appear before you today to discuss the Federal Select Agent Program.

While CDC administers the Select Agent Program with the Department of Agriculture, OIG is authorized to impose civil money penalties for violations of the regulations. We also audit, evaluate, and offer suggestions for program improvement. CDC reviews all potential select agent violations and immediately refers urgent or criminal matters to the FBI. In other matters, CDC further investigates and determines whether to exercise its authority to suspend or revoke registration or require remedial actions. If CDC concludes a civil violation may have occurred, it refers the case for OIG for potential enforcement.

OIG carefully evaluates every referral and decides whether to pursue the case and what penalty to seek based on the facts and circumstances of the particular case. In our experience, violations of the regulations pose varying risks to public health and safety. To date, OIG has imposed 20 CMPs totaling $2.4 million for select agent violations. Two of our cases have involved Dugway.

In April 2007, Dugway shipped anthrax to a research facility. The shipment included a certification that the anthrax was nonviable. The research facility tested the material and found the presence of a low concentration of viable anthrax. We found that Dugway ignored the results of its postinactivation viability test which showed viable anthrax was present. Later, in November 2010, a Government laboratory received a shipment from Dugway that included a vial of Botulinum neurotoxin. Small amounts of this select agent are exempt from the regulations. The packing slip indicated that the vial contained an exempt amount, but in fact, the shipment included a regulated amount. Dugway then self-reported two other unauthorized shipments of this select agent.

As a Federal entity, Dugway presents an enforcement challenge for OIG. Any CMP on a Federal entity would simply shift money within the Government at a net cost to taxpayers and may not promote better compliance. Consistent with our approach to date with other Federal entities, OIG issued Notice of Violation letters to Dugway for both cases. Both letters stated that OIG had determined Dugway had violated the select agent regulations and it should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis. Yesterday OIG received another referral from CDC on Dugway. We are reviewing the matter now.

Over the years OIG has audited Government and private entities for select agent compliance. For example, OIG audited six Federal laboratories and provided audit results to the heads of the relevant Federal agencies, putting them on notice of deficiencies. OIG is expanding our audits and evaluations of select agent management.

We will focus on CDC's oversight of the Select Agent Program and on the operation of HHS laboratories that handle select agents.

Through our enforcement work, OIG has also identified several opportunities to improve program compliance, oversight, and enforcement. As reflected in my written testimony, these opportunities focus on enhanced documentation requirements and increased authority for CDC inspectors. We stand ready to work with CDC and others in HHS to continue to improve the Select Agent Program and use our enforcement tools to promote compliance with these regulations that protect the health and safety of the American people.

Thank you again for inviting me to speak. I'd be happy to answer questions.

[The prepared statement of Mr. Demske follows:]

Testimony Before the United States House of Representatives
Committee on Energy and Commerce:
Subcommittee on Oversight and Investigations

"Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax"

Testimony of:

Gregory E. Demske
Chief Counsel to the Inspector General
Office of Counsel to the Inspector General
Office of Inspector General
Department of Health and Human Services

July 28, 2015
10 a.m.
Location: Rayburn House Office Building, Room 2123

Testimony of:
Gregory E. Demske
Chief Counsel to the Inspector General
Office of Inspector General, U.S. Department of Health and Human Services

Good morning, Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. I am Gregory Demske, Chief Counsel to the Inspector General for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I appreciate the opportunity to appear before you to discuss the Federal Select Agent Program (FSAP).

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act of 2002) established FSAP. FSAP is administered by the Centers for Disease Control and Prevention (CDC) and the Agricultural Select Agent Program within the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture. OIG is authorized to conduct investigations and to impose civil money penalties (CMPs) against an individual or entity that has violated FSAP regulations. OIG recognizes the importance of FSAP in promoting public health and safety.

This testimony discusses: (1) OIG's FSAP enforcement, (2) OIG's review of violations at the Department of Defense's Dugway Proving Ground Life Science Test Facility in Utah (Dugway), (3) OIG's audits of FSAP, and (4) opportunities to strengthen FSAP.

OIG Involvement in FSAP Enforcement

When CDC's Division of Select Agents and Toxins (DSAT) identifies a potential FSAP violation, it must first assess whether a potential crime, or a suspicious person or activity is involved. In those urgent situations, DSAT coordinates with the Federal Bureau of Investigation. With respect to FSAP matters, DSAT has broad authority to deny, suspend, or revoke an entity's registration, and may require an entity to enter into a Performance Improvement Plan. When DSAT identifies potential misconduct by an HHS employee, it coordinates with OIG to gather facts. OIG presents its findings to the appropriate agency so that it can determine whether any disciplinary action is warranted.

If, after DSAT's investigation, it concludes that a civil violation might have occurred, DSAT refers the case to OIG for potential enforcement. OIG evaluates the case and, if OIG concludes there is a violation, determines the appropriate disposition of the case.

OIG's Approach to Case Resolution

Since passage of the Bioterrorism Act of 2002, OIG has received 68 referrals involving 53 unique entities from DSAT for potential FSAP enforcement. OIG resolves each referral from DSAT in one of three ways: (1) imposing a CMP, (2) issuing a Notice of

Violation letter; or (3) closing the case. OIG found violations in 30 of the 68 referrals. OIG has imposed CMPs on 20 entities totaling $2,414,000 and issued 10 Notice of Violation letters to parties OIG determined violated FSAP regulations. OIG has closed 32 cases and has six referrals pending.

Given the seriousness of any FSAP violation, OIG carefully evaluates its enforcement options for each referral, by analyzing the facts and circumstances of the alleged violations. OIG considers the seriousness of the conduct, the security risk posed by the violation, the evidentiary strength of the case, the entity's response to the violation (including whether the conduct was self-disclosed), the number of violations, and any other relevant factors. Rather than applying a formula, OIG relies on its experience and exercises judgment to determine how to resolve a referral and to ensure consistency in our approach.

OIG has observed that violations pose variable levels of risk to the nation's security and the overall safety of entities and individuals possessing, using, or transferring select agents and toxins. In the referrals OIG has reviewed, we have considered the most serious or significant violations to include: actual or potential human exposure to a select agent or toxin, theft or loss of a select agent or toxin, performance of unapproved restricted experiments, and access to select agents or toxins by a restricted person. Other serious violations for which OIG has imposed penalties include: unauthorized transfers of a select agent or toxin, unauthorized access to a select agent or toxin, failure to maintain accurate inventory, and failure to have a biosafety and security plan commensurate with the risks associated with a particular select agent or toxin.

Civil Money Penalties: When OIG imposes CMPs, regulations require OIG to conduct a case-specific analysis to determine the appropriate penalty. OIG does not assign a dollar value to a specific regulatory provision, but rather evaluates factors outlined in the regulations, including: (1) the nature of the wrongdoing, including the length of noncompliance and whether the evidence demonstrates a pattern of noncompliance; (2) the entity's degree of culpability; (3) the entity's history of any prior offenses; (4) the entity's financial condition; and (5) other matters as justice may require.

Notice of Violation Letters: OIG has issued Notice of Violation letters when it has concluded that a violation of FSAP regulations occurred but we decided to exercise our discretion not to impose CMPs. In general, Notice of Violation letters describe the violation(s) and direct the entity to examine its current practices and policies governing select agents, and to implement corrective actions and safeguards to prevent future violations. A copy of each Notice of Violation letter is sent to DSAT. OIG has issued five Notice of Violation letters to Federal entities, three to universities, and two to other private entities.

Referral Closed: If OIG concludes the case does not merit a CMP or Notice of Violation letter, OIG closes the case and informs DSAT of the closure.

Approach to Federal Entities

In FSAP referrals involving violations by Federal entities, OIG has resolved matters by issuing Notice of Violation letters to high-ranking officials with oversight responsibility for the entities. While we believe OIG has the authority to impose a CMP on a Federal entity, we have not done so in prior cases on the basis of several considerations. Any money paid by a Federal entity would simply be moved from a Federal agency's budget to the General Fund of the Treasury. Although there would be no net receipt of money for the Federal Government, the Government would incur the cost of negotiating or disputing the CMP. CMP payments from Federal agencies are unlikely to promote better future compliance and, in fact, may reduce resources for the Federal entity's future compliance efforts. OIG's approach is consistent with other Federal agencies that issue letters, or take other nonmonetary action, in similar situations involving violations by Federal agencies. Since passage of the Bioterrorism Act of 2002, OIG has received 16 referrals regarding Federal entities and sent five Notice of Violation letters.

Dugway: 2007 Anthrax Violation

In April 2007, Dugway shipped anthrax to a research facility. The shipment included a certification that the anthrax was nonviable. The research facility tested the material upon receipt and found the presence of a low concentration of viable anthrax.

DSAT investigated and concluded that Dugway used a scientifically acceptable inactivation method to kill the anthrax, but that method was not part of Dugway's Standard Operating Procedures. DSAT also found that Dugway used a scientifically acceptable viability test, but that Dugway ignored the outcome of the test, which showed that viable anthrax was still present.

DSAT referred the potential violation to OIG for review on November 16, 2007. After considering all the evidence, OIG concluded that Dugway shipped viable anthrax without obtaining prior DSAT approval. On December 2, 2009, OIG issued a Notice of Violation letter to Dugway stating that OIG had determined Dugway had violated FSAP by making an unauthorized transfer of anthrax. The letter also stated that Dugway should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis.

Dugway: 2008 & 2010 Botulinum Neurotoxin Violations

On November 18, 2010, a Government laboratory received a shipment from Dugway that included a vial of Botulinum neurotoxin. The packing slip indicated that the vial contained a small amount of Botulinum neurotoxin that would be exempt from FSAP regulations. However, when the Government laboratory sought to use the Botulinum neurotoxin, it determined that the vial actually contained a greater amount of Botulinum neurotoxin that is not exempt from FSAP regulations. On April 29, 2011, the Government laboratory reported the unauthorized transfer to DSAT. DSAT concluded that Dugway had shipped Botulinum neurotoxin without obtaining the required DSAT prior authorization. Dugway also self-reported to DSAT two additional unauthorized shipments of Botulinum neurotoxin that occurred in 2008.

DSAT referred this case to OIG on June 16, 2011. OIG concluded that Dugway shipped Botulinum neurotoxin in amounts that were not exempt under FSAP regulations without obtaining prior DSAT approval. Based on these facts, including Dugway's corrective action and Dugway's status as a Federal entity, on November 3, 2011, OIG issued a Notice of Violation letter stating that OIG had determined Dugway had violated FSAP by making three unauthorized transfers of Botulinum neurotoxin. The letter also stated Dugway should examine its current policies and practices, take corrective action, and monitor its safeguards on an ongoing basis.

To date, OIG has not received a referral for any more recent potential violations involving Dugway.

OIG Audits

Over the years, in addition to our enforcement efforts, OIG has audited Government and private entities for FSAP compliance. For example, OIG audited six Federal laboratories' FSAP regulatory compliance. The audit results were provided to the head of the relevant Federal agency, putting it on notice of deficiencies and non-compliance. In 2011, OIG issued a report summarizing these audits. OIG found that DSAT did not effectively monitor and enforce certain FSAP regulatory provisions, resulting in violations that were not identified by DSAT. CDC concurred with OIG's recommendations for improvements to its FSAP oversight. OIG also audited transfers of select agents and found a high incidence of access by unapproved persons, typically at the point of delivery. CDC concurred with OIG's recommendations for enhancing controls on shipping and receipt of select agent packages.

Future OIG Work

OIG is expanding its audit and evaluation assessments of select agent management. Collaborative efforts are underway to define the scope and methodology of this work.

OIG will target its initial efforts on CDC's oversight of FSAP, which will shed light on the scope, magnitude, and potential implications of recent biosecurity breaches, and on HHS agencies' (*e.g.*, National Institutes of Health, Food and Drug Administration) operation of laboratories that handle select agents. Related efforts under active consideration are HHS agencies' decision-making processes and protocols; risk assessments, tracking, and monitoring; the volume, frequency, and nature of laboratory enforcement actions; and the development and implementation of corrective actions. OIG takes a risk-based approach to identify areas for audit or evaluation, so our efforts may be redirected to other areas, as warranted. OIG understands that CDC recently announced plans to conduct a comprehensive review of laboratory safety. OIG will coordinate with CDC and other HHS agencies to ensure that our work complements and advances effective oversight of FSAP through objective assessments and recommendations.

Opportunities to Strengthen FSAP

Through this testimony, OIG offers the following opportunities to strengthen and improve the Government's ability to administer FSAP and improve its ability to enforce violations of the regulations. OIG has identified these opportunities through our investigative and enforcement experience.

FSAP regulations should:

- require laboratories to document inactivation procedures, validation and safety/sterility testing procedures, and outcomes to ensure that a select agent or toxin is rendered nonvirulent;
- require registered entities to video entry/exit points and video specific laboratory select agent and toxin work;
- require registered entities to maintain additional records, including all documents created or maintained in the ordinary course of working with a select agent and toxin;
- expressly prohibit the destruction or alteration of any document that is required to be maintained under the regulations; and
- expand the document retention period for registered entities from three to six years to match the CMP statute of limitation period.

In addition, Federal inspectors' ability to conduct effective and meaningful oversight should be strengthened by:

- requiring any registered entity to make available for interview upon reasonable request by inspectors any individual who has accessed, possessed, used, or transferred a select agent or toxin;

- allowing inspectors to physically inspect, handle, or test material that is believed to be a select agent or toxin, when appropriate (consideration should be given to DSAT's ability to immediately transfer material, in accordance with the regulations, so that independent testing can be performed to determine whether particular material is covered by the regulations); and

- considering the viability of independent third-party testing of select agent or toxin material.

Conclusion

On the basis of our enforcement work, OIG has identified opportunities to strengthen FSAP that CDC should consider as it reviews how FSAP can be improved. In addition, OIG will continue to provide oversight through audits and evaluations of FSAP and use our CMP authority to take enforcement actions.

Thank you again for inviting me to speak about OIG's role in FSAP. I would be happy to answer your questions.

Mr. MURPHY. Thank you, Mr. Demske. Dr. Crosse, you are recognized for 5 minutes.

STATEMENT OF MARCIA CROSSE

Dr. CROSSE. Chairman Murphy, Ranking Member DeGette, and members of the subcommittee, I'm pleased to be here today to discuss GAO's work on high-containment laboratories. The biosafety and biosecurity practices in these laboratories are intended to reduce the exposure to biological agents and prevent their loss, theft, or misuse.

The recent shipments of live anthrax bacteria from DoD to U.S. and international laboratories, similar to last year's potential exposures of CDC personnel to live anthrax bacteria, shows multiple breakdowns in compliance with established policies and inadequate oversight of Federal high-containment laboratories. This is another example in an ongoing series of safety lapses which continue to occur, often with the same root cause as for prior incidents.

We've been lucky so far. Researchers in these labs work with high-risk biological agents that may result in serious or lethal infections and, in some instances, have the potential to be used in biological weapons. These labs do important work with pathogens to develop vaccines and countermeasures and to understand emerging infectious diseases. However, the pathogens handled by these laboratories also have the potential for high-consequence accidents. If the types of mistakes we've seen were to occur with a particularly transmissible pathogen like certain strains of influenza, not only would the laboratory workers or their close contacts be at risk but an epidemic could be triggered with consequences far beyond what we've seen to date.

GAO is currently conducting work for this committee to examine these issues, and the preliminary findings from our work show that DoD and CDC have begun to address weaknesses in the management of their high-containment laboratories but have not yet fully implemented these activities. The steps these agencies are taking are intended to address fundamental flaws in the oversight structure, reporting, and tracking of biosafety and biosecurity incidents after they have occurred. For example, DoD officials said that the Dugway incident is the first incident that DoD has tracked at the senior department level. Since 2012 DoD has been revising its policies and procedures including reporting requirements and expects to finalize these changes by this fall. But these changes will only cover a subset of DoD's high-containment laboratories.

Our ongoing work will also examine if DoD is implementing steps intended to improve the culture of safety at its laboratories so that future events are reduced or prevented.

Similarly, CDC began taking steps to address weaknesses identified in assessments of the June 2014 anthrax incident and other safety incidents in its own laboratories, but the agency has not yet completed implementing recommendations intended to improve its laboratory oversight. For example, an internal work group recommended that CDC develop agency-wide policies to provide clear and consistent requirements for biosafety for all agency laboratories. In response, CDC developed a Specimen Transport Policy

but has not developed other agency-wide policies, such as requirements for laboratory documentation and emergency protocols.

As I stated at the outset, the incidents you are examining today are part of a long series of safety lapses. Since 2007, GAO has reported on these issues and has made multiple recommendations to improve Federal oversight of high-containment laboratories. The Federal departments agreed with our recommendations and have conducted some activities to respond but have not implemented our key recommendation to establish a single Federal entity with responsibility for oversight of all high-containment laboratories.

We recommended the establishment of a single Federal entity to, one, conduct Government-wide strategic planning for requirements for high-containment laboratories, including assessments of their risks; and two, develop national standards for designing, constructing, commissioning, operating, and maintaining such laboratories.

We continue to believe that such an entity or some other mechanism to ensure higher-level oversight is needed in the face of the continuing proliferation of high-containment laboratories and the ongoing failures by agencies to fix their problems on their own.

In closing, the lapses we've seen are indicative of failures in a system that is supposed to have multiple levels of control, including cross-checks, inspections, training, procedures, and validated protocols that should prevent such accidents from occurring and certainly should prevent such incidents from recurring.

Mr. Chairman, this completes my remarks. I'd be happy to answer questions you or other members of the subcommittee may have.

[The prepared statement of Ms. Crosse follows:]

United States Government Accountability Office

Testimony

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

For Release on Delivery
Expected at 10:00 a.m. ET
Tuesday, July 28, 2015

HIGH-CONTAINMENT LABORATORIES

Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses

Statement of Marcia Crosse, Director, Health Care; John Neumann, Director, Natural Resources and Environment; and Timothy M. Persons, Chief Scientist

GAO-15-792T

GAO Highlights

Highlights of GAO-15-792T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

July 28, 2015

HIGH-CONTAINMENT LABORATORIES

Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses

Why GAO Did This Study

Recent safety lapses at high-containment laboratories raise questions about how federal departments and agencies manage high-risk biological agents. DOD and CDC both conduct research on high-risk biological agents at their respective laboratories. Biosafety and biosecurity practices in these laboratories are intended to reduce exposure to, and prevent loss, theft, or misuse of, biological agents. CDC regulates the possession, use, and transfer of certain biological agents that pose potentially severe threats to public health under the select agent program.

This statement summarizes (1) preliminary observations from ongoing GAO work on federal laboratories' biosafety and biosecurity policies and practices and (2) GAO's past work on oversight of high-containment laboratories. To conduct ongoing and past work, GAO reviewed documentation and interviewed federal agency officials, including those from DOD and CDC, about policies and procedures for high-containment laboratories; efforts to monitor compliance and evaluate effectiveness of biosafety and biosecurity policies and practices; and the status of federal oversight activities.

What GAO Recommends

GAO has previously made recommendations to agencies to enhance biosafety and biosecurity. Because this work is preliminary, GAO is making no new recommendations at this time. GAO shared preliminary observations from this statement with DOD and CDC and incorporated comments as appropriate.

View GAO-15-792T. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Recent safety lapses—including shipments of live anthrax bacteria from the Department of Defense (DOD) to U.S. and international laboratories and potential exposures of Centers for Disease Control and Prevention (CDC) laboratory personnel to live anthrax bacteria—have illustrated multiple breakdowns in compliance with established policies and inadequate oversight of high-containment laboratories. In these laboratories, researchers work with potentially high-risk biological agents that may result in serious or lethal infection in humans. Preliminary observations from GAO's ongoing work show that DOD and CDC have begun to address weaknesses in the management of their high-containment laboratories, but their activities have not yet been fully implemented. GAO's ongoing work will include further examination of the status of DOD's and CDC's activities to improve management of high-containment laboratories.

- DOD began taking steps to address weaknesses in its management of high-containment laboratories in 2012 by reviewing and revising biosecurity policies and procedures. According to officials, the revised biosecurity policies will require all DOD laboratories that conduct research with certain high-risk biological agents to submit all inspection reports to senior DOD management, which was not previously required. DOD plans to finalize these policies by September 2015. DOD also plans to make further changes to these policies as a result of its assessment of the May 2015 anthrax incident, after the first set of revisions is finalized. DOD has also begun to track biosafety and biosecurity incidents at the senior department level, such as potential exposures to or misuse of biological agents, which it had not done prior to the May 2015 anthrax incident. DOD officials said the May 2015 incident is the first incident that DOD has tracked at the senior department level.
- CDC also began taking steps to address weaknesses identified in internal and external working group assessments of the June 2014 anthrax incident and other safety incidents but has not yet completed implementing some recommendations intended to improve its laboratory oversight. For example, an internal workgroup recommended that CDC develop agency-wide policies to provide clear and consistent requirements for biosafety for all agency laboratories. In response, CDC developed a specimen transport policy but has not developed other agency-wide policies, such as requirements for laboratory documentation and emergency protocols.

Since 2007, GAO has reported on issues associated with high-containment laboratories and recommended improvements for federal oversight. GAO's prior work recommended the establishment of a single federal entity to (1) conduct government-wide strategic planning for requirements for high-containment laboratories, including assessment of their risks, and (2) develop national standards for designing, constructing, commissioning, operating, and maintaining such laboratories. Federal departments to which GAO's recommendations were addressed agreed with them and have conducted some activities to respond but have not implemented the recommendation to establish a single federal entity with responsibility for oversight of high-containment laboratories.

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

We are pleased to be here today as you examine issues related to the management of biological agents in high-containment laboratories and the federal select agent program.[1] High-containment laboratories are those laboratories in which researchers work with potentially high-risk biological agents, such as *Bacillus anthracis*, the bacterium that causes anthrax, which may result in serious or lethal infection in humans. High-containment laboratories also house agents that have the potential to seriously threaten animal health and disrupt the U.S. economy, such as highly pathogenic influenza viruses in birds. As recently as May 2015, the Department of Defense (DOD) announced that it had inadvertently shipped samples containing live anthrax bacteria to U.S. and international laboratories prior to discovering that procedures to inactivate the anthrax were incomplete.[2] The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), also reported several recent safety lapses, one of which, in June 2014, was also a result of inadequate inactivation procedures that potentially exposed personnel to live anthrax bacteria.[3] (See app. I for a timeline of the CDC safety lapses and the agency's assessments of these lapses.) These safety lapses have raised questions about how federal departments and agencies manage high-risk biological agents at their high-containment laboratories. We have previously examined federal

[1]The federal select agent program oversees the possession, use, and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.

[2]Inactivation is a procedure to render potentially high-risk biological agents unable to cause disease but still useful for research purposes, including, for example, vaccine development. DOD officials confirmed that safety lapses at DOD's high-containment laboratories, including improper inactivation of biological agents, had occurred for as many as 10 years prior to the May 2015 anthrax safety lapse. As of July 2015, DOD has confirmed that as a result of the May 2015 safety lapse, 86 laboratories in 20 states, the District of Columbia, and seven countries received shipments containing samples of live anthrax bacteria.

[3]In July 2014, CDC also reported that at least four additional safety lapses had occurred at its high-containment laboratories in the past 10 years, all of which were the result of improperly inactivated high-risk biological agents.

oversight of high-containment laboratories and recommended improvements to this oversight.[4]

The management of biological agents in laboratories follows the principles and practices of biosafety and biosecurity. Biosafety practices and programs are intended to reduce or eliminate exposure of individuals and the environment to potentially high-risk biological agents. Biosecurity practices and programs are intended to prevent the loss, theft, or misuse of high-risk biological agents and research-related information, by limiting access to facilities and information. Laboratories that conduct research on biological agents are assigned one of four biosafety level (BSL) designations, from BSL-1 to BSL-4.[5] High-containment laboratories include BSL-3 and BSL-4 laboratories.[6] Certain biological agents and toxins are also regulated under the federal select agent program. Select agents are biological agents and toxins (1) that have the potential to pose a severe threat to public health and safety, to animal or plant health, or to animal or plant products and (2) whose possession, use, and transfer are regulated by select agent rules.[7] CDC and the Animal and Plant Health

[4]See GAO, *High-Containment Laboratories: Recent Incidents of Biosafety Lapses*, GAO-14-785T (Washington, D.C.: July 16, 2014); *High-Containment Laboratories: Assessment of the Nation's Need is Missing*, GAO-13-466R (Washington, D.C.: Feb. 25, 2013); *High-Containment Laboratories: National Strategy for Oversight is Needed*, GAO-09-574 (Washington, D.C.: Sept. 21, 2009); and *High-Containment Laboratories: Preliminary Observations on the Oversight of the Proliferation of BSL-3 and BSL-4 Laboratories in the United States*, GAO-08-108T (Washington, D.C.: Oct. 4, 2007).

[5]Each level of containment describes the laboratory practices, safety equipment, and facility safeguards for the level of risk associated with handling particular biological agents. Laboratories are to be designed, constructed, and operated to (1) prevent accidental release of infectious or hazardous agents within the laboratory and (2) protect laboratory workers and the external environment, including the community, from exposure to the agents.

[6]The designations of animal biosafety level (ABSL) 3 and ABSL-4 are used for laboratories that work with animals infected with indigenous or exotic agents. The term BSL-3 Agriculture is used to describe laboratories where studies are conducted employing large agricultural animals. For purposes of this statement, we are using the term high-containment laboratories to refer to all laboratories at designated safety levels 3 and 4, regardless of whether they are animal, agriculture, or human health laboratories.

[7]For select agent rules, see 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.

Inspection Service (APHIS), within the U. S. Department of Agriculture (USDA), are responsible for overseeing the select agent program.[8]

Our testimony today will draw from our ongoing work examining the management of biological agents in federal high-containment laboratories, as well as our prior reports and testimonies on high-containment laboratories. In particular, this statement reflects our (1) preliminary observations from our ongoing work on biosafety and biosecurity of federal laboratories and (2) prior work examining federal oversight of high-containment laboratories from 2007 through 2014. In addition, we have begun work for the House Energy and Commerce Committee to examine inactivation methods and protocols for biological agents.[9] For this work, we are examining, among other issues, the relative strengths and weaknesses of the various types of inactivation methods and any current scientific issues involving inactivation protocols.

To provide preliminary observations from our ongoing federal laboratory biosafety and biosecurity work, we focused on DOD and CDC. We reviewed available federal department and agency policies and procedures for biosafety and biosecurity.[10] We also reviewed documents that outline requirements and processes for monitoring compliance with and evaluating the effectiveness of policies and procedures to manage biological agents in high-containment laboratories, as well as the frequency with which these activities are to occur. Monitoring and evaluation includes activities in the areas of inventory management, training, inspections, incident reporting, and after-action assessments and any mechanisms agencies may have to record and track these activities. Additionally, we reviewed available agency after-action reports and internal and external workgroup reports to identify any associated

[8]As part of CDC's and APHIS's responsibilities, they assess laboratory compliance with select agent regulations and maintain a list of select agents and toxins. While some agents and toxins studied in high-containment laboratories may be designated select agents and toxins, for the purposes of this review, we are not examining laboratory compliance with select agent regulations.

[9]This work will also examine attenuation procedures, which are methods of weakening biological agents such as viruses so that they no longer cause disease.

[10]Our ongoing work is examining biosafety and biosecurity management efforts among eight federal departments (including their component agencies): DOD, Department of Energy, Department of Homeland Security, Department of the Interior, Department of Veterans Affairs, HHS, USDA, and the Environmental Protection Agency.

recommendations intended to improve or enhance monitoring and evaluation activities and controls, and available agency documentation of plans and time frames for addressing these recommendations. We interviewed DOD and CDC officials to (1) obtain information on their efforts to monitor compliance with and evaluate the effectiveness of their policies and procedures and (2) discuss agency plans and time frames for implementing improvements and tracking their progress. We will use federal internal control standards, as well as department and agency policies and procedures and information obtained from interviews, to determine whether departments and agencies have appropriate protocols in place for monitoring and evaluation and are conducting these activities in accordance with written protocols.[11]

For our prior work on federal oversight of high-containment laboratories, we have summarized our findings from our 2007, 2009, 2013, and 2014 reports and testimonies.[12] To conduct this body of work, we reviewed documents such as those identifying any national needs assessments for high-containment laboratories, conducted literature reviews, and interviewed federal officials, including those from CDC and other federal agencies. Each of these reports provides more detailed information on its objectives, scope, and methodology.

We are conducting our ongoing work on biosafety and biosecurity of federal high-containment laboratories, which began in February 2015, in accordance with generally accepted government auditing standards. Because this work is ongoing, we are not making recommendations on DOD's or CDC's oversight of its high-containment laboratories at this time. We conducted our prior work on federal oversight of high-containment laboratories from August 2006 through July 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that

[11]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999). Internal control is synonymous with management control and comprises the plans, methods, and procedures used to meet missions, goals, and objectives.

[12]GAO-14-785T, GAO-13-466R, GAO-09-574, and GAO-08-108T.

the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

We shared our preliminary observations with DOD and CDC. DOD and CDC provided us with technical comments, which we have incorporated as appropriate.

Background

CDC partners with the National Institutes of Health to publish *Biosafety in Microbiological and Biomedical Laboratories*, which provides guidance on biosafety principles and practices for protecting laboratory personnel, the public, and the environment from exposure to biological agents for each biosafety level.[13] BSL-3 laboratories work with indigenous or exotic agents with known potential for aerosol 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 aerosol transmission and for which treatment may not be available.

CDC and APHIS oversee the select agent program. As part of that oversight, CDC and APHIS maintain a list of select agents and toxins, which they are to review and update at least biennially.[14] CDC is responsible for oversight of the possession, use, and transfer of select agents and toxins that could pose a threat to public health and safety, such as the virus that causes smallpox and the Ebola virus. APHIS is responsible for oversight of the possession, use, and transfer of select agents and toxins that could pose a threat to animal or plant health or animal or plant products, such as highly pathogenic avian influenza virus. Some select agents, such as the bacterium that causes anthrax, pose a threat to both human and animal health and are regulated by both agencies. Generally, entities (including federal agencies and private institutions) and individuals that possess, use, or transfer select agents must register with CDC or APHIS and must renew their registration every 3 years. CDC or APHIS may conduct an on-site inspection before issuing

[13]Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. (Atlanta, Ga.: December 2009). This document also provides some biosecurity guidelines for preventing loss, theft, or misuse of biological agents.

[14]CDC and APHIS were delegated authority by their respective department Secretaries to regulate the use, possession, and transfer of select agents.

a new certificate of registration or renewing an existing registration.[15] CDC and APHIS may also conduct interim inspections, such as annual inspections, to assess compliance with select agent regulations. High-containment laboratories may also conduct work with biological agents that have not been designated as select agents and are therefore not registered with the select agent program.

Many federal departments and agencies own and operate high-containment laboratories in the United States and abroad. For example, DOD conducts and supports research on detection, identification, and characterization of biological threats and the development of medical countermeasures against those threats at its high-containment laboratories in the United States and located overseas. As part of its bioterrorism preparedness and response program, and in addition to its responsibilities for overseeing other entities' laboratories under the select agent regulations, CDC also conducts research on potentially high-risk biological agents at its own high-containment laboratories.

Preliminary Observations on DOD's and CDC's Efforts to Address Weaknesses in the Management of Their High-Containment Laboratories

DOD and CDC had existing policies and procedures that addressed biosafety and biosecurity within their high-containment labs at the time the safety lapses occurred in 2014 and 2015. However, as a result of these lapses—which illustrated multiple breakdowns in compliance with established policies and procedures and inadequate oversight—both DOD and CDC have identified weaknesses in the management of their high-containment laboratories and have begun to take some steps to review and revise policies and procedures and improve monitoring and evaluation activities.

[15]42 C.F.R. §§ 73.7(f) & 73.18(b); 9 C.F.R. §§ 121.7(f) & 121.18(b); 7 C.F.R. §§ 331.7(f) & 331.18(b).

DOD Steps to Address Weaknesses in Laboratory Management

Our ongoing work shows that DOD has begun to take some steps to address weaknesses in the management of its high-containment laboratories but had not yet implemented them prior to the May 2015 anthrax safety lapse. After an internal reorganization in 2012, DOD began revising its policies and procedures for safeguarding select agents, including security standards for these agents, to streamline policies and improve monitoring and evaluation activities. DOD officials told us that the changes will include new requirements for all service laboratories (within Air Force, Army, and Navy) registered with the select agent program to submit all inspection reports, such as those from CDC's select agent office, to DOD senior management regardless of inspection findings. Officials stated that, prior to this new requirement, the laboratories were required to report only what they determined to be significant findings to DOD senior management, which officials stated was no longer acceptable. DOD expects to finalize the new policy by September 2015; Air Force, Army, and Navy will have 6 months to become compliant with the updated policy once it is finalized. In addition, DOD officials told us that they identified further changes that they plan to make to this policy as a result of the May 2015 anthrax safety lapse, which they will make after the current changes are finalized.

DOD plans to collect inspection reports from its select agent-registered laboratories; however, it does not plan to collect and monitor the results of any reports of inspections conducted at high-containment laboratories that are not registered with the select agent program but nonetheless conduct research on potentially high-risk biological agents. According to officials, DOD does not conduct department-level inspections of its high-containment laboratories, including those high-containment laboratories that do not conduct research with select agents and are not registered with the select agent program. Instead, DOD delegates responsibility for inspections to the services, where management responsibility for conducting or monitoring the results of laboratory inspections varies and may not lie with senior-level offices, depending upon the service. For example, DOD officials stated that high-containment Air Force laboratories are inspected by an office one level higher than the office in which the laboratory is located. Air Force officials told us that inspectors general at various levels of the service inspect Air Force laboratories. However, in our initial conversations, officials we spoke with did not tell us whether senior Air Force offices monitor the results of laboratory inspections. Our ongoing work will examine service-level responsibilities for conducting and monitoring the results of inspections and the extent to

which DOD, CDC's and APHIS's select agent offices, the services, and the laboratories communicate and coordinate to address significant findings and resolve deficiencies identified during inspections.

DOD has also begun to address weaknesses in its incident reporting requirements. DOD requires its laboratories to report potential exposures to and possible theft, loss, or misuse of select agents to CDC's or APHIS's select agent office, but, according to officials, DOD does not currently track these incidents or laboratories' responses to them at the department level. DOD officials told us that the May 2015 anthrax safety lapse is the first incident that DOD has tracked at the department level; the updated biosecurity policy will include requirements for tracking exposures and other biosafety and biosecurity incidents. Our ongoing work will include an examination of the nature of DOD's tracking and what the department might require from the laboratories or the services as a result of this tracking, such as identifying corrective actions or requiring another type of response.

CDC Steps to Address Weaknesses in Laboratory Management

Our ongoing work shows that CDC has begun to take a number of steps as a result of the recent safety lapses but has not yet completed implementing some agency recommendations intended to address weaknesses in its laboratory management. In October 2014, an internal workgroup established by CDC issued a report from its review of the 2014 safety lapses, which included recommendations to improve agency management of its laboratories and improve biosafety. Among its findings, the workgroup discovered considerable variation across CDC in the level of understanding, implementation, and enforcement of laboratory safety policies and quality systems. Their recommendations addressed weaknesses identified in six functional areas. Recommendations addressed weaknesses in areas of particular relevance to our ongoing work: (1) policy, authority, and enforcement; (2) training and education; and (3) communications and staff feedback.[16]

- **Policy, authority, and enforcement**. The workgroup noted that CDC lacked overarching biosafety policies, which limits accountability and

[16]The remaining three functional areas in which the workgroup found weaknesses and developed recommendations were (1) leadership, staffing, and organizational structure; (2) process and standard operating procedures; and (3) facilities, systems, and software.

enforcement. The workgroup also noted that CDC needed clear policies and effective training for leaders and managers to help them implement accountability measures, assure competency, and enforce biosafety adherence throughout agency laboratories. To address these gaps, the workgroup recommended that CDC (1) develop agency-wide policies to communicate biosafety requirements clearly and consistently to all of its laboratories and (2) enforce existing laboratory safety policies by clarifying the positive and negative consequences of adhering or not adhering to them.

- **Training and education**. The workgroup noted that CDC's training systems, competency and proficiency testing, and time-in-laboratory requirements varied greatly across the agency's laboratories. The workgroup recommended a comprehensive review and unification of training and education best practices across all CDC laboratories to improve laboratory science and safety.
- **Communications and staff feedback**. The workgroup noted CDC's need for comprehensive communication improvements to provide a transparent flow of information across the laboratory community regarding laboratory science and safety. The workgroup recommended that CDC should include clearer communication flow diagrams, point-of-decision signs, and improved notification systems to distribute information to neighboring laboratories when an event such as a potential exposure occurs.

In addition, in January 2015, an external advisory group completed its review of laboratory safety at CDC and identified recommendations that reinforced the internal workgroup's findings and recommendations. For example, this advisory group found that CDC lacked a clearly articulated safety mission, vision, or direction and recommended the creation of a biomedical scientist position in the CDC Director's office.

As we conduct our ongoing review of federal management of high-containment laboratories, we are assessing CDC's progress in implementing the recommendations from its internal and external workgroups. Our preliminary observations show that CDC has taken some steps to implement workgroup recommendations and address weaknesses in laboratory oversight but has not addressed some recommendations or fully implemented other activities. For example, CDC reported that, in response to the recommendation to develop overarching biosafety policies, it is developing policies for specimen transport and laboratory training. In addition, CDC developed a new procedure for scientists leaving the agency to account for any biological specimens they

may have been researching, which the agency rolled out in February 2015. This procedure was among those policies the workgroup recommended to be included in overarching agency policies. However, as of July 2015, CDC has not developed other agency-wide policies that include comprehensive requirements for laboratory biosafety, such as policies that outline requirements for appropriate laboratory documentation and for laboratories to maintain site-specific operational and emergency protocols, to fully address the workgroup recommendation. To address the recommendation made by the external advisory group to create a senior-level biomedical scientist position, CDC created a new Laboratory Science and Safety Office within the office of the CDC Director and established the position of Associate Director for Laboratory Science and Safety to lead the new office. The primary responsibility of the associate director is to establish additional agency-level policies for laboratory safety and communicate CDC's safety efforts to agency staff. As of July 2015, CDC had not yet filled this position with a permanent staff member.[17] In addition, CDC is taking other steps intended to improve the management of high-containment laboratories but has not yet completed these activities. For example, in its 2013 policy for sample and specimen management, CDC included a directive for the agency to implement an electronic inventory management system. According to officials, CDC rolled out its electronic specimen management system for inventorying biological agents to all of its infectious disease laboratories on March 30, 2015. However, CDC has not made the new system available to all agency laboratories; it expects to do so within the next 2 years.

[17]CDC posted the job vacancy in November 2014. CDC officials told us that the agency filled this position with an acting associate director until it could hire a permanent associate director.

Increased Federal Oversight of High-Containment Laboratories Continues to Be Needed

Since 2007, we have reported on several issues associated with high-containment laboratories and the risks posed by past biosafety incidents and recommended improvements for increased federal oversight. Our prior work included recommendations that address (1) the need for government-wide strategic planning for requirements for high-containment laboratories, including assessment of their risks; (2) the need for national standards for designing, constructing, commissioning, operating, and maintaining such laboratories; and (3) the need for federal oversight of biosafety and biosecurity at high-containment laboratories. HHS and other agencies to which the recommendations were directed have conducted some activities to respond but have not fully implemented most of the recommendations. For example,

- In our 2007 and 2009 reports, we found that the number of BSL-3 and BSL-4 laboratories in the United States had increased across federal, state, academic, and private sectors since the 2001 anthrax attacks but no federal agency was responsible for tracking this expansion.[18] In addition, in our 2009 report we identified potential biosafety and biosecurity risks associated with an increasing number of these laboratories.[19] We recommended that the National Security Advisor, in consultation with HHS, the Department of Homeland Security, DOD, USDA, and other appropriate federal departments, identify a single entity charged with periodic government-wide strategic evaluation of high-containment laboratories to (1) determine, among other things, the needed number, location, and mission of high-containment laboratories to meet national biodefense goals, as well as the type of federal oversight needed for these laboratories, and (2) develop national standards for the design, construction, commission, and operation of high-containment laboratories, including provisions for long-term maintenance, in consultation with the scientific community. We also recommended that HHS and USDA develop a clear definition of what constitutes exposure to select agents.[20] The administration, HHS, and USDA have addressed some

[18]GAO-08-108T and GAO-09-574.

[19]GAO-09-574.

[20]Our 2009 report included additional recommendations to enhance biosafety and biosecurity. For example, we also recommended that the Secretaries of HHS and USDA review existing inventory control systems and invest in and develop appropriate technologies to minimize the potential for the misuse of biological agents by laboratory or agency personnel. GAO-09-574.

of our recommendations. For example, in 2013, the administration's Office of Science and Technology Policy reported that it had begun to support periodic, government-wide assessments of national biodefense research and development needs and has taken some steps to examine the need for national standards for designing, constructing, commissioning, maintaining, and operating high-containment laboratories. CDC and USDA have developed scenarios to more clearly define what exposures to select agents they consider to be reportable.

- In our 2013 report and 2014 testimony, we found that no comprehensive assessment of the nation's need for high-containment laboratories, including research priorities and capacity, had yet been conducted.[21] We also found that no national standards for designing, constructing, commissioning, and operating high-containment laboratories, including provisions for long-term maintenance, had yet been developed.[22] In addition, no single federal entity has been assigned responsibility for oversight of high-containment laboratories.

In summary, the safety lapses of 2014 and 2015 continue to raise questions about the adequacy of (1) federal biosafety and biosecurity policies and procedures and (2) department and agency monitoring and evaluation activities, including appropriate levels of senior management involvement. Preliminary observations on DOD's and CDC's steps to address weaknesses in managing potentially high-risk biological agents in high-containment laboratories—as well as findings and recommendations from our previous work on high-containment laboratories—continue to highlight the need to consider how best the federal government as a whole and individual departments and agencies can strengthen laboratory oversight to help ensure the safety of laboratory personnel; prevent the loss, theft, or misuse of high-risk biological agents; and help recognize when individual safety lapses that appear to be isolated incidents point to systemic weaknesses, in order to help prevent safety lapses from continuing to happen.

[21]GAO-13-466R and GAO-14-785T.

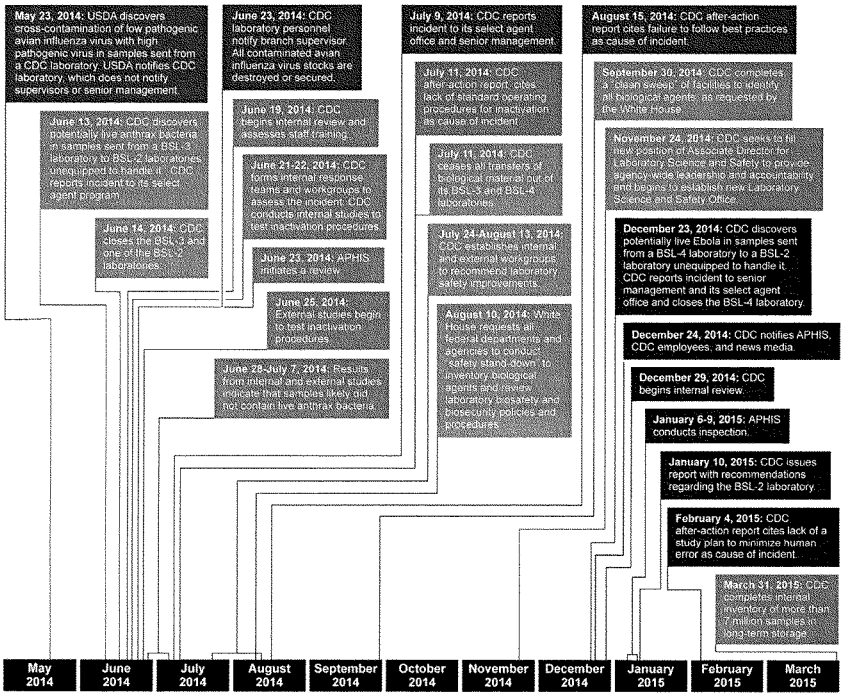
[22]Our 2014 testimony summarized the 2007, 2009, and 2013 reports, as well as provided our preliminary observations on the July 2014 CDC anthrax safety lapse. See GAO-14-785T.

Chairman Murphy, Ranking Member DeGette, and Members of the Subcommittee, this completes our prepared statement. We would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this statement, please contact Marcia Crosse, Director, Health Care at (202) 512-7114 or crossem@gao.gov; John Neumann, Director, Natural Resources and Environment at (202) 512-3841 or neumannj@gao.gov; or Timothy M. Persons, Chief Scientist at (202) 512-6412 or personst@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; Sushil Sharma, Assistant Director; Cheryl Arvidson; Nick Bartine; Colleen Corcoran; Shana R. Deitch; Melissa Duong; Terrance Horner, Jr.; Dan Royer; Elaine Vaurio; and Jennifer Whitworth.

Appendix I: Timeline of Recent Centers for Disease Control and Prevention (CDC) Safety Lapses and Related Assessments



Source: GAO analysis of CDC documents. | GAO-15-792T

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Mr. MURPHY. Thank you, Doctor. I will now recognize myself for 5 minutes of questioning of the witnesses. Dr. Sosin, at the end of your testimony you said we will work diligently and thoughtfully with all of our Federal partners and anyone sharing our commitment to protect Americans from biological threats. Please let the CDC know, I don't believe them anymore.

The USA Today article I referenced earlier said that the CDC refused to actually produce a policy to USA Today regarding the lab incident reports in this newly required lab safety office. When was that report actually written? Do you have any idea?

Dr. SOSIN. Thank you, Chairman. I was asked to appear here today, and I apologize for the lateness of testimony. I apologize that——

Mr. MURPHY. But do you know anything about this report that they are referring to in USA Today?

Dr. SOSIN. I know that an article came out last night. I did not know about that report and——

Mr. MURPHY. OK.

Dr. SOSIN [continuing]. And if——

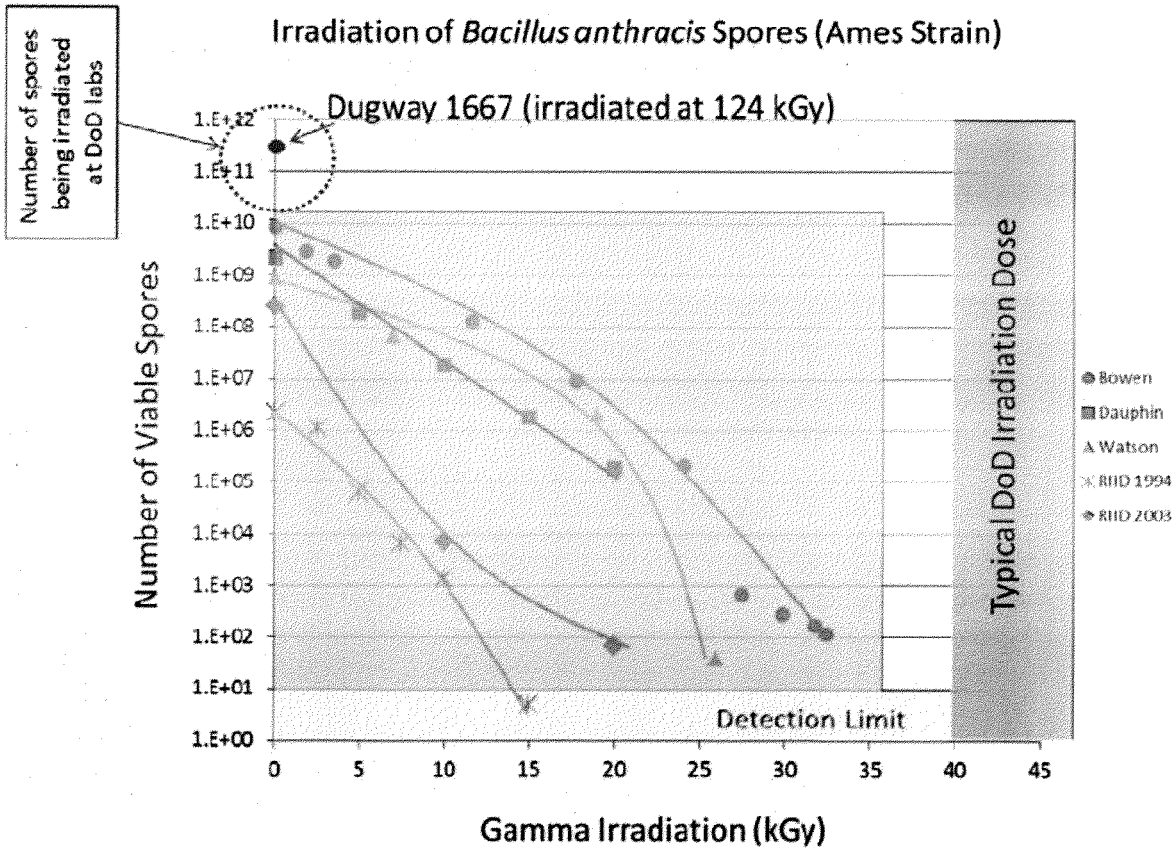
Mr. MURPHY. Well, could you——

Dr. SOSIN. We would be happy to assure that after this hearing we provide you answers to——

Mr. MURPHY. Well, this committee would like that report. I would like to know when it was written. If we could have that, that would be valuable. Thank you.

Dr. Hassell, I am trying to dumb this down. Now, if I put a cup of coffee in a microwave oven and turn it on, it gets hot in a certain amount of time. If I put a dozen cups of coffee in that same microwave, same amount of time, they are not going to all be heated, right? OK. Because we know that about radiation and mass, some physics principles.

[Slide follows.]


Irradiation of *Bacillus anthracis* Spores (Ames Strain)
Number of spores being irradiated at DoD labs
Dugway 1667 (irradiated at 124 kGy)
Number of Viable Spores
1.E+12
1.E+11
1.E+10
1.E+09
1.E+08
1.E+07
1.E+06
1.E+05
1.E+04
1.E+03
1.E+02
1.E+01
1.E+00
0
5
10
15
20
25
30
35
40
45
Gamma Irradiation (kGy)
Detection Limit
Typical DoD Irradiation Dose
Bowen
Dauphin
Watson
RIID 1994
RIID 2003

When I look here, and I believe this is from a report here, and it is on the graph there as well, is that—on the screen—that on the very upper left dot where it says the Dugway irradiation levels here, it is saying it is operating way out of the realm of the acceptable processes here. And the report states that the DoD routinely operates outside of validated experimental data for kill curves.

So based upon that finding, it sounds like validated experimental data does exist and all the DoD labs whose mission involved inactivation of anthrax were operating outside of it. Is that correct?

Dr. HASSELL. Yes, sir.

Mr. MURPHY. So is there—who is responsible for setting the number of spores and dosage of radiation? And are the protocols reevaluated routinely to determine that?

Dr. HASSELL. That is one of the next steps we are looking into. This original review was mainly focused on compliance to make sure that people were following the protocols they had and not shown there was the willful disregard for the protocols or nefarious intent.

Mr. MURPHY. You said it was willful?

Dr. HASSELL. It was not willful, nor was it nefarious. But what the graph shows, though, is they were working outside of that gray box that sort of shows experimental parameters that should have been the foundation for this work.

The next step in this is we are looking at the very accountability issue. How was that decision made to move outside of that realm? And as you noted, it wasn't just Dugway. All the labs were outside of that area.

Mr. MURPHY. Because somebody did make the decision. That is something that is important. We need to know because we like to think that there is a scientific rule set up that they are following and that all the labs are following that, too. So let me ask Dr. Hassell and Dr. Sosin: In response to these most recent shipments of live anthrax, have either of your agencies made any personnel changes or refer to anyone for their civil penalties or criminal prosecutions for these actions? Have either one of your agencies done that?

Dr. HASSELL. For DoD, that is that second part of the investigation that will kick off now looking at the accountability issue to determine that. And if I may, one of the issues is not only the individual that made that decision, if that was an individual that made that decision, but what was the process? Was there an overall systemic process that led people to perhaps gradually get outside of that experimental box? We are looking at both of those, but the accountability is taken very seriously by all seniors in the Department.

Mr. MURPHY. Dr. Sosin?

Dr. SOSIN. I would also like to acknowledge that we understand your concern and take it seriously. No disciplinary actions have been taken at CDC with respect to the DoD sample incident. In fact, CDC staff responded in a remarkable way to assure that all these samples were secured and destroyed and that the people that might have been exposed were protected.

Regarding the Select Agent Program, we continue to consider and take advice and input on how to change the nature of the program——

Mr. MURPHY. Do you work with the DoD? I mean, does the CDC work with other labs in terms of setting and reviewing standards on any regular basis or at all?

Dr. SOSIN. CDC works with DoD in a variety of ways.

Mr. MURPHY. With regard to this? So I am trying to find out—

Dr. SOSIN. Not with respect to setting standards——

Mr. MURPHY. OK.

Dr. SOSIN [continuing]. On anthrax.

Mr. MURPHY. And the reason is this: When we had our hearings for General Motors and someone made the decision of either making a spring this big or this big, and it cost a number of lives. And they refer to that as the GM shrug. People said, "Eh. Well, some engineer decided, on we go." And it is that area when we know when people adhere to scientific standards, I have the highest respect for them. When things begin to slip out—and I would agree, we are not looking at something nefarious or deliberate here, but to let anything slip by over time, that is the problem. And as Mr. Pallone pointed out, luckily no one has died yet from this, but we really have dodged the bullet for a long time.

But I see I am out of time. I recognize Ms. DeGette for 5 minutes.

Ms. DEGETTE. Now Dr. Crosse, you talked in your testimony about how people could be infected and even some kind of epidemic could be started if you got a particularly virulent agent that got released, correct?

Dr. CROSSE. Correct.

Ms. DEGETTE. In addition, we have got national security implications relating to the mishandling of these agents. Is that also correct?

Dr. CROSSE. That is also a concern.

Ms. DEGETTE. And that is if these agents, these active agents got into the wrong hands, right?

Dr. CROSSE. That is right.

Ms. DEGETTE. Now, you had a lot of recommendations that have not been fully implemented yet, is that right?

Dr. CROSSE. Yes, although—I mean, many of the recommendations they have taken at least some actions. The primary one where there has been no movement is to have some type of more centralized oversight.

Ms. DEGETTE. So to have a single Federal entity that could set the standards for all of the agencies, is that right?

Dr. CROSSE. That is right.

Ms. DEGETTE. Now Dr. Hassell, what is your agency's opinion about that recommendation of a single Federal entity?

Dr. HASSELL. It makes sense in many ways. I will say that within the Department itself, we are going to do that internally because it is so——

Ms. DEGETTE. OK. So if it makes sense in many ways, why haven't we done that? Why haven't you guys implemented that in cooperation with your fellow agencies?

Dr. HASSELL. Like I said, we are going to do that internally. We are in discussions now on these issues.

Ms. DEGETTE. But you don't disagree with the idea?

Dr. HASSELL. No, ma'am.

Ms. DEGETTE. And what about you, Dr. Sosin? What is your agency's view of this?

Dr. SOSIN. CDC works with APHIS at USDA as if we are one program. We work very closely. We do joint inspections on overlap agents. Whenever a change is proposed or considered in one program, it is discussed with the other program.

Ms. DEGETTE. Well, that is nice, but what about DoD?

Dr. SOSIN. So the oversight function of the lab—I am trying to understand your question. I believe——

Ms. DEGETTE. Well, OK.

Dr. SOSIN [continuing]. It is about oversight function, correct?

Ms. DEGETTE. What Dr. Crosse's agency is recommending is one single oversight agency that would set forth the protocols for the dispensing of these agents. And so I am asking each of your agencies if you would object to that kind of—it would make sense to me to get one protocol no matter which lab is dispensing it or whatever. What is your view on that?

Dr. SOSIN. Thank you. My view is that it is a complex decision, that there are constraints to having one standard for all procedures. Anthrax for example——

Ms. DEGETTE. What constraints would those be?

Dr. SOSIN. For example, with anthrax, there are many different uses of the products, DNA preps for developing vaccines——

Ms. DEGETTE. But in any case if you are sending it around, you don't want it to be live.

Dr. SOSIN. That is absolutely——

Ms. DEGETTE. That is not something that is—

Dr. SOSIN. No question.

Ms. DEGETTE [continuing]. Subject to debate. So if you can have one agency that could come up with the protocols about oversight on how you are going to make that not be live and how you are going to dispense it, you wouldn't object to that, would you?

Dr. SOSIN. We wouldn't object, and we believe that the Select Agent Program, the Federal Select Agent Program, would be the appropriate body to do that. It will take——

Ms. DEGETTE. OK. Could that have oversight over the DoD, too?

Dr. SOSIN. Absolutely.

Ms. DEGETTE. So do you think that you might cooperate to make that happen?

Dr. SOSIN. We will cooperate in any way to——

Ms. DEGETTE. OK. Let us know what we can do to help you because it seems to me that is an excellent recommendation, OK? And you are nodding, Dr. Hassell. Can you work with Dr. Sosin on that and his other colleagues?

Dr. HASSELL. Yes, ma'am, and that was——

Ms. DEGETTE. Thank you.

Dr. HASSELL [continuing]. Stated in the statement. We definitely are working together.

Ms. DEGETTE. OK. Now here is something else, having been on this committee for a long time. I have noticed this at all the Fed-

eral labs, not just the ones dealing with anthrax and other select agents but also our nuclear labs have the same problem of a culture of safety, and we have really struggled in this committee to get people to understand how important it is to have a culture of safety. So Dr. Hassell, can you think of anything we can do to systematize some kind of culture of safety?

Dr. HASSELL. That is a question I have myself, ma'am. I have spent 10 years at the DuPont Company, which goes back 200 years making gunpowder for Thomas Jefferson. And that safety culture is there. So one of the things I plan to do is go out and see those industry best practices for doing this that the Government——

Ms. DEGETTE. How long——

Ms. HASSELL [continuing]. Perhaps could adopt.

Ms. DEGETTE. How long have you been there?

Dr. HASSELL. At the——

Ms. DEGETTE. At DoD.

Dr. HASSELL. Just about a year today.

Ms. DEGETTE. OK. And Dr. Sosin, do you have some ideas about how we can increase the culture of safety at these labs?

Dr. SOSIN. I personally do not. I know that the CDC and CDC's Director take this issue incredibly seriously and have developed a series of ideas that will evolve.

Ms. DEGETTE. OK. I think we need you guys to supplement your testimony about this because this is really important. And I have one other question. I don't have time, but I would like a written answer for this. I would like to know why all of the problems in this particular incident seem to have come out of this one lab. Was it a problem with how they were handling this anthrax, how they were trying to treat it or is it a problem with the procedure itself? And maybe that is what you are investigating right now, but that seems like the crux of the problem.

Thank you, Mr. Chairman.

Mr. MURPHY. The gentlelady's time has expired. I will now recognize the vice chairman of the subcommittee, Mr. McKinley, for 5 minutes.

Mr. MCKINLEY. Thank you, Mr. Chairman. This is a subject I acknowledge is foreign to me. So I was delighted to try to hear and learn from some of your testimony on this. But I am just curious before I have got a list of six questions. I am trying to go back to the fundamentals. Why would we ship inactive cells to laboratories? What would you gain by shipping something that is dead?

Dr. HASSELL. Maybe we could——

Mr. MCKINLEY. You have to use the microphone.

Dr. HASSELL. So one of the aspects of this inactivated anthrax is that it maintains the shell that is around the original live spore. The physical structure is still there. That is important because that is the basis for the detection systems and the diagnostic systems that are developed.

Mr. MCKINLEY. OK. That——

Dr. HASSELL. So the closer we can get to that the better we are.

Mr. MCKINLEY. That helps a little bit to explain. Let's go back to something that the gentlelady from Colorado mentioned earlier that I didn't pick up in the reading. We are doing this in 200 laboratories around the country? Is that an accurate statement? We

are studying that in 200 laboratories? We have live anthrax in 200 laboratories?

Dr. SOSIN. The statement there, though, is 192 labs that receive this material were not intended to receive live anthrax. There are 181 registered entities within the Federal Select Agent Program registered to possess, use, or transfer Bacillus anthracis.

Mr. MCKINLEY. OK. So apparently there is some—I would struggle with that to understand why we have to have 300 or 200 looking at some of—I would really, especially given the circumstances of this. Dr. Crosse, before I get to—again, I am going to run out of time here I think—how would you grade the DoD's handling of this matter? Would you give them an A on how they handled it? An F? Give me a——

Dr. CROSSE. Well, since the incident was reported, they have moved pretty quickly to identify where the samples were sent, although that was still developing over the last few days and they have——

Mr. MCKINLEY. How would you grade it? Would you grade it passing? Acceptable? A B? A C?

Dr. CROSSE. I think their response, once it was discovered, has probably been a B. I think the activities leading up to it and the fact that this went on for so long is definitely a failure.

Mr. MCKINLEY. Well, I understand it has been going on for 10 years?

Dr. CROSSE. Yes. That is a failure and the fact that they have four different laboratories inactivating anthrax with four different methods and with four different chains of command that don't talk to one another.

Mr. MCKINLEY. Go back to Dr. Hassell. Since anthrax is probably the most dangerous agent that we can handle, I suppose it is more dangerous than Ebola. But getting it, getting that, is probably the biggest threat that we have in national security that someone doesn't get this agent. So in this case, has anyone tried to grow this live anthrax after they have received these products, with 200 laboratories? Have they tried to reactivate it?

Dr. HASSELL. It was grown to show the presence of the live spores. I may not be understanding your question. I apologize.

Mr. MCKINLEY. OK. Well, let me move on because I only have 1 minute left. And so is this the same type of anthrax that was used in 2001?

Dr. SOSIN. This is absolutely not the same type of anthrax used in 2001. This is a wild type anthrax. It was in a liquid formulation with extremely small numbers of spores in a 1 Ml sample. Very different situation, nonetheless, taken extremely serious.

Mr. MCKINLEY. So this is something that different—do you feel that our national security is more at risk because of the process we have been handling this for the last 10 years?

Dr. SOSIN. The CDC——

Mr. MCKINLEY. It is a yes or a no, isn't it?

Dr. SOSIN. I don't believe that these samples created such a risk. I believe that they were secured quickly and destroyed, that there are very small numbers of spores in this material and that it is naturally occurring type of anthrax.

Mr. MCKINLEY. Let me ask in the last—well, my thought process initially—why we were shipping this to seven foreign nations? Does someone have a written authorization? Is there one of those proverbial emails that someone was requesting this? And then who authorizes the shipment of that and under what process do they explain how they want to get it? Why would we ship to seven foreign nations?

Dr. HASSELL. So in several cases, those were actually DoD facilities that were located in those foreign nations, and other cases they were allies that——

Mr. MCKINLEY. We don't have enough DoD facilities in America that we have to go overseas? I am running out of time.

Mr. MURPHY. OK. I now recognize Mr. Green for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman. Unfortunately, the incident that led to today's hearing is not the first instance of issues of handling and shipment of bioagents at Dugway Proving Grounds. CDC and the Office of Inspector General examined safety lapses at Dugway in 2007. The result? The same kinds of problems we are hearing about today, failing to properly inactivate anthrax specimens. Is that correct, Dr. Hassell?

Dr. HASSELL. Yes, sir.

Mr. GREEN. Based on the previous problem, should Dugway have made a better effort to check its procedures and double-check the samples to see if the process worked?

Dr. HASSELL. That is my initial impression. We are going to be looking at that much more because there were some serious implications there, and we are going to be following up on that much more. So we can report back.

Mr. GREEN. Similarly when the CDC announced last year that it had inadvertently transferred live anthrax, did DoD as a precautionary measure direct its lab to check their own processes for ensuring that anthrax was inactivated properly?

Dr. HASSELL. No, sir.

Mr. GREEN. Why not?

Dr. HASSELL. I am not sure. That is a good question. We are going back and trying to figure out what were the steps leading up to this. It should have been better indicators that we could have taken action and detected this earlier.

Mr. GREEN. Well, again, I think the reason for the hearing is it seems kind of strange that, you know, CDC made a mistake and we had a problem with a DoD facility, and somebody in management authority didn't say let's check to make sure the DoD is doing it right because of what happened at the CDC, particularly because of the problem at Dugway. Nobody decided to do that?

Dr. HASSELL. It doesn't appear so, sir.

Mr. GREEN. Beyond the particulars of this anthrax incident, it is a fact that such shipments of live anthrax can accidentally occur raises serious questions about the handling of select agents at both Dugway and other DoD labs.

Dr. Hassell, based on the continuing problems we did find at Dugway, what assurance can you give the subcommittee that there is no long-standing safety problems at Dugway or at other DoD facilities that handle high-risk biological agents?

Dr. HASSELL. So that is a good question. We are trying to look and see if there are some general lessons we can learn from this and use it to ask some of the questions such as your previous question. Just internally, are there indicators here that would indicate we need to be asking other questions about other operations across the whole complex.

Mr. GREEN. What is DoD doing to look across all of its facilities and check their biosafety and biosecurity policies and procedure are adequate?

Dr. HASSELL. We are undertaking an effort now to look at that, as was pointed out earlier, the chain of command is disparate right now. So we are trying to tighten that up. We are going to make sure that the standards, for example, for the inactivated anthrax, we will ensure internally that that's standardized across all the laboratories. And then we can use that as the basis and see if there are other operations that we need to take some more actions on.

All four of those facilities do different activities. Dugway is largely a production facility. The other ones are more research facilities. So one size may not fit all, but there are definite lessons we could learn from this, and whenever possible, we will standardize.

Mr. GREEN. How is DoD ensuring a serious issue such as potential exposures or concerns about misuse are communicated from the laboratories to the senior leadership?

Dr. HASSELL. Some of the recommendations have been made previously we are going to be more vigorous on. The DoD instruction that was mentioned earlier that has been in process, that will include aspects that will bring all of the reporting forward to a higher level. So for example, the 2007 incident, that will not just remain—if that had happened today, that wouldn't just remain at Dugway or that immediate command. It would come all the way up to a central office within the Department. We would review all of those. We're in the process now of pulling in all of the Inspector General reports, CDC reports from all of the laboratories up to my office, and we're reviewing all of those to see if there are indicators and lessons to be learned.

Mr. GREEN. Well, following my colleague from West Virginia, so far we have been extremely fortunate these incidents at Dugway have not led to broader public health or security problems, and I hope today's hearing and other ongoing oversight of this incident serves as a call to action to tighten up these processes, not just for anthrax and at Dugway but other select agents and at all facilities. We don't want to have to have somebody here again, and I hope the Armed Services Committee is also looking at it and seeing that the issues are being corrected.

Mr. Chairman, I yield back my time.

Mr. MURPHY. The gentleman yields back. I now recognize Dr. Burgess for 5 minutes.

Mr. BURGESS. Thank you, Mr. Chairman. Thanks to our witnesses for being here today.

Dr. Sosin, let me just ask you a couple of questions basically about what we are doing to harden our public health infrastructure in locations where these agents may be under study because we have heard sort of a recurrent theme. I certainly appreciate what Ranking Member DeGette has said earlier. I mean, I have been on

this committee for a number of years as well, and it seems like there is a recurrent theme here. We want everything to be perfect, but there are human beings involved and sometimes they aren't perfect. So I remember reading—I was just a regular guy in private practice when the anthrax attack happened in 2001. I remember reading with just absolute horror what happened when those five individuals were infected and subsequently died, reading about their emergency room doctor's experience that here was a guy that didn't look that sick. He looked like the last 700 people that just walked in the door, but as we found out with anthrax, you can be a lot sicker than what you look. And by the time clinical deterioration begins, you are almost too late on the curve to rescue someone, although rescue is possible if you start early. Because unlike Ebola, anthrax is treatable with relatively common antibiotics.

So bearing in mind that Ebola experience from not quite a year ago, CDC was telling us last July, August, September, we got everybody up to speed about Ebola. We don't have to worry about Ebola coming to this country. The President made a statement that we don't have to worry about Ebola coming to this country. The CDC has done what it needs to do to get everybody prepared. And then it didn't happen.

So this is not quite the same thing, but you know you have got sites where this is under study. You know that unfortunately lapses can occur. So do you have like a 35- or 50-mile radius around these sites where you are at least notifying the people on the front lines, the emergency rooms, the emergency room doctors, that "this is something we are working on in your community"?

Dr. SOSIN. Thank you for that question. First with respect to hardening infrastructure, yes, there are support programs at the State and local level to address anthrax and other bioterrorism threats. As you pointed out, there are not only the routine treatments, there are some advanced medical countermeasures that have been developed such as antitoxin to help treat later stages of anthrax and vaccine. Those were actually brought to bear, the vaccine and antibiotics and prophylaxis in this incident.

The State authorities are informed of the institutions and their jurisdiction and the agents that are there as a part of their public health preparedness programs. There is no active outreach to the medical community in the absence of an incident, but we are quick to respond as we did in this instance with the information about how to diagnose, how to watch for, monitor, and how to treat.

Mr. BURGESS. Let me just interrupt you because my time is going to drift away from me. Could you provide the committee those materials that you provided——

Dr. SOSIN. Absolutely.

Mr. BURGESS [continuing]. To the emergency rooms and what radius around where the breach occurred, what the geographic radius was?

Dr. SOSIN. I will say that these materials were not sent to emergency departments, although we did consider it. We were monitoring the workers in the laboratories closely, and these materials were sent to the laboratories and to the State health departments.

Mr. BURGESS. But Dr. Sosin, that is the point.

Dr. SOSIN. Yes.

Mr. BURGESS. These people thought they were getting inactivated strains, and they were active. So somebody leaves work for a weekend and Sunday afternoon has got a low-grade temperature, just doesn't feel right. A family member says go down to the Care Now facility, and again, they will look well until they get deathly ill.

Dr. SOSIN. Absolutely.

Mr. BURGESS. That is the problem.

Dr. SOSIN. That is why these were isolated to laboratories, and we were working directly with the laboratories, the workers, and the health departments to monitor them.

Mr. BURGESS. Well, forgive me if I am unmollified, but the problem was you didn't know what you didn't know at that point. And certainly the people in the community who may have been the doctors and nurses and the caregivers who were seeing patients wouldn't have known that this was what they were up against.

I guess my concern is how do we get that information out there? How do we make people aware? Once you know that anthrax is in the consideration, OK. Fair enough. But before you know it, they look like the last 1,500 patients that have come through the door with a viral syndrome.

I do have a question that I need to ask Mr. Demske, and if we don't have time to get through all of it, maybe you can provide me an answer in writing. But when you look at the referrals for violations of the Federal Select Agent Program, CDC, NIH, United States Army Medical Research Institute of Infectious Diseases seem to be the top three. So you have an enforcement policy where you can actually fine, but you don't fine Federal agencies. Is that correct?

Mr. DEMSKE. To date we have not fined any Federal agencies. That's correct.

Mr. BURGESS. But that seemed—you know, that is what Willie Sutton would say. You robbed banks because that is where the money is. Right now, the violations, the multiple violators seem to be coming from those three groups. So can you get back to me in writing and discuss what you are doing to consider providing the same civil money penalties at any other lab, any other lab in the country would have to face if they had breach of these agents.

Mr. DEMSKE. Just to be clear, most of the referrals and most of the labs, incidents that have been referred to us, have not involved Federal entities but certainly there have been repeat instances at Federal entities, and we would be happy to provide you an answer.

Mr. BURGESS. The multiple offenders at CDC, NIH, and the United States Military. That is the problem.

Mr. MURPHY. It is the civil penalties and other penalties we need to know about from there. Thank you.

Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. We have heard about the importance of keeping labs safe and secure. Thus I would like to explore how labs both private and public that fail to meet critical safety standards and regulations are held accountable. Both CDC and HHS, through their Offices of Inspector General have roles and enforcement. CDC's division of select agents and toxins can refer entities, the Office of Inspector, for civil money penalties or cer-

tainly notices of violation. CDC could deny, revoke, or suspend a lab's registration or require a lab to enter into a performance improvement plan. Criminal charges can also be made in cases of misuse, unauthorized possession, or unauthorized transfer. So Dr. Sosin and Mr. Demske, could you briefly walk us through the different enforcement options and how you determine the appropriate response for a given violation?

Dr. SOSIN. Thank you for your question. You have correctly pointed out options, the administrative options the CDC has to suspend, deny, or revoke registration. The registration process itself is intended to screen and assure that there is good laboratory practice, good laboratory leadership and an appropriate use for the select agent materials.

So that process and a variety of other steps in the program are intended to assure that the entity itself is taking the appropriate steps that it needs to take. The decision to suspend or revoke is one taken very seriously on the importance of balance, particularly for facilities of the nature that you all are talking about here. These are important biodefense facilities doing important work, and the history of the program has been to work collaboratively with these programs to identify the specific problems and address them. But those are options, and the referral to FBI if there is a concern about suspicious activity or referral to OIG.

Mr. TONKO. Thank you. Mr. Demske?

Mr. DEMSKE. Yes. When we receive a referral from the CDC, one of our attorneys or multiple attorneys will review the allegations and the findings of the CDC, will often consult with the scientists and expert at CDC so that we make sure we understand those facts. If we believe that there has been a violation, it is our policy to them contact the entity that is the subject of the matter and give them the opportunity to provide us with information or arguments about why the penalty would not be appropriate. We take that into account, often again in consultation with CDC and decide whether to go forward with the case and we use our—looking across the experience of the cases that we have had, make a judgment about what we think the case should be valued at if we do seek a civil money penalty.

Mr. TONKO. Now, do your offices routinely work together to take action against those who are in violation?

Mr. DEMSKE. We certainly communicate and work together from our perspective to make sure that we understand the facts and the science in these matters for us to determine whether to go forward.

Mr. TONKO. And Dr. Sosin, what types of violations would result in a lab losing its registration?

Dr. SOSIN. I can tell you that the process of revoking a registration is one that is undertaken through careful efforts to help the laboratory address the concerns and improve its practices and that revocation would come only after the inability of that facility to make those changes or their decision to no longer be interested in doing that work. I can get further clarification of the specific measures if you'd like.

Mr. TONKO. And in your opinion, how often has that happened?

Dr. SOSIN. I believe that it has happened two times. I can get you the exact number.

Mr. TONKO. OK. I would also like to get a sense of the frequency of violations and actions to address them. Dr. Sosin, are you seeing any trends at the CDC in terms of enforcement actions, any trends in referrals to the Office of Inspector General for instance or performance improvement plans or lab registration actions?

Dr. SOSIN. The Federal Select Agent Program is constantly evolving in its approaches and tools such as the corrective action plan process are relatively new and evolving. So trends are hard to evaluate in that context. I know that at the request of this subcommittee, specific enforcement actions have been laid out in a response and should have the kind of information you would be looking for.

Mr. TONKO. OK, and I am out of time, but if Mr. Demske, if you could perhaps feed the panel with that same trend that you cite, any trends that you cite, that would be helpful.

Mr. DEMSKE. Yes.

Mr. TONKO. Thank you.

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

Mrs. BLACKBURN. Thank you, Mr. Chairman, and thank you to our witnesses for your patience. We appreciate this. As you know, we have got another hearing going on this morning.

Dr. Sosin, I want to come to you if I may. I have got a copy of Dr. Frieden's testimony from this committee last year, and he was testifying about the June 2014 anthrax incident. He said, and I am going to read from the testimony, and I am quoting. "These incidents should never have happened. The lack of adequate procedures and oversight that allowed them to happen was totally unacceptable. We will explore the broader implications of these incidents and incorporate the lessons learned from them to proactively prevent future incidents at laboratories across the Nation that work with pathogens."

So I want to know, can you explain why we didn't seem to learn the lessons? Can you talk about why there is another comprehensive review of safety and security of the bioterror labs? Why was not Congress notified? Why is another review necessary? Were the problems at the CDC not corrected? And then who is going to conduct the new review? And ultimately, who do we hold responsible for this?

Dr. SOSIN. Thank you for your questions. Pardon me if I need refreshing on some of them.

Mrs. BLACKBURN. I will be happy to refresh.

Dr. SOSIN. I am sure you will. I think it is important to recognize that the oversight program is not a CDC laboratory itself. It functions separately. Nonetheless, in hindsight, there has been reason to look more closely at anthrax inactivation. There is no question that that is necessary, and before a moratorium on the use and transfer of these materials will be lifted, we will have a policy about how to validate——

Mrs. BLACKBURN. Whoa, whoa, whoa. Wait a minute. That was supposed to be done. So why was it not done? Who is responsible that it did not get tended to last year?

Dr. SOSIN. The work of a complex laboratory, microbiological laboratory, has thousands of procedures and potential vulnerabilities.

Mrs. BLACKBURN. So you are saying no one person is in charge, that it is done by committee?

Dr. SOSIN. No. I am saying that the nature, the current nature of the Federal Select Agent Program is one of setting broad standards to achieve high laboratory performance but does not review each individual specific procedure at each entity. There will need to be——

Mrs. BLACKBURN. Well, did the procedures call for notifying Congress?

Dr. SOSIN. I am sorry?

Mrs. BLACKBURN. Did the procedures call for notifying Congress if you need to do a review, if you have another incident?

Dr. SOSIN. So——

Mrs. BLACKBURN. So that is not a part of your best business processes?

Dr. SOSIN. I apologize if Congress was not notified regarding the review that Dr. Frieden requested we take internally of the Federal Select Agent Program at CDC. That review is not a review of CDC labs and procedures. That is a review of what opportunities we have——

Mrs. BLACKBURN. OK. Well, let me ask you this——

Dr. SOSIN [continuing]. To improve the oversight program.

Mrs. BLACKBURN [continuing]. This way. Going back to his testimony where he says that it never should have happened, lack of adequate procedures, totally unacceptable, going to put the processes in place, and incorporate the lessons learned. Was this not done last year?

Dr. SOSIN. Many things were done. This was not addressed.

Mrs. BLACKBURN. So, OK. So it was not addressed? That is the answer that I wanted a yes or no. Either it was done or it was not done, and that is what we want to know.

And see this is what is part of is so frustrating to the taxpayers who are footing the bill for this because you all feel like you have immunity if you will, and you don't have to move forward and do the job because you have a continuing appropriation. You just don't do the job until it is convenient.

Dr. SOSIN. Congressman, I don't believe that——

Mrs. BLACKBURN. So you mess up once. You mess up twice. You mess up 86 times, and it is no skin off your back because nobody is responsible, because you operate by committee, because we ask you to do something and report back to us. What do you do, sit around and go, well, we will get around to it later? Maybe we need to give you around to it and have you go get the job done.

Dr. SOSIN. Perhaps I am misunderstanding——

Mrs. BLACKBURN. The fact that we are having to have another hearing and look at this is something that is frustrating. You should realize that there was a mistake and immediately move forward to correct the procedures and the policies and then should change the way that things are done. And I know I am running out of time, and I will yield back the balance of my time.

Dr. SOSIN. I do think it is important to clarify that the CDC error with anthrax was addressed. It was a different situation. What I did acknowledge is that as the Federal Select Agent Program, with

anthrax, with inactivation, in hindsight we should have and we will address inactivation procedures before that is used again.

Mr. MURPHY. I am sure you can understand——

Dr. SOSIN. Absolutely.

Mr. MURPHY [continuing]. We have heard that before.

Dr. SOSIN. I understand.

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

Ms. CASTOR. Thank you, Mr. Chairman. Regarding the DoD review of the Dugway incident and the science surrounding inactivation protocols, the DoD review concluded that one of the root causes of the Dugway incident was scientific uncertainty about the process of inactivating anthrax spores. The review stated that this uncertainty led to the creation of protocols that do not completely or permanently inactivate anthrax spores. And although this instance only recently raised questions about the inadequacy of these procedures, the Department knew of this uncertainty for quite a while.

So Dr. Hassell, if the Department was aware of the potential inadequacy of the inactivation process using gamma irradiation, why didn't the Department have better verification procedures to ensure the spores were properly inactivated before shipping them?

Dr. HASSELL. So that is a good question because it really separates there were two issues involved. One was the inactivation was ineffective, and then the other one was that the viability testing didn't catch the fact that the first was not 100 percent effective.

Regarding the inactivation, there are several scientific publications and, you know, peer-reviewed journals in the scientific literature that have shown different what we call death curves for killing anthrax. What we need to do now is to try to pull all those together, get a consensus view of those, work with a body of subject matter experts, work in consensus with CDC and try to figure out what——

Ms. CASTOR. Well, why didn't you do that before if the Department knew of this uncertainty for a while?

Dr. HASSELL. It appears that that was somewhat localized, that it wasn't universally acknowledged.

Ms. CASTOR. What does that mean?

Dr. HASSELL. Well, each individual laboratory set its own standards. And so this wasn't raised up to a central body——

Ms. CASTOR. And you are acknowledging now that was not acceptable. Those standards were not acceptable.

Dr. HASSELL. Was not acceptable and going forward, it will have to be done in concert so the——

Ms. CASTOR. So is the DoD reviewing all of its protocols and procedures to ensure that there are not similar gaps in the scientific literature for the inactivation of other dangerous toxins and pathogens?

Dr. HASSELL. We will be doing that, definitely. We are going to take a——

Ms. CASTOR. So you are doing that for anthrax and for other toxins?

Dr. HASSELL. Right. We are going to see if there are any lessons learned from that that we can then apply across the board.

Ms. CASTOR. How confident are you that people are going to take that seriously? There are gaps in science. There are discrepancies. How will you come to reconcile? Certainly you would err on the side of safety?

Dr. HASSELL. Yes, ma'am, absolutely.

Ms. CASTOR. But take us through what is going to happen specifically in that review.

Dr. HASSELL. Well, anthrax is particularly hard to kill. So we are taking on the biggest challenge up front. So that should give us our biggest challenges, both in the activation and on this viability testing afterwards. Things that we learn from both of those we will then take forward and apply them.

Ms. CASTOR. And when there is a difference of opinion, who is going to be the responsible party where we can go back and say, wow. We had this hearing. The DoD said, another agency said we will address these gaps. If and when we have to have another hearing, who is it that we will identify? Or if you could provide that to the committee because there is this problem with no personal accountability, don't you agree?

Dr. HASSELL. Yes, ma'am, and the second part of this investigation we will be looking at the accountability. We will have some of those people identified, and we will certainly provide that to the committee.

Ms. CASTOR. Thank you. I would like to turn to Dr. Sosin to ask some questions about the CDC's role in overseeing the Select Agent Program. Dr. Sosin, why is there such variation across labs as to how they inactivate anthrax?

Dr. SOSIN. Thank you for your question. As mentioned earlier, there are a variety of needs for materials that come from dead anthrax, and the laboratories, some research, some production for proficiency testing of labs, et cetera, have different roles and purposes as well. So CDC historically has required a validated procedure, either published and followed or validated within that laboratory and proof of sterility testing. I think to your earlier question about accountability, the exemption of a select agent, anthrax becoming now exempt because it is dead, is a requirement of the Federal Select Agent Program. And until we have a procedure that increases confidence that we can safely do that——

Ms. CASTOR. Because——

Dr. SOSIN [continuing]. We will not lift that moratorium.

Ms. CASTOR. Well, I appreciate that, but you can see that we are very concerned.

Dr. SOSIN. Absolutely.

Ms. CASTOR. Are we to expect similar variations in inactivation protocols for other select agents and toxins? And how do we address that?

Dr. SOSIN. As Dr. Hassell pointed out, the nature of a spore being extremely hearty and difficult to kill, plus the fact in this instance we were, or the Department of Defense was trying to kill the organisms without disrupting the organism creates a challenge in safety. The attempt now is to set an appropriately wide margin. If you go back to the chairman's figure that he showed, the DoD shows the dosing and a gap between the kill curve and the dosing. That gap wasn't happening here. Clearly there were production

runs that were growing anthrax and should have highlighted that the procedure was not adequate.

Going forward we will make sure that there is a safety margin and achieve consensus with the broad input that we have opportunity to get to assure that we are taking the right margin.

Ms. CASTOR. I am out of time. Thank you.

Mr. MURPHY. Thank you. Now I recognize Mr. Griffith for 5 minutes.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. Dr. Hassell, if you could, we have got folks out there receiving this. You answered a previous question related to the foreign nations and said some of those were DoD facilities. Were they all DoD facilities? And if not DoD facilities, were all the facilities that were completely controlled by the United States Government? Yes or no.

Dr. HASSELL. No.

Mr. GRIFFITH. So some of these would have gone to facilities not controlled by the United States Government. How certain can we be that these folks who were receiving live samples, and I believe it was over the course we now know of like 10 years, didn't discover this before they necessarily told us and have been out there growing some of their own samples and siphoning off some? So when we are told that you all hunted it down and you have killed or acquired all of the live anthrax, how certain of that can we be? Because it doesn't sound like to me we can be very certain if somebody was taking some of that anthrax and skimming off some of the live for use in other ways.

Dr. HASSELL. So the non-DoD facilities that you refer to, those are some of our most trusted allies. We do many things with these allies across the board, not just for chembio——

Mr. GRIFFITH. They are trusted, but if they wanted to do research on biological weapons, this would have given them an opportunity to acquire that or at least to acquire the base material to start the cultures with. Isn't that true? Yes or no.

Dr. HASSELL. It is true, but they were already doing most of that work. They just—we were trying to use a common material across the board so everyone was testing on the same material so that we could compare the results that we have.

Mr. GRIFFITH. And how——

Dr. HASSELL. But they do have those programs already.

Mr. GRIFFITH. How comfortable are you that those facilities had better protocols than we do in that we don't have some worker who might have taken what was supposed to be some dead cells, generated the live cells, and gone out with a sample that he might have then got, he or she may have then given to a foreign agent?

Dr. HASSELL. In some of those cases, they already have the material now. Like I say this was soon-to-be dead material, and we do have records that that's all been destroyed.

Mr. GRIFFITH. What you found has all been destroyed but since it was live, there could be more than what you knew about. Yes or no. Yes, the answer is yes. All right. Let's move on.

Dr. Sosin, you said that the CDC acted reasonably in tracking down the live anthrax and then securing or killing it. Dr. Crosse, you indicated that you would give them a B once it was discovered,

but Mr. Demske, you didn't get notified until yesterday to investigate the problem that was discovered in May. Isn't that correct?

Mr. DEMSKE. That is correct, yes.

Mr. GRIFFITH. So we have got at least 60 days since the problem was discovered before you were notified. Isn't that true?

Mr. DEMSKE. Yes.

Mr. GRIFFITH. I don't consider that a B or acting reasonably. Do you?

Mr. DEMSKE. Well, we are not the front lines of an emergent situation. That would have to go to the FDA and with the scientists and the CDC. So it is normal for CDC to do investigative work on its own before it would refer a matter to us, and that actually helps us because the evidence is more developed when we receive it.

Mr. GRIFFITH. So you think 60 days is reasonable before you're notified to do your investigation?

Mr. DEMSKE. Yes.

Mr. GRIFFITH. OK. And as a part of that, they are doing their investigations and so forth. But don't you think it is kind of interesting that you got notified yesterday? Do you think that our hearing might have sped that time up a little bit?

Mr. DEMSKE. I have no information about that.

Mr. GRIFFITH. But when you filed your testimony, you said to date OIG has not received a referral for any more recent potential violations involving Dugway which was in reference to the 2008 and 2010 incidents.

Mr. DEMSKE. That is right. We submitted the testimony on Friday. At that time we had not received it. I would say—my opinion is that oversight by this committee is a very effective way at spurring attention to this matter within the Government.

Mr. GRIFFITH. I just wish we didn't have to do it so often. Dr. Sosin, you are the acting director of National Center for Injury Prevention and Control. I noticed in the report referred to by the chairman earlier that Stephen Moore is the Acting Director of his department. What is the relationship between your two areas and why is everybody over there acting and nobody is permanent?

Dr. SOSIN. I am sorry. The information you have about my acting director role is old. I was previously for nine months acting director there. I have been for nearly or over a decade actually the Deputy Director for the Office of Public Health Preparedness and Response. Dr. Monroe I think you are referring to is the Acting Associate Director for Laboratory Science and Safety, is an outstanding laboratory scientist who comes from the Center of Emerging Infections.

Mr. GRIFFITH. And he is——

Dr. SOSIN. And he is in an acting role because we are trying to hire a top-notch laboratory scientist to lead the Laboratory Safety and Science effort.

Mr. GRIFFITH. And do you answer to him or do you just work with him?

Dr. SOSIN. I work with him.

Mr. GRIFFITH. I yield back. Thank you, Mr. Chairman.

Mr. MURPHY. Mr. Pallone, you are now recognized for 5 minutes.

Mr. PALLONE. Thank you. As the investigation into the Dugway incident continues, we are learning that more and more labs re-

ceived these lives anthrax shipments in addition to the 86 labs to which DoD directly sent shipments. There had been additional 106 labs that received secondary transfers. So we are now talking about nearly 200 labs. And as more labs are involved, the opportunities for error only increase.

So I do want to understand whether it is necessary to have so many different labs involved with dangerous biological agents. I know Ms. DeGette mentioned this in her opening statement. So Dr. Crosse, do you have an opinion on the number of labs that are working with anthrax?

Dr. CROSSE. Well, I don't think we know the number of labs that are working with anthrax. I think that is one of the issues. Well, we have information of where the—are you talking about the——

Dr. SOSIN. I just heard entities.

Dr. CROSSE. Yes.

Dr. SOSIN. Anthrax is a select agent.

Dr. CROSSE. That is right. I am sorry. Anthrax we do know. We do not know all of the high-containment laboratories that exist. We have controls for a subset of dangerous pathogens. There are other highly infectious pathogens that require a biosafety level three laboratory, and they do not all have to be registered with the Select Agent Program. We do know for anthrax. My apologies.

Mr. PALLONE. So Dr. Crosse, GAO has recommended the establishment of the single Federal entity to conduct Government-wide strategic planning and oversight for high-containment labs. This would include developing national standards for designing, constructing, operating, and maintaining such labs. Can you elaborate on this recommendation?

Dr. CROSSE. Yes. We think it is important that there be a more comprehensive set of plans for how many labs are needed. You know, there have been a great increase in the number of labs over the last decade. Since the anthrax attacks in 2001, a number of different Federal agencies have expanded the number of labs that they have. Academic institutions have built labs. Some States have built labs. And a lot of private entities have built labs. And they are very expensive. We don't know what really is needed.

As we have heard today, they are developing their own validation procedures. And there's not necessarily an assurance of consistency. And so while inspections can be performed at that these laboratories, the kinds of reportings of problems have only typically been going to a level above the laboratory, too. So they are not going up to the top of departments or to organizations.

And so I think that we are concerned that there hasn't been kind of a consistent set of standards in place, a consistent understanding of what the needs are, a consistent plan developed for where these laboratories ought to be built and maintained, and what the costs are going to be over the long term for maintaining this kind of infrastructure and whether it is in line with the needs.

Mr. PALLONE. Well, have you gotten feedback from the Federal Government agencies that operate these high-containment labs with regard to this recommendation to establish a single Federal entity? I know you mentioned some obstacles to that, but what other obstacles would there be to implement it?

Dr. CROSSE. Well, you know, I think that it is not clear where that organization should be located. As we've heard today, it is difficult to retrofit this kind of control on top of an existing enterprise. Different departments want to have control over what their own needs are. Different companies want to be able to compete for contracts from the Federal Government. And so going back and retrofitting them kind of control is complicated. We have not gotten traction on the concept of moving forward to try to centralize this control.

Mr. PALLONE. Let me just then ask again, do you believe that the establishment of these national standards and oversight might address some of the gaps that led to the recent incidents at DoD and CDC? And how could Congress help in establishing uniform standards and procedures?

Dr. CROSSE. We do believe that having more consistent lines of authority would be helpful. DoD I think in its report on the Dugway incidents has pointed out that the different laboratories handling anthrax were in different chains of command and never came together, that there wasn't a sharing of information, and they didn't have top-level knowledge of what was going on in these laboratories and how the procedures were being conducted. That is the type of thing we think would be helpful, and we would be happy with you and members of the committee to try to develop some kind of proposals.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. MURPHY. Thank you. I now recognize Dr. Bucshon for 5 minutes.

Mr. BUCSHON. Thank you, Mr. Chairman. I mean, to me this hearing is astounding, honestly. And I hate to admit but in the 4 ½ years that I have been here, this is not the only Government agencies that we are hearing, testifying in front of a Congress saying they are establishing new policies. Sorry we messed up. Sorry we did this. Sorry we did that. And you know why? Because there is no accountability. There is no accountability across the Federal Government in my view. No one is responsible. People are in their jobs for short periods of time. Dr. Hassell, you have been on your job for a year. If we really pressed you, you would say, well, I don't know. I have only been in my job for a year, so I don't know what they did before me. I mean, this is a decade-long process, and I personally get tired of hearing about how we are establishing new policies in this. This is anthrax. We should have had policies for decades. It is ridiculous.

And you know, that is the problem. There is almost contempt against congressional oversight. Every hearing I go to—and it is almost people walk out of the room and they go, well, they didn't get us this time and they can't get us. There's nothing they can do to us. That is what—I mean, this is just ridiculous.

So Dr. Hassell, how can there not be standardize protocols for this in the Federal Government after decades and decades of this? How can that not happen? I mean, that is just the question I have. Dr. Hassell, how could—you made the statement, you know, "We are standardizing how we deal with this." How can it not be standardized?

Dr. HASSELL. I could answer for DoD. Part of it was, as noted earlier, that the different chains of command have been one of the fundamental problems here because each laboratory reports up to a different chain. They meet too high up in the organization. So yes, I have been in place for a year, but I take this very personally.

Mr. BUCSHON. I am not criticizing you.

Dr. HASSELL. Right. No, no——

Mr. BUCSHON. I am just saying——

Dr. HASSELL. No, no, but I am saying I take——

Mr. BUCSHON. In fairness, you have only been there a year. You are right. You can't be accountable for what happened 10 years ago. I agree with you.

Dr. HASSELL. But I own it now, so I take personal responsibility to work with other people in the department to make sure these things are standardized, and I will not recommend to the Undersecretary that we lift the moratorium until I am confident that we have the proper scientific basis for our operations and that we have received, we have achieved the right level of standardization——

Mr. BUCSHON. I appreciate that. The reality is that, if people were losing their jobs, this would be standardized. And Dr. Sosin, I mean, you said—they asked, how do you solve this problem? You said, well, I don't know how we solve the problem essentially is what you said in your earlier testimony.

I mean, I know how to solve it. How many people across the Government have been fired over this problem? Who has lost their job at CDC, at DoD? Or who is still doing the same thing, even though they literally sent a national security risk, anthrax, around the world? And as Mr. Griffith found out, non-DoD properties. I don't care if they are allies. That doesn't matter.

And not to mention the fact how many people are protected from being fired because they are part of a Federal Government union that does not allow them to be held accountable.

Dr. SOSIN. Congressman——

Mr. BUCSHON. I want to know answers.

Dr. SOSIN. I would love to have you come visit CDC and see how accountable the scientists and professional staff are at CDC. We take this incredibly seriously. There are——

Mr. BUCSHON. I am not saying that you don't——

Dr. SOSIN. There are regulations and rules——

Mr. BUCSHON [continuing]. But who has lost their jobs? Who lost their job?

Dr. SOSIN. There are regulations and rules around the use and transfer of anthrax, live anthrax. This particular incident was about an exempted material, which was not considered a select agent. And new actions will be taken to address it.

Mr. BUCSHON. What, you are going to put in some more policies? By action, what do you mean?

Dr. SOSIN. For example——

Mr. BUCSHON. Well, for me it means the people responsible for doing this lose their job.

Dr. SOSIN. For example, before a material can be considered killed, we need to have a validated procedure within the lab experience.

Mr. BUCSHON. But how—to my question, how come you haven't had that?

Dr. SOSIN. Hindsight——

Mr. BUCSHON. This is for decades.

Dr. SOSIN [continuing]. We should have had it. We have already—I have acknowledged that in hindsight, with this organism and the vulnerability here, we should have done this before.

Mr. BUCSHON. I mean, the reality——

Dr. SOSIN. And we are going to do it now.

Mr. BUCSHON. I mean, the Federal Government hasn't known what constitutes dead anthrax until this came up? I mean, I just don't——

Dr. SOSIN. The reliance is——

Mr. BUCSHON. Failing to find why there is a problem——

Dr. SOSIN [continuing]. Testing, testing the material in the laboratory to see if there is growth. And that process in this instance failed.

Mr. BUCSHON. OK. I yield back, Mr. Chairman.

Mr. MURPHY. Thank you. I now recognize Mr. Flores for 5 minutes.

Mr. FLORES. OK. Thank you, Mr. Chairman. It is unfortunate that we have to have another hearing, another oversight hearing like this. You know, continuing along the theme that Dr. Bucshon raised, there was a quote in USA Today in the article that came out yesterday that says the root cause of all this is a lack of accountability. Incidents don't get reported, and consequences don't occur. And I think many of us have expressed our frustration, not only in the agencies represented here, the two agencies that are the subject of the problems, but across the Government and the VA, for instance. It has allowed for cover-ups on waiting lists, and only three people have been fired at the VA. Three hundred thousand people in the VA and only three have been fired. And it gets back to one of the root causes: It is too hard to fire a Federal union employee.

So Dr. Hassell, of the individuals at the Dugway Proving Ground, what are the percentages of uniformed versus civilian at that facility?

Dr. HASSELL. I don't have that information, sir. I can get it to you. It is mostly civilian.

Mr. FLORES. And of the civilian, what percentage are unionized?

Dr. HASSELL. I am not sure.

Mr. FLORES. I would appreciate if you could get us responses from both of those.

Dr. HASSELL. Yes.

Mr. FLORES. And if that is the case, have you taken action against any of those employees, any civilian employee or any uniformed employee?

Dr. HASSELL. To date, no.

Mr. FLORES. OK.

Dr. HASSELL. There is an investigation that's starting to look into this. If we do take action, we want to make sure that it is taken at the right place, to make sure that the person who is truly accountable is held accountable.

Mr. FLORES. Well, that is all real nice, but how many mistakes are happening right now because there is no accountability? I mean, do you know today that we are not shipping other live agents around right now? Do you know that? How can you know?

Dr. HASSELL. As we pointed out, just because the anthrax itself is so hard to kill and presents such a challenge, that has been stopped. So that I can assure you is not happening.

Mr. FLORES. OK. Anything else? What is the next one, though? Where are the other vulnerabilities? I mean, we had Ebola last year, not from you but from the CDC. I mean, Dr. Sosin, how can you be sure that we don't have any other incidents like this going out right today.

Dr. SOSIN. Certainty is hard to provide. As we understand the organism and the process of assuring its sterility. There is no evidence that these materials that are presumed inactivated are not inactivated. We have seen no evidence of a signal event, growth or disease or injury. That doesn't mean we don't take this seriously, and we don't consider whether additional procedures need to be implemented on inactivation of select agents. This is certainly going on now with respect to anthrax and we'll apply what we would consider in a broader context for other selected agents.

Mr. FLORES. Just for the committee's sake, walk through the ownership of the different elements of the Federal Select Agent process as respects your two agencies. Can you tell me who owns what part? And I have just got a minute so can you—just give me the highlights, Dr. Sosin.

Dr. SOSIN. Well, I can tell you——

Mr. FLORES. What parts do you own and then where do you hand off to?

Dr. SOSIN. The Federal Select Agent Program is an oversight program so the main activities that are involved and the main improvements that have been made through the execution of this program over the last 12 years includes screening and assessing facilities and staff for their suitability to work with anthrax. That means that the facility is an appropriate facility, has good laboratory practice, and has appropriate role to work with that material. It also includes the FBI's review of personnel reliability, of all of those who will be using it, includes a set of requirements to elevate biosafety and biosecurity, inventory management, access controls, those kinds of measures. And it includes a process and an ability to detect and respond including the notification of jurisdictions that have these facilities in site including what we did here with the anthrax response, being able to go in, investigate, identify whether people are at risk, secure the samples and look into what caused them.

Mr. FLORES. OK. Now this process involves not only private-sector institutions as well as public-sector institutions, is that correct?

Dr. SOSIN. That is correct, for the select agents.

Mr. FLORES. So where are you finding the best practices coming from today? I mean, Dr. Hassell was talking about going to the private sector to find best practices. So Dr. Hassell, where are we finding the best practices today? Private sector or public sector?

Dr. HASSELL. It is a combination of both. I am just saying we are going to go look at the private sector. That often doesn't happen in Government as the first reaction. The Department of Defense——

Mr. FLORES. You need to look at both.

Dr. SOSIN. The Department of Defense, the Centers for Disease Control, the NIH, these are outstanding facilities. They are doing cutting-edge, critical work which has some risk. These are places where best practices and not-best practices will occur because of the broad range of practices that do occur.

Mr. FLORES. OK. I have additional questions. I will submit them for the record later on. Thank you, Mr. Chairman.

Mr. MCKINLEY [presiding]. Thank you. And the gentleman from Oklahoma, Mr. Mullin, is recognized for 5 minutes.

Mr. MULLIN. Thank you, Mr. Chairman. I appreciate you guys being here. I am sure you are having a blast and enjoying your time here, but it is very frustrating for me to see what has taken place and to hear you guys say you have protocols, protocols. You are looking into it. You are looking into it. How long does it take to look into this? It is really hard for me to follow this. Dr. Hassell, is it the practice of the DoD, the labs, to send out a death certificate with select agents when they leave, is that correct?

Dr. HASSELL. It has been, yes.

Mr. MULLIN. It has been? How long has that been going on?

Dr. HASSELL. I believe—I apologize. I am not sure when the death—I think the information——

Mr. MULLIN. What kind of information is on that death certificate, the one that is similar to this one right here?

Dr. HASSELL. I am not sure how long that has been part of the process. We have been looking at just the overall inactivation. We have been looking at that back 12 years. I am not sure at what point the death certificate was initiated. I can—I will find out.

Mr. MULLIN. Well, this dates back to 5 years ago. So we know it has been going on for at least 5 years, right?

Dr. HASSELL. Right.

Mr. MULLIN. Then why is it that the private lab that found the active anthrax, why didn't it have a death certificate with it?

Dr. HASSELL. Because when it was originally tested they didn't see growth. One of the things we are looking into——

Mr. MULLIN. But if it shipped out—you just said it is the practice of DoD with any shipment that is leaving to have a death certificate. Why wasn't there one that was shipped to a private lab?

Dr. HASSELL. Oh, I am sorry. So for that particular operation, we were setting out blind tests. People were seeing whether or not——

Mr. MULLIN. With active anthrax in it?

Dr. HASSELL. It was a suit to see if people could detect the presence of these. This was to identify some new performers.

Mr. MULLIN. So we knowingly shipped live anthrax.

Dr. HASSELL. I am sorry, say again?

Mr. MULLIN. Well, you said you were shipping it to him to see if they could find it. It didn't have a death certificate, so I am assuming you knowingly shipped live anthrax to this private lab because it didn't have a death certificate. I forget what that——

Dr. HASSELL. No, it just—we did not provide the shipping because of what the agent was? We did not knowingly ship live agent, absolutely not.

Mr. MULLIN. Did the shipment then have——

Dr. HASSELL. We just did not include their——

Mr. MULLIN [continuing]. At your place or some other place a death certificate?

Dr. HASSELL. Yes.

Mr. MULLIN. Who produced a death certificate?

Dr. HASSELL. The originator at Dugway.

Mr. MULLIN. And what was the test that was performed to show that it was dead? And what is the difference between the tests that the private lab showed that it was live?

Dr. HASSELL. They were very similar and——

Mr. MULLIN. Well, they couldn't have because one showed it dead, one showed it live.

Dr. HASSELL. Well, that is what we are looking at because one of the key differentiators for what Dugway did——

Mr. MULLIN. So who is responsible for that? Is that Dr. Sosin? Is that his group? Who is responsible for showing the procedures to find out that it is dead?

Dr. HASSELL. Going forward we are going to adopt the CDC's procedure.

Mr. MULLIN. No, no, no. Who is responsible for it at that time, not going forward? Who is responsible for it at the time? If it wasn't your group, Dr. Hassell——

Dr. HASSELL. It was Dugway.

Mr. MULLIN [continuing]. Whose group was it?

Dr. HASSELL. It was Dugway. They developed——

Mr. MULLIN. And who is over Dugway?

Dr. HASSELL [continuing]. The testing.

Mr. MULLIN. Who do they fall underneath? Do they fall underneath Dr. Hassell, Dr. Sosin, Dr. Demske? Who oversees Dugway?

Dr. HASSELL. The Army.

Mr. MULLIN. OK.

Dr. HASSELL. That is why——

Mr. MULLIN. Narrow it down for me here. Help me figure out who is responsible. Who is the chain of command that is responsible for the death certificate for the procedures to show that the agent leaving is truly dead?

Dr. HASSELL. Are you talking about the chain of command at the laboratory or just for the certificate?

Mr. MULLIN. I am talking about the chain of command to find out that the anthrax is shipping out. This isn't a hard question. Who is finding out for sure the procedures to find that the agent is dead?

Dr. HASSELL. It would be the——

Mr. MULLIN. You don't know?

Dr. HASSELL. It would be the scientist that——

Mr. MULLIN. You don't know. Dr. Sosin, can you answer that question?

Dr. SOSIN. I can't answer——

Mr. MULLIN. Dr. Demske, can you answer that that question?

Mr. DEMSKE. Not specifically. I——

Mr. MULLIN. OK. Then this brings in my last question because as I was going through the background information to prepare for this hearing, I couldn't figure it out, either. There are so many different people that touched this. There is no clear line of chain of command. As a business owner, you have got to have someone responsible for something. This goes back to a line of questions that was already asked. No one can be fired because no one takes responsibility for it because no one has responsibility for it. We just assume that everybody is doing their job, and yet we are shipping out live anthrax and no one takes responsibility for it.

Dr. Hassell, you said that you were going to leave it locked down where they couldn't be shipped, for nothing to be shipped until you declared a line of command and procedures, right? How long is that going to take?

Dr. HASSELL. It is going to take a minimum of 6 months we believe.

Mr. MULLIN. A minimum? If you could just find out all the players in it, you ought to be able to lay it out and put somebody in charge to oversee it.

Dr. HASSELL. I am sorry. I was referring more just to put the procedures—the scientific studies that need to identify the gaps but the——

Mr. MULLIN. My point that I am getting to is we had live anthrax shipped out. No one takes responsibility for it. When I asked a question to find out who is responsible for it, no one can answer it. I think we have identified the problem. It is time for someone to take responsibility. Thank you, Mr. Chairman. I yield back.

Mr. MCKINLEY. Thank you, and we have Collins from New York for 5 minutes.

Mr. COLLINS. Thank you, Mr. Chairman, and maybe I should maybe help us all step back a second. Clearly a bacteria-grown agent such as anthrax or C. diff with spores, completely different than a virus, right? Easy to kill a virus. So part of the concern I have heard as one of the last questioners is we know there is a lot of biological agents, a lot of potential weapon issues going on. And I think the concern of the committee is if we have this with anthrax, might we have it with something else like SARS, like smallpox, like whatever. But that is where maybe—not to give you suggestions in your testimony. You might want to help the committee differentiate bacteria from virus, just to give them the confidence level. There is a different ball game going on.

Now you use radiation because you are trying to penetrate the spore, correct? For your—you want to penetrate the spore, which is very hard. So the way that you prove it is dead, the death certificate, is you take a sample and put it in culture and try to grow it. Correct? You tell me—and you really didn't make that real clear here. I am guessing the problem is they put it in culture for a month, and it should have been in culture for 6 months. Is it safe to assume that they just didn't run the culture test long enough?

Dr. SOSIN. We can't identify for certain whether that was an issue, but it is a possibility. Anthrax grows in culture within 2 days generally. So it is——

Mr. COLLINS. No, it can, but it can last 6 months. And this is where you take something like anthrax or C. diff which is a spore, it can pop up in 5 months' time.

Dr. SOSIN. It can survive as a spore, yes.

Mr. COLLINS. That is correct. So if it is surviving as a spore for 5 months and somebody is creating a death certificate after 2 months, they are saying it is dead——

Dr. SOSIN. I am sorry, Congressman. When you put a spore in a fertile environment, it germinates and grows——

Mr. COLLINS. Right.

Dr. SOSIN [continuing]. And that, with anthrax, happens within 48 hours, generally within 24 hours. So in a fertile environment, you would expect to see that growth.

Mr. COLLINS. I can beg to differ with you. I have some experience in this. I have seen it where it doesn't grow in a month. It doesn't grow in 2 months. And then all of a sudden in 5 months, it shows up. I would suggest respectfully that I believe the big issue here was it wasn't radiated with enough intensity, so it wasn't killed. But to validate it was dead, they put it in culture to see if it would grow. And if it was in culture for 48 hours and it didn't grow and they gave it a death certificate, then I can tell you what your problem is right now. You didn't put it in the culture long enough. I think in best practices in industry, in industry best practices, you are going to see that batch sit in the refrigerator or sit in the freezer for 6 months, and you are going to have that culture, that spore in culture for 6 months, not for 48 hours. And I think you would have to agree, if it is in that culture for 6 months, it is deader than a doornail and you will have more assurance than if it is only in culture for 48 hours. And again, this is different than a virus. So I just think some of that confusion is going on here as to when is—because you do the death certificate at the lab after it has been radiated and held in isolation until the culture test is run. And then you say "OK, I didn't see anything. So it is dead." Now that entire batch is good to go as dead virus, hence exempt, et cetera, et cetera. And that is what happened. It was then shipped out exempt because it had the death certificate.

But I guess the issue would be—I am assuming that is up to the lab to decide how long they are going to grow it in culture, is that correct? That is a lab procedure, not a CDC or——

Dr. SOSIN. At this point in time, the sterility testing, viability testing is a laboratory procedure, but there will be additional requirements as a result of this incident.

Mr. COLLINS. And I do think—and that is what I would encourage you to do. That is why I think it falls apart. You do trust these labs to all be at the top of their game. But in best practices, and this one an example, I can assure you best practice in private industry on anthrax and on C. diff is 6 months. It is 6 months of testing so you know it is dead. It is not 48 hours. That is best practice coming out of private industry. I yield back. Thank you.

Mr. MCKINLEY. Thank you. And we now recognize the congresswoman from Indiana, Mrs. Brooks, for 5 minutes.

Mrs. BROOKS. Thank you, Mr. Chairman, and thank you for holding this important hearing. And I have to say in my prior role before joining the committee, I was chair on the Subcommittee on

Emergency Preparedness, Response, and Communications for Homeland Security, and it really opened my eyes to the vital need to better protect the American people and our country from bio attacks and from biodefense incidents. And I will say that at that time I learned that this administration did away with a position that had been in place under the Clinton administration, under the Bush administration, called the Special Assistant to the President for Biodefense. And I think we learned about that position being eliminated when the Ebola attack, when Ebola hit this country, and I think it kind of goes to the point of I think what Dr. Crosse is talking about is that as a Government, we are not—there is no central line of authority. There is no central entity. There is no person who all of these issues bubble up to that as a Government we have a massive enterprise with so many different well-intentioned, hard-working scientists and Government workers. But yet, there is—when it comes to biodefense for this country, it is not organized and we are not doing a good enough job.

I have to tell you that later this week we are going to be introducing legislation that addresses the need to strengthen and streamline the existing biodefense initiatives BARDA and the CDC. And so Dr. Sosin, I have a question. If lab workers or other medical professionals had been exposed to live anthrax samples, are you confident as to whether or not we would have had proper vaccines and therapeutics in place to save lives?

Dr. SOSIN. Yes, I am confident we do.

Mrs. BROOKS. Are you confident, Dr. Hassell?

Dr. HASSELL. Yes, ma'am.

Mrs. BROOKS. OK. Mr. Demske and Dr. Crosse, are you confident that we have enough proper vaccines and therapeutics in place to save lives?

Mr. DEMSKE. I don't have sufficient information to answer that question.

Dr. CROSSE. Nor do I.

Mrs. BROOKS. Dr. Sosin, would that be for the workers that are being exposed or how about with respect to the community, building on Congressman Burgess' question about one of these individuals, if they had been exposed and presented to an ER. Can you, you know, explain to me what your view is if you have one about our national strategic stockpile and the coordination within the Government enterprise with respect to the national stockpile.

Dr. SOSIN. Thank you for that question. The strategic national stockpile actually did provide vaccine for the States that had workers who were receiving prophylaxis. So I am confident that we have the ability to do it. We have a vast supply of countermeasures for anthrax. The nature of the event that you might be trying to prepare for always determines whether you have enough. But there have been a variety of processes and procedures to review the requirements that have been set by the Federal Government for this threat, and we meet those current requirements.

Mrs. BROOKS. Dr. Hassell, any comments on our stockpile and how we can ensure that we have the medical countermeasures in place across the board for incidents?

Dr. HASSELL. No, ma'am. That is really my colleagues' purview.

Mrs. BROOKS. Dr. Crosse and Mr. Demske, what I think this event, going back to what this event shows us, is that while we are trying to respond at a managerial level. Are you familiar with the private sector's involvement with the medical countermeasures, development, and procurement? Are either of you involved in that at all.

Dr. CROSSE. I have done some past work looking at, for example, how the Federal Government has built flexible manufacturing facilities to be able to respond, and those are private sector entities. Mr. Demske?

Mr. DEMSKE. I am sorry. I have nothing to add.

Mrs. BROOKS. OK. I would like to go back to, and I guess if I could actually—I might have a little bit of time with respect to the death certificate.

Building on the congressman's question about the death certificate, could both of you please explain with a little bit more detail how that process works, what is required to be placed on the death certificate, and if you are sending these spores to another lab, what is it that the one lab should have that the other lab then—what is common in looking at the death certificate. Is the organism required to be listed or it is not listed when you do this sample blind test? Can you please go into a bit more detail? I am sorry my time is up, but I would ask if we might have just a couple of more minutes?

Mr. MCKINLEY. One more.

Mrs. BROOKS. One more minute?

Mr. MCKINLEY. You will have to yield.

Mrs. BROOKS. And then if you could please submit any further explanation in writing?

Dr. HASSELL. So it might be, if I may, we can submit a more full explanation of how that is used. I will say, though, we are considering not using a death certificate in our current operation. At least we are reevaluating that because it may send the wrong message. So that is one thing when I worked more with my colleagues about that very issue because we have concerns about what message that sends.

Mrs. BROOKS. Dr. Sosin?

Dr. SOSIN. The laboratory itself makes the determination about death certificates and the sending process. That is not a select agent regulation or requirement.

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

Mr. MCKINLEY. Thank you.

Ms. DEGETTE. Chairman, I would like to strike the last word.

Mr. MCKINLEY. We have one more——

Ms. DEGETTE. Oh, OK.

Mr. MCKINLEY. We have one more on this. The Chair now recognizes the Congressman from North Carolina, Mr. Hudson.

Ms. DEGETTE. Sorry.

Mr. HUDSON. Thank you, Mr. Chairman, and thanks to the panel for bearing with us here until the end. Would you like to expand on that answer at all, my colleague's question about the death certificates and the practice? Were you able to fully answer that?

Dr. HASSELL. For myself, I need to get some more detail on that and give a better answer to that for all three of you that were interested in that issue.

Mr. HUDSON. OK. I offer you some time if you got anything else you want to say.

Dr. SOSIN. No. I know that CDC does issue a death certificate with materials, inactivated materials that it sends out on the occasions when it needs to. I do not know the particular details of that death certificate.

Mr. HUDSON. Well, I would appreciate it if you all would follow up with that because my understanding is DoD in particular, it is common practice to send the death certificate, even when you are doing this sort of blind sample. And in this case, it wasn't sent until much later. So I would love to see a little more thorough answer on that. So thank you for that.

Overall, if anyone on the panel wants to, I am trying to grasp the mission of the Federal Select Agent Program, your understanding of the mission of the program, and do you think it is being fulfilled? I would open that up to anybody.

Dr. SOSIN. Well, clearly the incidents that you have seen are serious, are the kinds of indicators that we need to do more, and I think the important message from us is that over the history of this program, since the regulations, the authorization in 2002 and the new regs in 2003, this program has continued to receive input and advice from a broad spectrum which is needed, advice from Congress, advice from the public, advice from Federal and non-Federal entities to improve the program. And the program has changed and improved over time.

That said, this incident and these incidents have elevated the importance of some procedures requiring more direct oversight and review, and we will address that.

So there is a broad question, and many of those questions about BSL–3 that are not select agent, questions about how many labs. These are important, critical policy questions. Congress has an important role to play in them. The Federal interagency has an important role to play in them. CDC will contribute to the debate about the pros and cons of the different approaches. But when consensus is achieved or direction is given, we will follow those directions.

Mr. HUDSON. So in your opinion, the mission is worthy and salvageable I guess to try and use laymen's terms?

Dr. SOSIN. Absolutely.

Mr. HUDSON. OK.

Dr. SOSIN. We are committed to this work.

Mr. HUDSON. Dr. Hassell, you know, the Dugway has had problems in the past, continues to have problems, you know. It has been referenced plenty of times here today. Just in summation, how does this continue to keep happening and how do you see us getting out of this cycle?

Dr. HASSELL. So I mentioned earlier that this falls under the Army. So speaking on their behalf, I can tell you that the Army takes this very seriously, at the highest level. Now that is something that sounds easy to say, but I can assure you, in my interactions with them, this is taken very personally and very seriously

at the highest level. So the Secretary of the Army on down is taking action on this. They are going to look at issues specific to Dugway but not limiting it to that, looking at the chain of command across the board. And it is not just so that this could be a better reporting chain up. There may be opportunities that arise from this for better interaction across from them. The laboratory at USAMRIID for example may have some capabilities. Perhaps the organizational structure was preventing them, their free flow of information. I am not sure that is the case, but I am hoping that is some of the outfall from this. But you know, just getting all the laboratories working better together, standardizing where it is appropriate, and then moving forward.

Mr. HUDSON. Well, I appreciate that. I guess I would offer this up to the GAO or the OIG. What existing tools does CDC have that it is currently not using that would allow it to better oversee and take corrective actions against labs that commit violations? Either one of you.

Dr. CROSSE. Well, we have a concern that the reporting when incidents occur is really just to one level up from the laboratory and that more senior management in an organization is not necessarily informed, that the Select Agent Program is really focused, you know, within that laboratory but not necessarily ensuring that accountability up the chain of command over that laboratory is occurring. You know, we also are just undertaking work at the request of this committee to look at inactivation procedures and the extent to which there are scientific questions for how that should be done, where there are best practices, what types of methods are being used, how that information is shared, you know, what the current scientific issues are, and how the methods are validated and whether that information is being shared across this enterprise. And that is a concern that clearly labs have been operating on their own, and the information has not been being shared across the enterprise.

Mr. HUDSON. I appreciate that. Mr. Chairman, I am out of time. If you wouldn't mind maybe answering in writing if you have just a summary of some of the tools, I would appreciate your testimony as well. Thank you, Mr. Chairman. I yield back.

Mr. MCKINLEY. Thank you. And before we conclude, I think Ranking Member DeGette, you had a question?

Ms. DEGETTE. Yes, thank you, Mr. Chairman. I just wanted to thank the witnesses for coming and also relay a conversation I had with Chairman Murphy, which is I am really urging him to have a hearing later this fall, towards the end of the year, after you all have figured out what your improvements in the standardization and the oversight are going to be. What I have found during my many years on this committee is when we have some crisis like this, the witnesses come in. They say we need to do better. OIG and GAO come in and say there are things that can be done, and then another year goes by and we have another breach. So I have urged the chairman and I think he is in agreement to really hold your feet to the fire to make sure that these improvements, these gaps that you have identified are filled, that the standards and the coordination, the plans are completed. And I believe he will have

that hearing, and on both sides of the aisle, we would agree that needs to be done. Thank you very much.

Mr. MCKINLEY. And I would also ask hopefully, when we talk to them, that we also have some accountability. You have heard several of the questions have been about how many people are going to lose their job over every fail over the last 10 years on this. So I think that is something that we are going to be looking for, is to see how many people have lost their job as a result of this unaccountability.

So with that, in conclusion, I would like to thank all the witnesses and the members that participated in today's hearing. I remind members that they have 10 business days to submit questions for the record, and I ask that all witnesses all agree to respond promptly to those questions. And with that, the subcommittee is adjourned.

[Whereupon, at 12:09 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

One year ago, we held a hearing to review an incident involving the handling of anthrax in Ziploc bags at the CDC—a troubling instance where safety practices were ignored despite the potential for lethal consequences. That should have been a wake up call, yet here we are a year later, examining yet another anthrax incident. This time it's the "inadvertent" shipment of live anthrax from a Defense Department lab in Dugway, an Army facility in Utah. These shipments went across our country and around the world. How? Dugway failed to inactivate anthrax and then failed to detect that the anthrax was still alive.

According to the Defense Department's most recent figures, live anthrax was shipped to at least 192 commercial companies, academic institutions, and Federal labs. Since this anthrax was supposed to be "inactivated," the controls over who received the shipments weren't as stringent as they might have been if it was known the anthrax was live. This is not just a public health concern, it is also a very real national security concern.

Just last week the Defense Department issued a report detailing its review of the events surrounding the shipments of live anthrax. The report acknowledged a lack of specific, validated standards to guide the development of protocols, processes, and quality assurance measures. In fact, in most cases, the Defense Department observed that each of its laboratories followed its own procedures and protocols.

We are reminded today, this is not an isolated incident. The Government Accountability Office, the nonpartisan Government watchdog, highlights in written testimony that these "recent safety lapses have illustrated multiple breakdowns in compliance with established policies and inadequate oversight." The committee remains concerned that oversight is fragmented because no single entity is in charge of overseeing high-containment laboratories that handle select agents.

We need to find out why these events keep happening and what the Federal Government plans to do to stop this troubling pattern of safety lapses at our bioterrorism labs. These blunders need to stop now. We need to learn from the mistakes of the past and stop repeating them once and for all. Otherwise I am afraid we'll be right back here next summer discussing the latest security lapse.

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

July 24, 2015

TO: Members, Subcommittee on Oversight and Investigations

FROM: Committee Majority Staff

RE: Hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

On July 28, 2015, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled, "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

In late May 2015, the Department of Defense (DoD) acknowledged 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. These shipments revealed that Dugway's process for inactivating anthrax with radiation was not fully effective, and that sterility testing used to validate and ensure that the inactivation process was working had failed to detect the live anthrax spores. After learning about these problems, DoD determined that the scope of the live anthrax distribution was more widespread, and has occurred over nearly a ten-year period. The DoD internal review so far shows live anthrax has been shipped to 86 facilities spanning 7 foreign countries, 20 States, and the District of Columbia, with 21 personnel on post-exposure prophylaxis.

The Dugway shipments are the most recent instance of a series of high-profile incidents involving the mishandling of dangerous pathogens known as select agents.[1] This hearing builds on both the Committee's prior work on the Federal Select Agent Program (FSAP), and the U.S. Government Accountability Office's (GAO) work in response to Committee requests.[2] A year ago, the Committee held a hearing on a different anthrax incident, specifically an incident that occurred in June 2014 at the Centers for Disease Control and Prevention (CDC) laboratory where

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[1] Over the last year, the Committee has been examining the following incidents: (1) June 2014 CDC inadvertent transfer of live anthrax between CDC labs resulting in the potential exposure of 81 CDC staff and the closure of a bioterrorism rapid response lab; (2) Spring 2014 CDC inadvertent shipment of highly pathogenic H5N1 influenza to a USDA lab with a two-month lag time before CDC leadership had been made aware of the incident; (3) July 2014 FDA report of finding vials of smallpox and 327 other vials of dangerous biological agents that had never registered or accounted for but were allegedly housed in a storage room in an NIH building for more than 40 years without anybody knowing about it; and (4) December 2014 CDC inadvertent transfer of potentially live Ebola virus from a biosafety level 4 lab to a lower biosafety level 2 lab.

[2] *See, e.g.*, "Review of CDC Anthrax Lab Incident," Hearing before the Subcommittee on Oversight and Investigations, House Energy and Commerce Committee, Serial No. 113-160 (July 16, 2014); and "Germs, Viruses, and Secrets: the Silent Proliferation of Bio-Laboratories in the United States," 110th Congress (October 4, 2007).

as many as 84 CDC employees were exposed to live anthrax, because established safety practices were not followed. 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.[3] 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 Federal Drug Administration (FDA) lab on the National Institutes for Health (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.

Last year's hearing on the CDC anthrax incident and recent GAO reports emphasized three general themes: (1) no single entity in the Federal government is in charge of overseeing high-containment laboratories that handle select agents; (2) current oversight of high-containment laboratories is fragmented; and (3) CDC as a regulator of the FSAP presents a conflict of interest because CDC funds labs in the FSAP and has not effectively policed its own labs in handling select agents. GAO is currently undertaking reviews in response to bipartisan committee requests on Federal agency management of select agents[4] and scientific issues related to the inactivation of select agents.[5]

The purpose of this hearing is to address the following: (1) whether Dugway shipments of live anthrax and the overall performance record of labs handling select agents make a sufficient case that the FSAP needs to be substantially strengthened and reformed, and if so, (2) what changes and reforms to the FSAP will lead to substantial improvements in performance?

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[3] 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.

[4] Letter from The Honorable Fred Upton, Chairman, House Energy and Commerce Committee; The Honorable Henry Waxman, Ranking Member; The Honorable Tim Murphy, Chairman, Subcommittee on Oversight and Investigations; The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations; The Honorable Joseph R. Pitts, Chairman, Subcommittee on Health; and The Honorable Frank Pallone, Ranking Member, Subcommittee on Health to The Honorable Gene L. Dodaro, Comptroller General, Government Accountability Office (July 31, 2014).

[5] Letter from The Honorable Fred Upton, Chairman, House Energy and Commerce Committee; The Honorable Frank Pallone, Ranking Member; The Honorable Tim Murphy, Chairman, Subcommittee on Oversight and Investigations; and The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations to The Honorable Gene L. Dodaro, Comptroller General, Government Accountability Office (May 7, 2015).

I. WITNESSES

- Dr. D. Christian Hassell, Deputy Assistant Secretary of Defense for Chemical and Biological Defense, Department of Defense;
- Dr. Dan Sosin, Deputy Director for the Office of Public Health Preparedness and Response, Centers for Disease Control and Prevention;
- Gregory Demske, Counsel to the Inspector General, Office of Inspector General, U.S. Department of Health and Human Services; and,
- Dr. Marcia Crosse, Director, Healthcare, Government Accountability Office.

II. BACKGROUND

A. Federal Select Agent Program

Creation of the Federal Select Agent Program

The FSAP was established by the Antiterrorism and Effective Death Penalty Act of 1996, following the Oklahoma City bombing in 1995. This law required the Department of Health and Human Services (HHS) to identify a list of organisms and toxins (known as select agents) that could potentially be used for bioterrorist attacks and to regulate their transfer, though not their possession. The FSAP regulates 65 select agents and toxins. The select agent list is reviewed at least every 2 years to determine if agents need to be added to or deleted from the list.[6] 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.[7] The USA Patriot Act also made it a criminal offense for any individual to knowingly possess any biological agent, toxin, or delivery system in type or quantity not justified by a peaceful purpose.[8]

Congress later enacted the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which (1) expanded the select agent program to include not only the regulation of the transfer, but also the use and possession of select agents and (2) increased safeguards and security requirements.[9] The 2002 Act also establishes civil money penalties for persons violating the regulations and additional criminal penalties for knowingly possessing a

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[6] Federal Select Agent Program, About Us, http://www.selectagents.gov/about.html.
[7] USA Patriot Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001).
[8] *Id.*
[9] 42 U.S.C. § 262a.

select agent or toxin without registering it or knowingly transferring a select agent or toxin to an unregistered person.[10]

DSAT's and APHIS's Regulatory Role

The 2002 Act requires HHS to regulate select agents. Within HHS, this responsibility has been assigned to CDC, Division of Select Agents and Toxins (DSAT).[11] CDC regulates select agents that could pose a severe threat to public health and safety. The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) regulates select agents and toxins that could pose a severe threat to animal or plant health. CDC and APHIS establish select agent regulations and monitor and enforce compliance with Federal select agent regulations.[12]

DSAT regulates and inspects 284 labs and other entities for the possession, use, or transfer of biological select agents and toxins (BSAT), in accordance with HHS select agent regulations.[13] CDC laboratories that possess BSAT fall under this regulatory responsibility.[14] As of July 10, 2014, there are 324 entities registered with the FSAP for possession, use, or transfer of select agents.[15] There are 11,034 individuals with active approvals to access select agents at FSAP-registered entities.[16] There are 472 CDC staff with active security risk assessment approvals to access select agents.[17] About 15 percent of entities registered to work with select agents were subject to inspection overlap (multiple Federal agencies inspecting within a 2-year period).[18]

All inspections include review of biosafety practices, security, incident response, training, and records management. Since 2005, DSAT has conducted 9 inspections at the CDC Roybal campus that included the BSL-3 laboratories in Building 18. Four of these inspections were done jointly with APHIS. In September 2012, CDC reported that APHIS agreed to assume lead responsibility for inspections of CDC laboratories that are regulated under the FSAP.[19]

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[10] *Id.*
[11] For FY 2013, CDC DSAT spent $13,682,997.
[12] Federal Select Agent Program, About us, http://www.selectagents.gov/about.html.
[13] 42 C.F.R. part 73.
[14] CDC FY 2015 Congressional Justification, 310. CDC's website on the FSAP states there are 347 entities registered and inspected by the Federal Select Agent Program.
[15] E-mail from CDC staff to Committee staff, July 11, 2014. CDC's website, however, states there are 347 entities registered and inspected by the Federal Select Agent Program.
[16] *Id.*
[17] *Id.*
[18] GAO, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program," GAO-13-154 (January 2013) http://www.gao.gov/products/GAO-13-154.
[19] *Id.*

HHS OIG's Law Enforcement Role

Section 19 of the select agent regulations requires that incidents of theft, loss, or release of select agents and toxins be reported to either DSAT or APHIS select agent regulators. DSAT refers cases of significant regulatory non-compliance to HHS Office of Inspector General (OIG) for investigation and to assess whether the imposition of civil money penalties would be appropriate. To date, the DSAT has made 68 referrals to HHS OIG for potential FSAP enforcement actions. Out of those referrals, the OIG found violations in 30 of the 68 referrals. The OIG resolved 20 cases with civil monetary penalty settlements and issued 10 notice of violation letters. The OIG also closed 3 referrals for 1 Federal entity after the OIG's Office of Audit Services issued an audit report to the entity with audit findings that addressed the violations in the referral. For the 20 entities receiving civil monetary penalties, the OIG collected more than $2.4 million for violations of the 2002 Act. However, about 75 percent of the total amount was imposed on only 2 entities, with an average settlement amount for the other 18 entities of approximately $54,000.[20] HHS OIG has not imposed civil monetary penalties on any Federal government agency entity, even though Federal government agency entities are the leading offenders with multiple violations.

The FBI's Role

The Federal Bureau of Investigation (FBI) has several roles in the FSAP.[21] First, the FBI screens scientists who submit applications to participate in the program pursuant to the USA Patriot Act for reliability. The FBI conducts a database check against 11 restricted persons categories, but no interviews or other background investigations are involved. The entity in the Federal select agent program would be responsible for the suitability assessment. The FBI estimates doing 30,000 reliability assessments with less than 300 denied.

Second, the FBI helps protect the FSAP by raising security awareness in the research community, and helping coordinate security in the event of theft, loss, or release of a select agent. For example, the FBI helped secure and transport the smallpox vials discovered last year on the NIH campus. The FBI can also assist CDC, USDA, and the entity in accounting for select agents that may be stolen, lost, or released. The FBI has a Weapons of Mass Destruction (WMD) directorate with WMD coordinators in 56 field offices who serve as local resources as part of a response.

Third, the FBI serves as a criminal back-stop to the FSAP, conducting criminal investigations when necessary. In the event of a theft, loss, or release, the FBI conducts a Threat Credibility Evaluation—with the FBI labs, CDC, and possibly others—to determine whether there is any intent to use the select agent as a weapon, so inherently dangerous it has no legitimate research purpose, or if an entity is egregiously non-compliant (such as an entity decertified from the FSAP that refused to transfer or destroy its select agents[22]). While the FBI

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[20] Letter from Inspector General Daniel Levinson, Department of Health and and Human Services Office of Inspector General, to The Honorable Fred Upton, Chairman, Committee. on Energy & Commerce, et. al (July 20, 2015); E-mail from HHS OIG staff to Committee staff, July 21, 2015.
[21] Information in this section is derived from a bipartisan committee staff briefing from the FBI on July 20, 2015.
[22] This example is an illustration, and not an actual case.

has investigated and prosecuted crimes related to select agents, there have been only a handful of cases and only 1 has involved a legitimate researcher, who was prosecuted for misleading authorities about missing vials of bubonic plague in 2003.

B. Reaction to the May 2015 Anthrax Incident

In late May 2015, DoD acknowledged that Dugway, an Army facility in Utah, had inadvertently shipped live anthrax to a commercial laboratory in Maryland as well as to other contract labs. DoD has since determined that the scope of the live anthrax distribution was more widespread, and over nearly a ten-year period.

Department of Defense Review

On July 23, 2015, DoD publicly released the results of its review of its safety practices for generating and handling inactivated anthrax.[23] According to DoD's report, on May 22, 2015, a private company notified CDC that inactivated anthrax in its possession was live. CDC's ensuing investigation determined that the live anthrax originated at Dugway. Ultimately, DoD found live anthrax had been shipped to 86 facilities spanning 7 foreign countries, 20 States and the District of Columbia, with 21 personnel on post-exposure prophylaxis.[24]

DoD's review was unable to definitively determine the root cause for how and why Dugway shipped live anthrax. One of the stated reasons DoD was unable to identify a root cause is the "absence of specific scientific community standards" for inactivating anthrax and "continuing scientific uncertainty regarding the survival, injury, and repair of spores exposed to gamma radiation."[25] That said, DoD found that deficiencies in sample sizes and inadequate validation procedures after irradiation may have contributed to undetected live anthrax. Further, although its labs had safety protocols and procedures, DoD found that these procedures were not standardized.[26]

DoD's review made a series of recommended corrective actions. Broadly, DoD recommends enhancing quality assurance, implementing a more extensive scientific peer review process, and improving program management for inactivating and conducting viability testing of anthrax.[27] More specific recommendations include standardizing anthrax inactivation protocols across DoD laboratories, establish and manage an environmental surface sampling program, conduct audits and inspections of DoD laboratories utilizing select agents, revise the death certificate process, and prioritize research and development for those pathogens where

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[23] Committee for Comprehensive Review of DoD Laboratory Procedures, Processes, and Protocols Associated with Inactivating Bacillus anthracis Spores, "Inadvertent Shipment of Live *Bacillus anthracis* Spores by DoD" (July 13, 2015).
[24] *Id.*
[25] *Id.* at 4.
[26] *Id.*
[27] *Id.* at 18.

information is lacking.[28] Regarding the last recommendation, DoD noted that all the laboratories failed to recognize the importance of knowledge gaps.[29]

FSAP Entity Inspection Report

From May 26 to May 28, 2015, following the discovery that live anthrax was shipped, CDC inspectors from DSAT conducted an inspection and issued a report.[30] In its report, the DSAT inspectors observed that the Standard Operating Procedures (SOP) for the irradiation of anthrax spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator, which resulted in inactivation failures. As a result, the DSAT inspectors recommended that Dugway provide an updated SOP where all steps in the preparation of the spore suspensions have been verified to not inhibit their inactivation. The DSAT inspectors also observed that the method used for inactivation, Cobalt 60 gamma irradiation, was not validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation before creating spore suspensions that would be released from the facility. The report recommended that Dugway provide documentation validating the method of inactivation to ensure that each preparation does not contain viable spores or cells after irradiation. Ultimately, as a result of live anthrax being shipped across the world, the report ordered Dugway to suspend any shipment "inactivated" anthrax preparations, and that they are to be considered select agents until proven otherwise.[31]

USA TODAY Investigation

Shortly after DoD acknowledged that one of its facilities shipped live anthrax to contract labs, USA TODAY released its findings after its extensive investigation of America's biolabs. Its investigation uncovered hundreds of life threatening accidents and revealed many labs' repeated failures to correct past observation, biosafety, and security concerns.[32] Such disregard for safety protocol poses a major public health problem. For example, a 25-year-old researcher died due to a San Francisco VA Medical Center lab's failure to "adequately supervise and protect workers in the research lab" and train workers about warning signs of infection.[33] Since 2012, at least 50 incidents of failures to fulfill safety protocol have occurred.[34] One lab with a history of non-compliance was cited for 9 of the same violations on 4 consecutive inspections over the span of 1 year.[35] Another lab received a letter from CDC in February of 2014, alerting that it "has failed to address safety issues over the course of the last four years."[36] Despite these repeated transgressions, CDC inspectors have allowed some of these labs to continue their

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[28] *Id.* at 18-22.
[29] *Id.* at 22.
[30] DSAT and APHIS Entity Inspection Report: Life Science Test Facility (June 5, 2015).
[31] *Id.*
[32] Alison Young and Nick Penzenstadler, *Inside America's Secretive Biolabs,* USA TODAY, May 28, 2015, http://www.usatoday.com/story/news/2015/05/28/biolabs-pathogens-location-incidents/26587505/.
[33] *Id.*
[34] *Id.*
[35] Alison Young, *CDC to Review Oversight of Bioterror Labs after* USA TODAY *Investigation*, USA TODAY, July 21, 2015, http://www.usatoday.com/story/news/2015/07/21/cdc-review-oversight-bioterror-labs-after-usa-today-investigation/30458589/.
[36] *Id.*

work.[37] USA TODAY also reported that CDC is launching a comprehensive review of how it regulates its bioterror labs.[38]

C. The Federal Select Agent Program's Performance

The DoD shipments may reflect broader concerns with Federal laboratories, especially because safety incidents at high-containment labs have not been isolated events. As DoD acknowledged in its review of the live anthrax shipments, laboratory biosafety protocols and procedures are not standardized amongst DoD laboratories due to the fact that laboratories are managed under multiple chains of command.[39] Further, there is a lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures.[40] These key findings, along with ongoing work by government watchdogs, indicate that these laboratories need better oversight and national standards and protocols.

GAO Reports

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.[41] The expansion began in response to the need to develop medical countermeasures and better risk evaluations after the anthrax attacks in 2001.[42] And since no single agency is in charge of the expansion, no Federal agency can determine the associated risk posed by the expansion.[43] In fact, aspects of the FSAP—particularly those provided by HHS and the USDA—depend on entities' monitoring themselves and reporting incidents to the regulators. For example, with respect to a certification that a select agent had been rendered sterile (that is, noninfectious), DSAT officials told GAO, that "the burden of validating non-viability and non-functionality remains on the individual or entity possessing the select agent, toxin, or regulated nucleic acid."[44] DSAT does not approve each entity's scientific procedure. Instead, DSAT strongly recommends that "an entity maintain information on file in support of the method used for rendering a select agent non-viable . . . so that the entity is able to demonstrate that the agent . . . is no longer subject to the select agent regulations."[45] For these reasons, 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.[46]

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[37] *Id.*
[38] *Id.*
[39] Action Memo for Deputy Secretary of Defense following the Report of the Comprehensive Review of Department of Defense Laboratory Procedures, Processes, and Protocols Associated with Inactivating *Bacillus anthracis* (Anthrax) spores (July 22, 2015).
[40] *Id.*
[41] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.
[42] *Id.*
[43] *Id.*
[44] Testimony of Nancy Kingsbury, Managing Director, Applied Research and Methods, GAO, Hearing before the House Energy and Commerce Subcommittee on Oversight and Investigations, "Review of CDC Anthrax Lab Incident," Serial No. 113-160, 39-40 (July 16, 2014).
[45] *Id.*
[46] *Id.*

2011 HHS OIG Report

In 2011, the HHS OIG issued a report after a nationwide review of Federal laboratories' compliance with select agent regulations.[47] The review included labs at CDC, NIH, and FDA. The OIG found some of the labs had weaknesses that allowed access to select agents by unapproved individuals. These same labs did not maintain accurate inventory and/or access records as required. For example, during a reorganization of laboratory space at CDC, a scientist found two select agent vials stored in a drawer in a laboratory area that was not listed on the lab's certificate of registration and was not secured as select agents. The OIG found that most laboratories reviewed did not ensure that approved individuals received select agent training. One CDC lab did not provide biosafety and security training to 88 of its 168 approved individuals before granting them access to select agent areas. Plans for two labs reviewed did not meet one or more regulatory requirements for developing and implementing security plans. The incident response plan for two labs did not function as intended. At one FDA lab, emergency announcements could not be heard over the public address system in select agent laboratory and storage areas.

Finally, the OIG found that DSAT did not effectively monitor and enforce certain Federal select agent regulations at the laboratories. Specifically, DSAT inspections did not always identify noncompliance with Federal select agent regulations, and DSAT personnel entered incorrect select agent registration information into its national registry database for one laboratory. According to the OIG, these weaknesses may have contributed to the labs not being in full compliance, "which may have put public health and safety at increased risk."[48]

The OIG has also found that 11 of 15 representative universities investigated did not fully comply with the select agent regulations. The OIG determined that none of the 8 representative State, local, private, or commercial laboratories investigated were in full compliance.[49]

D. <u>CDC Lab Research</u>

High containment laboratories, which conduct research on bioweapon agents, have proliferated since the 2001 anthrax attacks in which spores mailed to news media offices and 2 U.S. senators killed 5 people and infected 17 others.[50] 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.[51] GAO had

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[47] HHS OIG, "Nationwide Review of Federal Laboratories' Compliance with Select Agency Regulations" (July 2011), *redacted version available at* http://docs.house.gov/meetings/IF/IF02/20140716/102479/HHRG-113-IF02-20140716-SD014.pdf.
[48] *Id.*
[49] *Id.*
[50] 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.
[51] 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.

recommended in 2009[52] that the National Security Advisor make a single Federal agency responsible for assessing lab standards, but in its 2013 report, GAO noted that the National Security Staff and the Office of Science and Technology Policy (OSTP) rejected the recommendation as "unnecessarily broad and cumbersome."[53]

CDC and NIH have established 4 main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.[54] 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.

CDC works to protect Americans from rare but deadly pathogens like Hantavirus pulmonary syndrome, Ebola and Marburg viral hemorrhagic fevers, rabies, monkeypox, smallpox, and anthrax.[55] Because the pathogens that cause these diseases are so deadly, with many of them considered bioterrorism threats that are regulated as Tier 1 select agents, CDC maintains biosafety level BSL-3 and BSL-4 laboratories. These labs support epidemiologic investigations, research, and prevention efforts to reduce the public health threat of these hazardous and infectious high-consequence pathogens. According to an April 2014 U.S. government report to the United Nations, CDC reported spending a total of more than $30 million in 2013 on select agent research.[56]

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[52] GAO, "High-Containment Laboratories: National Strategy for Oversight Is Needed," GAO-09-1036T (September 21, 2009) http://gao.gov/assets/130/123358.pdf.

[53] 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.

[54] 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/

[55] CDC FY 2015 Congressional Justification 101.

[56] *See* United States of America, Confidence Building Measure Return covering 2013, Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Submitted to the United Nations on April 15, 2014, at 79-90 http://www.unog.ch/80256EDD006B8954/(httpAssets)/7B8EB5C27800D7A9C1257CC3005010BE/$file/BWC_CBM_2014_UnitedStates_PUBLIC.pdf.

E. Safety Stand-Down

On August 18, 2014, in response to biosafety lapses that occurred in 2014 – including the smallpox incident where FDA lab employees discovered decades-old vials of smallpox in its lab on NIH's campus – the White House announced a Safety Stand-Down for Federal laboratories. In a memorandum, Lisa Monaco, Assistant to the President for Homeland Security and Counterterrorism, and John Holdren, Assistant to the President for Science and Technology, urged all Federal departments and agencies that worked with infectious agents to take immediate and long-term steps to enhance safety and security of research to minimize the potential for future incidents. All Federal agencies that possessed, used, or transferred select agents were urged to perform a Safety Stand-Down, including an immediate sweep of their facilities to verify that all select agents in their possession were appropriately registered, stored, and disposed of in accordance with applicable regulations.

During the Safety Stand-Down, Federal agencies conducted sweeps at over 4,000 facilities across the United States and in U.S. facilities abroad, which included examining inventory and documentation for over 40 million samples. As a result of this review, the White House reported on December 16, 2014, that there were 27 instances in which select agents were not properly registered with the FSAP. Agencies reported the adjudication and final disposition for the materials, and there were no indications of human exposure to the select agents.

The U.S. Government is conducting parallel Federal and non-Federal reviews that will result in specific recommendations to strengthen the government's biosafety and biosecurity practices and oversight system for Federally funded activities. Through the Federal Experts Security Advisory Panel (FESAP), a coordinated Federal review is being conducted to: (1) identify needs and gaps and make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for select agents; (2) identify actions and any regulatory changes necessary to improve biosafety and biosecurity; and (3) identify an approach to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer select agents. In addition, the National Science and Technology Council has stablished an interagency Fast Track Action Committee to conduct a comprehensive review of the impact that the select agent regulations have had on science, technology, and national security.

III. ISSUES

The following issues may be examined at the hearing:

- How can oversight of select agents be improved?
- Were the safety breaches an isolated incident, or part of a pattern at DoD labs?
- What lessons can be derived from the investigations of this incident?
- Are there broader implications from this incident beyond DoD about the oversight of select agents and of all high-containment labs throughout the U.S.?

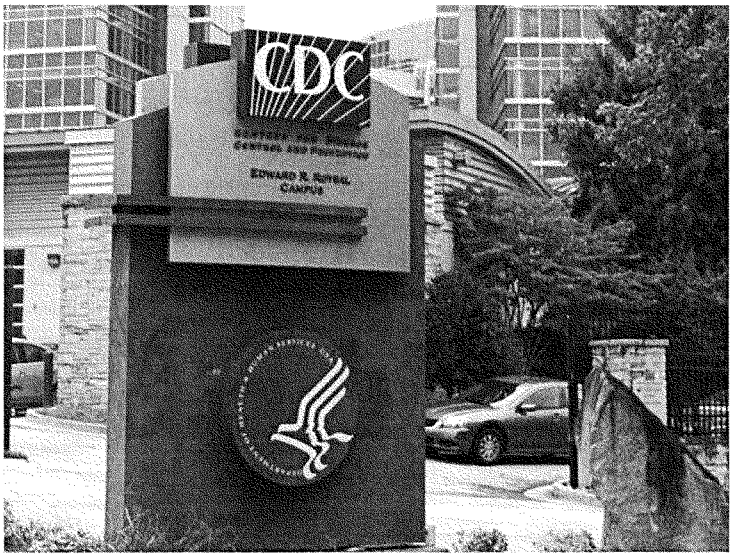
- Is Congressional action necessary? If so, what actions?
- What are the most effective ways to improve biosafety?

IV. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Alan Slobodin, Jessica Donlon, or Brittany Havens of the Committee staff at (202) 225-2927.

CDC lacked key lab incident reporting policy despite scrutiny, promises

Alison Young, USA TODAY 10:58 p.m. EDT July 27, 2015



(Photo: Jessica McGowan, Getty Images)

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Despite several serious, high-profile lab accidents and promises to Congress of reforms, the Centers for Disease Control and Prevention didn't issue a policy until last week to ensure the agency's top lab safety official received reports of mishaps, documents obtained by USA TODAY show.

The revelation is contrary to what the CDC told USA TODAY for a July 9 article about recent lab accidents at the agency and whether CDC staff are failing to report "near miss" incidents. The CDC, in a written statement for that article, had said it already had a policy in place for centralized reporting — a critical component for identifying safety trends.

But that was not true, according to a copy of the policy — dated in 2013 — that USA TODAY obtained under the federal Freedom of Information Act (FOIA) late last week.

The CDC did not issue to its staff a new version of its policy, which requires reports be sent to the top lab safety office, until July 20, according to records the CDC provided to USA TODAY on Monday. The agency said it made a mistake in the information it previously provided to the newspaper on July 8. The agency said its updated incident reporting policy was under development at the time USA TODAY asked its questions but wasn't finalized.

"There's what's being said, and what's being done," said Sean Kaufman, a biosafety consultant and former CDC employee, who testified before Congress last summer about the agency's lab safety issues.

"A fear of the congressional staff was that CDC was just going to say they were going to do things to put the fire out and not really do things. And that appears to really be what's happening," Kaufman said Monday.

While Congress last summer focused on failures at labs operated by the CDC, an investigations subcommittee of the House Energy and Commerce Committee will hold a hearing at 10 a.m. Tuesday to examine the adequacy of the oversight CDC lab inspectors provide to hundreds of other research facilities working with potential bioterror pathogens. The hearing will focus on lax testing and biosafety practices that resulted in an Army biodefense facility mistakenly shipping live anthrax specimens that. as of Monday. had been located in 192 labs in the USA and seven foreign countries.

Citing an ongoing USA TODAY investigation of lab safety nationwide, the subcommittee has said it plans to explore larger questions about whether regulation of labs working with "select agent" pathogens needs to be strengthened. "Select agent" is the federal government's term for 65 viruses, bacteria and toxins that have the potential to be used as bioweapons or that pose severe threats to public health or agriculture. They include anthrax, Ebola and the pathogens that cause smallpox, plague, botulism and other serious diseases.

Oversight and Investigations Subcommittee Chairman Tim Murphy, R-Pa., said Tuesday's hearing "is an important opportunity for Congress to hold the agencies' feet to the fire" and demand a more careful system.

"When it comes to handling select agents, there is no room for error; however, repeated lapses from federal agencies have raised serious concerns, both from the committee and the press," Murphy said Monday. "This newspaper in particular has brought to light a number of serious concerns about the lack of a consistent and thorough protocol among agencies."

Since January, the CDC has refused to release toUSA TODAYcopies of all its lab incident reports for facilities in Atlanta and Fort Collins, Colo., during 2013 and 2014. The agency, in response to the newspaper's FOIA request, has said it will take until sometime in 2018 to compile and release the records — even though it has granted the request "expedited" processing status in recognition of a compelling need for the public to have access to the information. USA TODAY has appealed the delays as excessive.

USA TODAY filed its FOIA request for a copy of the CDC's lab incident reporting policy on July 13 because earlier in the month the agency had refused to voluntarily provide a copy of the policy or even say when it was enacted. Before saying it had a policy that sent all lab incidents to a newly created top lab safety office, the CDC had given a series of changing answers about whether any single office at the agency collects and reviews lab incidents to spot emerging safety issues.

Ultimately the policy document, referenced by its formal name in the agency's July 8 statement to USA TODAY, turned out to be from 2013 and did not require routing of incident reports to the top lab safety office — which was created last year amid congressional scrutiny. Only as the CDC FOIA Office prepared to send a copy of the existing 2013 policy to the newspaper last week did the agency's top lab officials send out a revised policy on July 20.

The latest documents obtained byUSA TODAY also show that the CDC's acting top lab safety official emphasized in a memo last week the importance of reporting all incidents as well as "near misses" that occur in labs. The memo follows USA TODAY's reporting earlier in the month that raised questions about whether CDC staff are reporting all potential lab mishaps, or only a narrow subset of the most serious potential exposures to pathogens.

"CDC requires reporting of all incidents; however, the best safety programs also track 'near misses' to fix potential problems before someone gets hurt," wrote Stephan Monroe, the CDC's acting associate director for laboratory science and safety, in the July 20 memo. "We encourage you to evaluate whether otherwise minor incidents meet the definition of a near miss, and if so, to report them."

The CDC declined to make Monroe available for an interview. Under the policy documents issued last week, incident reports now eventually go to Monroe's office. This top lab safety office was created a year ago by CDC Director Tom Frieden to be the agency's single point of accountability on lab safety issues in the wake of serious CDC lab incidents with anthrax, Ebola and a deadly strain of bird flu that called into question the agency's safety culture and prompted the congressional hearing last summer.

Yet a permanent director for the office still hasn't been hired. Monroe is the office's third interim lab safety director; he has held the position since May.

The CDC's evolving lab incident reporting policy and failure to find a full-time lab safety director raised questions among some biosafety experts about whether the agency had taken meaningful action to address its safety problems.

"They keep making the same mistakes. It's incredible," said Richard Ebright, a biosafety expert from Rutgers university in New Jersey, who also testified at last summer's hearing on the CDC's lab safety issues. "They set up this office so they could say they were doing something."

Ebright said the CDC's July 20 lab incident reporting policy and a diagram for who decides what should be reported is overly complicated, provides too many layers of bureaucratic review and appears to be designed to avoid — rather than encourage — documentation and independent review of incidents that could prevent future mishaps.

"This is intentionally designed to ensure that nothing or almost nothing reaches the office," Ebright said after reviewing the documents released to USA TODAY. He said all potential incidents should be reported directly to the top lab safety office so a consistent review standard is applied.

"The root cause of all of this is a lack of accountability: Incidents don't get reported and consequences don't occur," Ebright said.

Read full coverage of USA TODAY's ongoing investigation of lab safety issues at:biolabs.usatoday.com

Follow USA TODAY investigative reporter Alison Young on Twitter: @alisonannyoung

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

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Minority (202) 225-3641

September 1, 2015

Dr. Chris Hassell
DASD for Chemical and Biological Defense
3050 Defense Pentagon
Room 5B1064
Washington, D.C. 20301

Dear Dr. Hassell:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, to testify at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on September 15, 2015. Your responses should be mailed to Jessica Wilkerson, Oversight Associate, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to jessica.wilkerson@mail.house.gov.

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

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachments

CHARRTS No.: HECCOI-01-001
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman Brooks
Witness: Dr. Hassell
Question: #1

Worker Safety at Labs

Question: Are the workers at the labs that ship and receive the anthrax samples, those that verify the death certificates, provided with the anthrax vaccine ahead of time?

Answer: Yes, the anthrax vaccine is made available to all workers that work with anthrax.

CHARRTS No.: HECCOI-01-002
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman Brooks
Witness: Dr. Hassell
Question: #2

Worker Safety at Labs

Question: If workers are not provided the vaccine, why and when is there one readily available for use and distribution?

Answer: The anthrax vaccine is made available to all workers that work with anthrax.

CHARRTS No.: HECCOI-01-003
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman Brooks
Witness: Dr. Hassell
Question: #3

Worker Safety at Labs

Question: What measures do these labs have in place for immediate response should a worker be exposed to live anthrax?

Answer: All laboratories that conduct research with Biological Select Agents and Toxins (BSAT) are required to maintain a site-specific Incident Response Plan and Occupational Health Plan to remain compliant with the Select Agent Regulations. The specific immediate response measures are addressed within the plans at each laboratory and include requirements for medical evaluation, treatment (if appropriate) and post-exposure management.

CHARRTS No.: HECCOI-01-004
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman Brooks
Witness: Dr. Hassell
Question: #4

Worker Safety at Labs

Question: Do you consider these measures adequate?

Answer: Yes. The laboratory Incident Response Plans and Occupational Health Plans are adequate and compliant with the Select Agent Regulations and with DoD policy.

CHARRTS No.: HECCOI-01-005
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman DeGette
Witness: Dr. Hassell
Question: #5

Culture of Safety

Question: Please describe to the Committee steps that DoD may take to increase the culture of safety at the labs that are part of the Federal Select Agent Program.

Answer: The DoD review team established immediately after the May 2015 incident identified several overarching recommendations: enhance quality assurance, establish a peer-review process, and improve program management. Each of these has specific recommendations within them that will be studied and implemented. The Deputy Secretary of Defense issued a memorandum on September 2, 2015, that designated the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program. In this role, the Secretary of the Army is responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT. The Army has established a working group that is identifying and comparing best practices in DoD, industry, and academia for enhancements to the DoD program. In addition, all DoD facilities that inactivate anthrax spores are under a moratorium for inactivation and shipping of inactivated anthrax until consistent and robust standards can be put in place.

CHARRTS No.: HECCOI-01-006
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman DeGette
Witness: Dr. Hassell
Question: #6

Dugway Proving Ground

Question: Please provide additional detail as to why DoD believes that the problems discussed in this hearing took place in one specific lab, Dugway Proving Ground.

Answer: The Comprehensive Review Report, finalized on July 13, 2015, substantiated that DoD sent live anthrax to multiple labs that were expecting to receive inactivated anthrax. The Centers for Disease Control and Prevention (CDC) found that DPG failed to adequately inactivate anthrax spores and failed to validate that the inactivation was successful before creating samples that would be released from the facility. The Review Committee's key finding was a lack of specific validated standards to guide the development of protocols, processes, and quality assurance measures for the irradiation and viability testing of inactivated anthrax spores. It was confirmed through testing at other DoD laboratories that the only batches of inactivated anthrax which contained live anthrax came from DPG.

CHARRTS No.: HECCOI-01-007
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congressman Tonko
Witness: Dr. Hassell
Question: #7

Uniformed and Civilians at Dugway Proving Ground

Question: What percentage of uniformed versus civilian employees at Dugway Proving Ground?

Answer: The uniformed personnel assigned to Dugway are less than one percent of the overall workforce.

CHARRTS No.: HECCOI-01-008
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congressman Tonko
Witness: Dr. Hassell
Question: #8

Civilian Employees at Dugway Proving Ground

Question: What percentage of civilian employees at Dugway Proving Ground are unionized?

Answer: Eighty percent of the DoD civilian employees working at Dugway Proving Ground are represented by bargaining units.

CHARRTS No.: HECCOI-01-009
Hearing Date: July 28, 2015
Committee: HECCOI
Member: Congresswoman Brooks
Witness: Dr. Hassell
Question: #9

Death Certificates

Question: Please provide a detailed explanation of how the process for death certificates work, including what information is required to be included in the certificate.

Answer: There is currently no DoD standardized process for creating death certificates after inactivation of biological material or standardized format for the information. The DPG death certificates currently list the name of the organism, place and date of sterilization, total dosage used to irradiate, procedure used to confirm inactivation, references, and the date of confirmation. The Deputy Secretary of Defense issued a memorandum on September 2, 2015, that designated the Secretary of the Army as the DoD Executive Agent for the DoD Biological Select Agent and Toxin (BSAT) Biosafety Program. In this role, the Secretary of the Army is responsible for the technical review, inspection, and harmonization of biosafety protocols and procedures across DoD laboratories that handle BSAT. The Army has established a working group that is identifying and comparing best practices in DoD, industry, and academia for enhancements to the DoD program, including use and format of death certificates.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Majority (202) 225-2927
Minority (202) 225-3641

September 1, 2015

Dr. Dan Sosin
Deputy Director
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Sosin:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, to testify at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

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

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachments

Centers for Disease Control and Prevention's
Responses to Questions for the Record from July 28, 2015 hearing,
"Continuing Concerns with the Federal Select Agent
Program: Department of Defense Shipments of Live Anthrax"
Energy and Commerce Subcommittee on Oversight and Investigations

The Honorable Frank Pallone, Jr.

1. **DoD completed a review of the inadvertent anthrax shipments and found that procedures to irradiate and kill anthrax spores may be ineffective. The review determined that there is a lack of standardized procedures across DoD labs, and there may be insufficient scientific information on how best to irradiate anthrax.**

    a. **What is CDC doing to ensure that inactivation procedures across the Federal Select Agent Program are effective?**

Response: Action by Laboratory Scientists at Centers for Disease Control and Prevention. Scientists from the Centers for Disease Control and Prevention (CDC) are participating in interagency scientific discussions with the Department of Defense (DOD) and other agencies to identify needed research that could identify the reasons for the failure of spore inactivation and sterility testing. These discussions are to guide research intended to inform the development of safer and more effective procedures that may allow the exclusion of inactivated *B. anthracis* spores from the select agent regulations.

Action by CDC under Federal Select Agent Program. The Federal Select Agent Program (FSAP) is a collaboration between CDC's Division of Select Agents and Toxins (DSAT) and the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS), Agriculture Select Agent Services (AgSAS). On June 2, 2015, he FSAP obtained a moratorium on the use and transfer of inactivated *B. anthracis* to prevent inadvertent exposure until safer and more effective procedures regarding inactivated *B. anthracis* can be developed based on the interagency scientific discussion and research into the matter. FSAP also developed a policy regarding the "Inactivation of *Bacillus anthracis*." The policy states that all regulated vegetative cell and spore preparations of Bacillus anthracis strains will continue to be regulated as select agents even after inactivation. And HHS and USDA plan to publish Notices of Proposed Rulemaking (NPRM) in the Federal Register in 2016 requesting public comment on proposed biosafety requirements, including specific provisions for the inactivation of select agents. Until the reasons for failure of inactivation and sterility testing can be determined, and consistently safe and effective procedures established, select agent strains of *B. anthracis* that have been through inactivation procedures will remain select agents as stated in the FSAP policy.

    b. **Is the agency considering additional rule making or other guidance to ensure that labs are using scientifically validated methods of inactivating dangerous pathogens and toxins?**

Response: Yes. In 2016 HHS and USDA plan to publish NPRMs in the Federal Register to request public comment on proposed biosafety requirements, including specific provisions for the inactivation of select agents.

2. **In the past year, the Centers for Disease Control and Prevention (CDC) reported a number of incidents in its high-containment laboratories.**

    a. **What steps has the CDC taken in the past year to address the incidents involving CDC's laboratories and prevent them from recurring?**

Response: In 2014, there were incidents at CDC labs involving research samples of anthrax, influenza A (H5N1), and Ebola virus. Comprehensive internal and external reviews were conducted of each incident, and CDC created both internal and external workgroups to more broadly review the Agency's laboratory safety procedures and protocols, which resulted in recommendations for improving safety.

In addition to addressing these specific recommendations, CDC has taken broad steps to enhance laboratory performance and safety across the agency. Highlights of improvements made at CDC in the past year to address the incidents involving CDC's laboratories include:

- Establishing an external Laboratory Safety Workgroup comprised of leading experts in the fields of biosafety, laboratory science, and research to provide input into laboratory safety improvements.
- Establishing a new leadership position that reports to the CDC Director to provide agency-wide leadership and accountability for laboratory science, safety, and quality
- Establishing a Laboratory Safety Review Board to review and approve all existing and new protocols for the inactivation and/or transfer of biological materials from BSL-3 and BSL-4 laboratories to lower levels of containment.
- Expanding biosafety training at CDC, including a complete review of the current biosafety training to prioritize training objectives and identify any existing or new training courses to support the development of a standardized, competency-based training curriculum at CDC.
- Establishing a new Biological Risk Assessment Course to train staff to identify and mitigate risks associated with laboratory procedures involving work with biological agents.
- Initiating a pilot project to expand external accreditation for CDC laboratories to realize the full implementation of strong quality management systems across CDC
- Conducting a search of approximately 1,000 rooms of lab-related space to ensure proper storage of select agents.
- Completing a self-initiated, box-by-box and vial-by-vial inventory of more than seven million samples in long-term storage for the infectious disease laboratories.
- Providing information for the public about laboratory safety at CDC on our website.[1]

3. **The July 28, 2015, hearing focused both on the Department of Defense's (DoD) inadvertent shipments of live anthrax from Dugway Proving Ground over a period of more than 10 years and incidents at CDC's laboratories in the past year or so.**

    a. **Are these two situations related, and if so, how?**

[1] www.cdc.gov/lab-safety

Response: Both incidents involved inadvertent potential exposures to live *B. anthracis* that had undergone inactivation procedures. However, the causes of the potential exposures were different. The CDC incident resulted from the use of an experimental inactivation protocol directed by an individual scientist. The DoD incident involved an error in institutional oversight and the routine use of a procedure that was inadequate to ensure effective inactivation.

4. In July 2015, CDC Director Tom Frieden announced a comprehensive review of how the CDC regulates laboratory safety and security, nationwide. Dr. Frieden noted that the report will be managed by the director of the Office of Public Health Preparedness and Response.

a. What motivated CDC to conduct this comprehensive review?

Response: Although much work has been done to enhance the effectiveness of CDC's regulatory oversight of laboratories that handle select agents and toxins, more work remains. This internal review of CDC's Division of Select Agents and Toxins in its role as part of the FSAP announced by Dr. Frieden in July is part of CDC's ongoing work to improve safety at laboratories that handle some of the most dangerous pathogens. The time was right, with new leadership in our Office of Public Health Preparedness and Response, for a thorough review of our program to ensure it is meeting its mandate and objectives, especially in light of recent incidents involving select agents.

b. How is this new review different from last year's examination of CDC lab safety?

Response: The new review focuses on the role of CDC's Division of Select Agents and Toxins as a regulator of facilities throughout the United States that possess, use, or transfer select agents and toxins. By contrast, the various internal and external reviews conducted last year focused on safety practices within CDC laboratories, and focused both on select agent and non-select agent laboratories.

c. Will there be overlap between the two reports?

Response: Although, broadly speaking, the various reviews have a common aim—to promote safety at laboratories that handle dangerous materials—each has a distinct focus. The review of CDC's regulatory program is focused on CDC's Division of Select Agents and Toxins, and its role in administering the Federal Select Agent Program. The various internal and external reviews conducted last year focused on safety practices within CDC laboratories.

**CDC Responses to Member Requests for the Record (Attachment 2)
from July 28, 2015 hearing,
"Continuing Concerns with the Federal Select Agent
Program: Department of Defense Shipments of Live Anthrax"**

The Honorable Tim Murphy

Please provide the policy memo referenced in the USA Today article regarding CDC's requirement that reports be sent to the top lab safety office.

Response: The attached guidance was shared widely with CDC laboratory staff and leadership in 2013, prior to the establishment of a CDC-wide office of laboratory science and safety. When Dr. Steve Monroe was named as Acting Associate Director for Laboratory Science and Safety in May 2015, he began receiving notifications of incidents relevant to lab safety. Updated guidance (attached) was distributed to staff in July 2015 and revised in November 2015 reflecting this and other enhancements to the notification procedures.

The Honorable Diana DeGette

1. **Please describe to the Committee steps that CDC may take to increase the culture of safety at the labs that are a part of the Federal Select Agent Program.**

Response: As noted in response to Representative Pallone's question #2, CDC has taken a number of significant steps to increase the culture of safety at laboratories across CDC (including those that are regulated under FSAP), including institutional changes that reflect the commitment going forward to sustain and build on these improvements. Highlights include:

- Establishing a new leadership position that reports to the CDC Director to provide agency-wide leadership and accountability for laboratory science, safety, and quality.
- Establishing a Laboratory Safety Review Board to review and approve all existing and new protocols for the inactivation and/or transfer of biological materials from BSL-3 and BSL-4 laboratories to lower levels of containment.
- Expanding biosafety training at CDC, including establishing a new Biological Risk Assessment Course to train staff to identify and mitigate risks associated with laboratory procedures involving work with biological agents.
- Establishing an external Laboratory Safety Workgroup comprised of leading experts in the fields of biosafety, laboratory science, and research to provide input into laboratory safety improvements.

In addition, as noted at the hearing, CDC is conducting an internal review of the Division of Select Agents and Toxins, which includes consideration of safety at laboratories under the FSAP. When finalized, CDC will provide the report to the Committee.

2. **Please provide additional detail as to why the CDC believes that the problems discussed in this hearing took place at one specific lab, the Dugway Proving Ground.**

Response: Based on its on-site investigation under the FSAP, inspectors from CDC's Division of Select Agents and Toxins determined that Dugway's Standard Operating Procedures for the

irradiation of *B. anthracis* spore suspensions did not account for the variable amounts of spores treated in the gamma cell irradiator. Inspectors from that Division also determined that the method used for inactivation of the *B. anthracis* spore suspensions, Cobalt 60 gamma irradiation, had not been validated using standardized control spore samples at varying concentrations, volumes, and levels of irradiation. In responding to this incident under the FSAP, the Division also contacted other institutions that perform similar inactivation procedures and had them test their stocks for viability using a standard protocol developed by CDC subject matter experts. Only materials inactivated at Dugway showed evidence of growth using this protocol.

The Honorable Michael C. Burgess

1. **Please provide to the Committee the materials that the CDC provided to the emergency rooms around the breach area.**

Response: As part of the response efforts, CDC provided materials to state and local health departments, who used their local-level expertise to determine how and to whom to disseminate the information. These materials were designed to help state and local health departments assist laboratories and healthcare providers in affected areas to monitor for symptoms and signs of anthrax illness in laboratory employees who either handled the samples or worked in the laboratories where these samples were handled. These materials were provided to assist with clinical monitoring in the very unlikely event that an exposed individual were to develop anthrax illness. CDC also provided a link to the latest clinical management guidelines for anthrax.[2]

The referenced materials, which are attached, included:

- Instructions for monitoring for anthrax symptoms;
- Form that laboratory staff can use to monitor their symptoms each day;
- Tool that healthcare providers can use to monitor workers' symptoms each week;
- Fact sheet about the symptoms of anthrax;
- Fact sheet about ciprofloxacin; and
- Fact sheet about doxycycline.

2. **What was the geographic radius used to determine which emergency rooms should receive those materials?**

Response: As noted above, decisions as to dissemination of information were made by state and local health departments. As part of the response effort, CDC provided the materials to state and local health departments.

[2] http://wwwnc.cdc.gov/eid/article/20/2/13-0687_article

The Honorable Paul Tonka

1. **How many times has a lab lost its registration?**

   Since 2003, there have been two registrations for possession, use, and transfer of select agents and toxins that have been revoked.

2. **Please provide details on the specific enforcement actions that the CDC has taken against labs that have violated the Federal Select Agent Program.**

Response: As part of the Federal Select Agent Program, CDC has taken the following administrative or enforcement actions:

- Administrative actions: Since 2003, there have been four denials of registration, seven suspensions of registrations and two revocations of registration.
- Referrals to the HHS Office of the Inspector General (HHS-OIG): Since 2003, there have been 79 referrals to HHS-OIG for alleged violations of the select agent regulations. In that time, HHS-OIG has levied over $2,414,000 in civil monetary penalties against 20 entities for violations of HHS select agent regulations.
- Referral to the Federal Bureau of Investigations (FBI): Since 2003, there have been 55 such referrals requesting further investigation. To date, no referral has resulted in a criminal prosecution.

The Honorable Susan Brooks

Please provide a detailed explanation of how the process for death certificates work, including what information is required to be included in the certificate.

Response: Since the FSAP applies only to select agents and toxins, it does not regulate substances that were but no longer are select agents or toxins. Accordingly, the FSAP regulations do not require a certificate of analysis or inactivation with transfer of an inactivated select agent.

However, in light of recent incidents that raise questions about the adequacy of inactivation in some circumstances, and in order to improve safety in our own laboratories, one of the steps CDC has taken internally in the last year is to institute a requirement for Material Transfer Certificates (MTC) (*i.e.,* death certificate) for the movement (within CDC as well as from CDC laboratories to external sites) of all materials from higher to lower levels of biosafety containment. MTCs are required to be completed prior to the movement of the materials and to contain: information on the unique sample identifiers; information on whether or not the material is live or inactivated; the inactivation protocol if material is inactivated; contact information for both the sender and recipient; and signatures from the laboratory scientist and their supervisor.

The Honorable Richard Hudson

Please provide additional detail on the practice of sending death certificates with inactivated materials. In particular, why was the death certificate sent with the "blind sample" test not provided until much later?

Response: We defer to DOD on this issue, which pertains to DOD practices related to transfers by DOD. As noted in response to the previous question, death certificates are not required under the FSAP regulations.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

Congress of the United States
House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
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Minority (202) 225–3641

September 1, 2015

Mr. Gregory Demske, Esq.
Chief Counsel
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Demske:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, to testify at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on September 15, 2015. Your responses should be mailed to Jessica Wilkerson, Oversight Associate, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to jessica.wilkerson@mail.house.gov.

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

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachments

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

September 15, 2015

The Honorable Tim Murphy
Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

I am writing in response to your September 1, 2015, letter regarding questions for the record from Representative Michael C. Burgess, Representative Susan Brooks, and Representative Richard Hudson. These questions relate to my testimony before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

If you have any questions, please contact me or your staff may contact Christopher Seagle, Director of External Affairs, at (202) 260-7006 or Christopher.Seagle@oig.hhs.gov.

Sincerely,

[redacted]

Gregory E. Demske
Chief Counsel to the Inspector General

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

Enclosures:
Responses to questions for the record from Representatives Burgess, Brooks and Hudson

Gregory E. Demske, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, responses to additional questions for the record (QFRs)[1] following the hearing on July 28, 2015, before the House Energy and Commerce Subcommittee on Oversight and Investigations entitled: "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Question from The Honorable Michael C. Burgess:

"The OIG reported to the committee that the U.S. Army Medical Research Institute of Infectious Disease (USAMRIID) had the third-most referrals from the CDC for potential FSAP enforcement, with three, and that Dugway also has three CDC referrals. According to that referral list, the CDC, the NIH, and USAMRIID had the most referrals in the FDAP.

a. **What does it say to you that these leading federal agencies in handling select agents had the most referrals?"**

Response: OIG has not made any determinations about overall Federal laboratory compliance with the FSAP regulation based on the total number of CDC referrals. A referral, or the total number of referrals, does not itself establish that a particular laboratory is not in compliance with the FSAP regulations. OIG evaluates each FSAP referral through the same case-by-case fact-specific approach, regardless of whether a laboratory is Federal or non-Federal. OIG has found that some Federal entities have violated the FSAP regulations on multiple occasions. OIG has heightened concerns with any entity, including a Federal laboratory, that has multiple FSAP violations.

b. **"Do you think that this reflects well on the OIG enforcement discretion policy of not imposing civil monetary penalties on federal government entities?"**

Response: Many factors may affect FSAP compliance by a Federal or non-Federal entity. OIG has not established a causal link between CDC referrals and OIG's practice to date of not imposing CMPs against Federal laboratories. OIG continues to believe there are significant policy arguments that weigh against penalizing Federal laboratories in violation of the FSAP regulations. Nevertheless, given the extent, severity, and repeated nature of FSAP violations by some Federal entities, OIG is reexamining how to best use its CMP authority to promote better compliance at such Federal laboratories.

[1] Pursuant to Attachment 1 - Additional Questions for the Record

Question from The Honorable Susan Brooks:

"This event shows us that we need to not only solve these problems from a managerial level, but be prepared to respond appropriately if these do fall into the wrong hands.

a. **Absent a strong commitment from the federal government to partner with the private sector on MCM development and procurement, do you believe the federal government is capable of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola?"**

Response: OIG has not evaluated: (i) Whether and how the Federal government should partner with the private sector on MCM development and procurement, or (ii) The Federal government's capability of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola. Therefore, OIG does not have information responsive to this inquiry.

Gregory E. Demske, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, responses to Member Requests for the Record[2] following the hearing on July 28, 2015, before the House Energy and Commerce Subcommittee on Oversight and Investigations entitled: "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Question from The Honorable Michael C. Burgess:

"Please explain what OIG is doing to consider providing the same civil monetary penalties to federal labs or agencies that non-federal labs would face if they committed the same violations."

Response: OIG is committed to promoting efficient and effective government and using its CMP authority to promote FSAP compliance. Although OIG continues to believe there are significant policy arguments that weigh against penalizing Federal entities, OIG is considering whether these arguments can be overcome in some circumstances. Given the extent, severity, and repeated nature of FSAP violations by some Federal entities, OIG is considering how to best use its CMP authority to promote better compliance at such Federal entities.

OIG evaluates each FSAP referral through the same case-by-case, fact-specific approach, regardless of whether a laboratory is Federal or non-Federal. OIG does not employ a formula or test to determine whether a case is pursued for potential CMPs, requires additional investigating, or is closed. The status of the entity does not impact OIG's determination of whether a FSAP violation occurred. Historically, OIG has addressed FSAP violations by Federal entities by issuing Notice of Violation letters to high-ranking officials with oversight responsibility for the entities. OIG has also issued Notice of Violation Letters to non-Federal entities, such as corporate and university laboratories.

While we believe OIG has the authority to impose a CMP on a Federal entity, we have not done so in prior cases on the basis of several considerations. Any money paid by a Federal entity would simply be moved from a Federal agency's budget to the General Fund of the Treasury. Although there would be no net receipt of money for the Federal Government, the Government would incur the cost of negotiating or disputing the CMP. CMP payments from Federal agencies may not promote better future compliance and, in fact, may reduce resources for the Federal entity's future compliance efforts.

Further, the enforcement and litigation process for Federal entities would differ from the process for non-Federal entities and may result in additional expenditure of Federal resources. OIG regularly imposes CMPs for many types of violations on non-Federal entities and individuals, whose administrative and judicial appeal rights are well established in regulation and practice.

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[2] Pursuant to Attachment 2 – Member Requests for the Record

If OIG imposes a CMP on a Federal agency, there is no clear process for resolving the matter, the process would differ for HHS and non-HHS Federal entities, and the matter may need to be submitted to the DOJ Office of Legal Counsel. These process issues do not preclude a CMP against a Federal entity, but they do add to the complexity, uncertainty of result, and commitment of resources that may be necessary to actually transfer money from the offending Federal agency to the General Fund of the Treasury.

While these considerations remain valid, OIG is evaluating how to apply the CMP to Federal entities going forward. We are particularly concerned with whether our past enforcement approach is sufficient for Federal entities that have engaged in repeated or severe FSAP violations. OIG is considering how to best promote FSAP compliance at such entities, including through means such as detailed reports to agency leadership, factual findings with respect to responsible individuals, and the imposition of CMPs. In short, OIG will consider imposing CMPs on Federal entities in pending and future cases.

Question from The Honorable Richard Hudson:

"Please provide a summary of the existing tools that CDC has that would allow it to better oversee and take corrective actions against labs that commit violations."

Response: CDC's Division of Select Agents and Toxins (DSAT) oversight includes: site inspections, denials, revocations, suspensions, and performance improvement plans. OIG has not performed an evaluation of CDC's oversight tools. However, OIG has recognized several areas that present opportunities to improve the Government's ability to administer FSAP and improve OIG's ability to enforce violations of the regulations. These opportunities were outlined in my written testimony and include:

- requiring laboratories to document inactivation procedures, validation and safety/sterility testing procedures, and outcomes to ensure that a select agent or toxin is rendered nonvirulent;
- requiring registered entities to video entry/exit points and video specific laboratory select agent and toxin work;
- requiring registered entities to maintain additional records, including all documents created or maintained in the ordinary course of working with a select agent and toxin;
- expressly prohibiting the destruction or alteration of any document that is required to be maintained under the regulations; and
- expanding the document retention period for registered entities from three to six years to match the CMP statute of limitation period.

In addition, Federal inspectors' ability to conduct effective and meaningful oversight should be strengthened by:

- requiring any registered entity to make available for interview upon reasonable request by inspectors any individual who has accessed, possessed, used, or transferred a select agent or toxin;
- allowing inspectors to physically inspect, handle, or test material that is believed to be a select agent or toxin, when appropriate (consideration should be given to DSAT's ability to immediately transfer material, in accordance with the regulations, so that independent testing can be performed to determine whether particular material is covered by the regulations); and
- considering the viability of independent third-party testing of select agent or toxin material.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS

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September 1, 2015

Dr. Marcia Crosse
Director
Healthcare
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548

Dear Dr. Crosse:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Tuesday, July 28, 2015, to testify at the hearing entitled "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests with a transmittal letter by the close of business on September 15, 2015. Your responses should be mailed to Jessica Wilkerson, Oversight Associate, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to jessica.wilkerson@mail.house.gov.

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

Sincerely,

Tim Murphy

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachments

GAO U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

September 15, 2015

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
House of Representatives

Subject: Laboratory Safety Issues – GAO Responses to Questions for the Record

This letter notifies you of our enclosed responses to questions for the record, following the July 28, 2015 hearing, "Continuing Concerns with the Federal Select Agent Program: Department of Defense Shipments of Live Anthrax." We are pleased to be able to provide you with the requested information. If you or your staff have any questions about our responses, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov, John Neumann at (202) 512-3841 or neumannj@gao.gov, or Timothy M. Persons at (202) 512-6412 or personst@gao.gov.

Marcia Crosse
Director, Health Care

John Neumann
Director, Natural Resources and Environment

Timothy M. Persons
Chief Scientist

Enclosure

The Honorable Susan Brooks

1. **This event shows us that we need to not only solve these problems from a managerial level, but be prepared to respond appropriately if these do fall into the wrong hands.**
    a. **Absent a strong commitment from the federal government to partner with the private sector on MCM development and procurement, do you believe the federal government is capable of acquiring the MCMs needed to protect the United States against threats like anthrax, smallpox, or Ebola?**

Department of Health and Human Services (HHS)

Since 2004, Congress has authorized over $8 billion for developing and procuring medical countermeasures for chemical, biological, radiological, and nuclear threats—including for anthrax, smallpox, and Ebola—for the civilian population. HHS leads federal efforts to oversee the development and procurement of medical countermeasures for the civilian population and works in coordination with other federal departments to do so.

- The Project BioShield Act of 2004 authorized the appropriation of approximately $5.6 billion from fiscal year 2004 through fiscal year 2013 for the Project BioShield Special Reserve Fund, and funds totaling this amount were appropriated. The act helped to create a government countermeasure market by authorizing the government to commit to making the Special Reserve Fund available to purchase certain medical countermeasures from the private sector, including those countermeasures that may not be approved, cleared, or licensed by the Food and Drug Administration. Project BioShield funds may be used to award contracts to private sector researchers and developers for the purposes of procuring medical countermeasures.[1]
- In 2013, the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) authorized an additional $2.8 billion to be available from fiscal year 2014 through fiscal year 2018 for countermeasure procurement, and Congress has appropriated $255 million in each of fiscal years 2014 and 2015. PAHPRA also explicitly allows Project BioShield countermeasure procurement contracts to include costs for countermeasure development.
- The Consolidated and Further Continuing Appropriations Act, 2015 appropriated additional funds to HHS, including for the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health, to support the development and procurement of medical countermeasures for Ebola.

We previously reported on some challenges that the federal government faces in developing and procuring medical countermeasures, such as the high failure rate in research and development and difficulties meeting regulatory requirements.[2] Despite these challenges, HHS

[1]HHS's Biomedical Advanced Research and Development Authority, created in 2006, oversees and supports advanced development and procurement of some medical countermeasures from the private sector into the Strategic National Stockpile—the national repository for medications, medical supplies, and equipment for use in a public health emergency.

[2]See GAO, Public Health Preparedness: Developing and Acquiring Medical Countermeasures Against Chemical, Biological, Radiological, and Nuclear Agents, GAO-11-567T (Washington, D.C.: Apr. 13, 2011).

has made progress in developing and procuring some medical countermeasures and continues to fund medical countermeasure development and procurement in partnership with the private sector. In December 2013, we reported that HHS spent approximately $3.6 billion in contracts with the private sector for advanced research, development, and procurement of medical countermeasures from fiscal year 2010 through fiscal year 2013.[3] Of this amount, HHS spent 30 percent for countermeasures against influenza, 20 percent for smallpox countermeasures, and 19 percent for anthrax countermeasures. Our December 2013 report provides additional information regarding HHS's spending on advanced research, development, and procurement of these medical countermeasures for this period.

Department of Defense (DOD)

While HHS leads federal efforts to develop and procure medical countermeasures for the civilian population, DOD is responsible for research, development, and procurement of medical countermeasures to prevent or mitigate the health effects of biological agents and naturally-occurring diseases on armed forces personnel. From fiscal years 2001 through 2013, DOD budgeted about $4.3 billion for developing and procuring medical countermeasures against biological threats.[4] DOD also coordinates with HHS on efforts to develop, acquire, and jointly stockpile medical countermeasures needed for both civilians and armed forces personnel, as appropriate.

United States Department of Agriculture (USDA)

In other efforts, Homeland Security Presidential Directive 9 directed the Secretary of Agriculture to develop a stockpile with resources to respond to the most damaging animal diseases affecting human health and the economy, including highly pathogenic avian influenza. The Secretary assigned this responsibility to USDA's Animal and Plant Health Inspection Service (APHIS). From 2006 through 2010, APHIS allocated approximately $33 million to develop the National Veterinary Stockpile and acquire critical resources to combat animal disease threats, including vaccines, diagnostic test kits, personal protective equipment, animal handling equipment, and antiviral medication.[5]

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[3]See GAO, *National Preparedness: HHS Is Monitoring the Progress of Its Medical Countermeasure Efforts but Has Not Provided Previously Recommended Spending Estimates*, GAO-14-90 (Washington, D.C.: Dec. 27, 2013).

[4]See GAO, *Biological Defense: DOD Has Strengthened Coordination on Medical Countermeasures but Can Improve Its Process for Threat Prioritization* GAO-14-442 (Washington, D.C.: May 15, 2014).

[5]See GAO, *Homeland Security: Actions Needed to Improve Response to Potential Terrorist Attacks and Natural Disasters Affecting Food and Agriculture*, GAO-11-652 (Washington, D.C.: Aug. 19, 2011).

The Honorable Richard Hudson

1. Please provide a summary of the existing tools that CDC has that would allow it to better oversee and take corrective actions against labs that commit violations.

Under the federal select agent program, CDC and APHIS have oversight of entities (including federal agencies and private institutions) and individuals that possess, use, or transfer select agents.[6] As part of that oversight, CDC and APHIS maintain a list of select agents and toxins, which they are to review and update at least biennially. Generally, entities working with these select agents must register with CDC or APHIS and renew their registration every 3 years. CDC or APHIS may conduct an on-site inspection before issuing a new certificate of registration or renewing an existing registration. CDC and APHIS may also conduct interim inspections, such as annual inspections, to assess compliance with select agent regulations. To assist entities with compliance with the select agent regulations, CDC and APHIS make various resources, including guidance documents, frequently asked questions, and webinars, available through the select agent website (http://www.selectagents.gov).

CDC and APHIS have the authority to deny, suspend, or revoke registration to use, possess, or transfer select agents and toxins if an entity or individual is in violation of the program's requirements. Additionally, any violations of the select agent regulation provisions may be subject to a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of an entity. Individuals in violation of the select agent regulations may also be subject to criminal fines, imprisonment, or both.

In addition to its oversight tools under the federal select agent program, CDC has also taken steps to improve oversight of its own laboratories—including both its select-agent registered and non-select agent-registered high-containment laboratories—following the 2014 incidents involving incomplete inactivation of and potential exposures to research samples of anthrax, avian influenza, and Ebola virus. In 2014 and 2015, CDC convened workgroups to review the agency's laboratory safety procedures and protocols and conduct internal and external reviews of these incidents, which resulted in recommendations for improving laboratory safety. CDC has begun to implement these recommendations to improve laboratory safety practices and procedures across the agency, with the stated goal of increasing CDC's culture of safety. These ongoing efforts include:

- Establishing a new leadership position that will report to the CDC Director to provide agency-wide leadership and accountability for laboratory science, safety, and quality;
- Continuing engagement with an external Laboratory Safety Workgroup to enhance best practices in laboratory safety and quality within CDC;
- Expanding biosafety training at CDC;
- Revamping and implementing new and enhanced procedures for prompt reporting of laboratory incidents to CDC leadership and staff;
- Rolling out a new electronic specimen inventory management system;

[6]The federal select agent program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to pose a severe threat to public, animal, or plant health or to animal or plant products.

- Enhancing procedures for custodianship of specimens with new entrance and exit processes for laboratory staff;
- Convening a Laboratory Safety Review Board to conduct safety reviews of laboratory protocols for work in biosafety level 3 (BSL-3) and BSL-4 laboratories; and
- Expanding external accreditation for CDC laboratories.

In our testimony before the subcommittee on July 28, 2015, we provided our preliminary observations on CDC's efforts to implement workgroup recommendations and address some weaknesses in the agency's management of its own laboratories.[7] The testimony also highlighted our prior recommendations for improving federal oversight of high-containment laboratories, including the need for a single federal oversight entity. As we conduct our ongoing review of federal management of biological agents in high-containment laboratories, we will continue to assess CDC's progress in implementing workgroup recommendations.

[7]See GAO, *High-Containment Laboratories: Preliminary Observations on Federal Efforts to Address Weaknesses Exposed by Recent Safety Lapses*, GAO-15-792T (Washington, D.C.: July 28, 2015).