REVIEW OF CDC ANTHRAX LAB INCIDENT

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRTEENTH CONGRESS

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[1] The appendices to Mr. Ebright's testimony are available at http://docs.house.gov/meetings/IF/IF02/20140716/102479/HHRG-113-IF02-Wstate-EbrightR-20140716-SD001.pdf.

[2] The document binder is available at http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=102479.

REVIEW OF CDC ANTHRAX LAB INCIDENT

WEDNESDAY, JULY 16, 2014

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

The subcommittee met, pursuant to call at 10:00 a.m., in room 2123, Rayburn House Office Building, Hon. Tim Murphy (chairman of the subcommittee) presiding.

Present: Representatives Murphy, Blackburn, Gingrey, Harper, Griffith, Johnson, Long, Ellmers, Barton, Upton (ex officio), DeGette, Braley, Schakowsky, Castor, Tonko, Green, and Waxman (ex officio).

Staff Present: Sean Bonyun, Communications Director; Leighton Brown, Press Assistant; Karen Christian, Chief Counsel, Oversight; Noelle Clemente, Press Secretary; Andy Duberstein, Deputy Press Secretary; Carrie-Lee Early, Detailee, Oversight; Brad Grantz, Policy Coordinator, O&I; Brittany Havens, Legislative Clerk; Sean Hayes, Deputy Chief Counsel, O&I; Emily Newman, Counsel, O&I; Alan Slobodin, Deputy Chief Counsel, O&I; Phil Barnett, Staff Director; Peter Bodner, Counsel; Brian Cohen, Staff Director, O&I, Senior Policy Advisor; Lisa Goldman, Counsel; and Elizabeth Letter, Press Secretary.

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

Mr. MURPHY. Good morning. The subcommittee on Oversight and Investigations today examines the Center for Disease Control and Prevention's anthrax incident last month that potentially exposed dozens of CDC researchers to live anthrax because established safety procedures were not followed.

Last Friday, the CDC director announced the findings of CDC's own internal review of the incident and the corrective actions being taken. CDC's review identified a fundamental flaw. The Agency had no written study plan to ensure the safety of its workers and the proper handling of live biological agents.

Like anthrax, the Department of Agriculture's investigation revealed more disturbing detail. During the inspection, CDC workers could not locate some of their anthrax samples. It took more than a week for the inspectors and CDC management to track down the anthrax samples that are in CDC's custody. Agriculture inspectors also uncovered that CDC was transferring dangerous material from biological containment labs in Ziploc bags. Disinfectant that CDC

labs use for decontamination has expired. This is troubling, and it is completely unacceptable.

The Centers for Disease Control and Prevention is supposed to be the gold standard of the U.S. public health system, and it has been tarnished. We rely on CDC to protect us and uphold the highest standards of safety, but the recent anthrax event and newly-disclosed incidents have raised very serious questions about CDC's ability to safeguard properly-selected agents in its own labs.

The CDC director has called the potential anthrax exposure a wakeup call, but our investigation has uncovered this is not CDC's first wakeup call. I am not even sure "wakeup call" is the proper term. It is a gross and dangerous understatement. It was a potentially very dangerous failure. Wakeup call is catching something before the danger exists. Once a person is exposed to the serious pathogens, the danger is of a much higher magnitude.

In 2006, the CDC Bioterrorism Lab sent live anthrax to two outside labs on the mistaken belief that the shipped anthrax was inactivated. Later that same year, inadequate inactivation procedures led another CDC lab to inadvertently ship live botulinum to an outside lab. In 2009, CDC learned from newly-available test methods that a strain of brucella, which can cause a highly-contagious infection, had been shipped to outside labs since 2001 because researchers had believed that it was a less dangerous strain. One must question the scientific qualifications of these scientists.

Reports by government watchdogs demonstrate that these events are not isolated incidents. Between 2008 and 2010, the HHS Office of Inspector General, or OIG, issued three reports documenting concerns that CDC labs, such as ensuring physical security of select agents and ensuring personnel receive required training. An audit in 2010 found that a CDC scientist discovered select agents in a drawer in an unsecured lab during a reorganization, and another CDC scientist found 16 vials of a select agent stored in an unsecured freezer that was reportedly left over from an outbreak investigation many years earlier.

This is reminiscent of the recent discovery of smallpox vials in a storage room on the NIH campus. This smallpox was in a place that no one knew it was there, and it was also discovered by accident.

In 2011, the OIG found that CDC did not monitor and enforce effectively certain select agent regulations at Federal laboratories, including those at the CDC. In addition to the Inspector General audits, several GAO reports in recent years have raised concerns about oversight of high containment labs, including those at CDC.

Despite the number of red flags, these incidents keep happening. We learned last Friday that CDC scientists in March shipped influenza strains to a Department of Agriculture lab that was contaminated with a very deadly flu virus. This cross-contamination was discovered on May 23rd, 2014, but it took 6 weeks for this to be reported to CDC leadership.

What we have here is a pattern of reoccurring issues, of complacency, and a lax culture of safety. This is not sound science, and this will not be tolerated. These practices put the health of the American public at risk. It is sloppy, and it is inexcusable.

Now, Dr. Frieden, I thank you for testifying today. I have questions about whether the corrective actions you have announced will ultimately solve the problems. We will be looking forward to your testimony. CDC has already reassigned one lab official from his duties. Taking personnel actions, though, will not address problems that based on the number of incidents and reports over the years appear to be systemic.

CDC needs to reassure that proper policies are implemented and followed. Dr. Frieden, you said last Friday that you were distressed about the delay of notification about the influenza shipments. I want to know if you are concerned about why CDC workers are not reporting everything, and whether you have reason to believe that they may be afraid to report these incidents.

CDC is not going to solve human errors unless it gets as much information as possible from its own people. Since 2007, there have been 17 reports at CDC indicating that a worker was potentially exposed to a select agent or toxin. Thankfully, as far as we are aware, no one at CDC has become sick from improper handling of select agents. But CDC should not assume that its luck with these near miss events will continue. Sooner or later that luck will run out, and someone will get very sick or die.

CDC needs to strengthen its safety procedures. The risk from these deadly pathogens require failsafe mechanisms and redundancies similar to those used in other contexts, such as handling weapons. The subcommittee will also review the oversight system of Federal laboratories, compliance with select agent regulations, and to explore the possibility of an independent agency to oversee the CDC labs.

I thank all the witnesses for testifying today, and I now recognize the ranking member, Ms. DeGette.

[The prepared statement of Mr. Murphy follows:]

PREPARED STATEMENT OF HON. TIM MURPHY

The subcommittee today examines the CDC anthrax incident last month that potentially exposed dozens of CDC researchers to live anthrax because established safety procedures were not followed.

Last Friday, the CDC Director announced the findings of CDC's own internal review of the incident and the corrective actions being taken. CDC's review identified a fundamental flaw: the agency had no written study plan to ensure the safety of its workers and the proper handling of live biological agents, like anthrax. The Department of Agriculture's investigation revealed more disturbing details. During the inspection, CDC workers could not locate some of their anthrax samples. It took more than a week for the inspectors and CDC management to track down the anthrax samples that are in CDC's custody. Agriculture inspectors also uncovered that CDC was transferring dangerous materials from biocontainment labs in Ziploc bags. Disinfectant that CDC labs used for decontamination was expired.

This is troubling and it is completely unacceptable.

The Centers for Disease Control is supposed to be the gold standard in the U.S. public health system and it has been tarnished. We rely on CDC to protect us and uphold the highest standards of safety. But the recent anthrax event and newly disclosed incidents have raised very serious questions about the CDC's ability to safeguard properly select agents in its own labs.

The CDC Director has called the potential anthrax exposure a "wake up" call. But as our investigation has uncovered, this is not CDC's first "wake up" call. I'm not even sure "wake up" call is the proper term.

A "wake up call?" That is a gross and dangerous understatement. It was a potentially very dangerous failure. A "wake up" call is catching before the danger occurs.

Once a person is exposed to a serious pathogen, the danger is of a much higher magnitude.

In 2006, the CDC bioterrorism lab sent live anthrax to two outside labs on a mistaken belief that the shipped anthrax was inactivated. Later that same year, inadequate inactivation procedures led another CDC lab to inadvertently ship live botulinum to an outside lab.

In 2009, CDC learned from newly available test methods that a strain of Brucella, which can cause a highly contagious infection, had been shipped to outside labs since 2001 because researchers had believed that it was a less dangerous strain. One must question the scientific qualification of such scientists.

Reports by government watchdogs demonstrate that these events are not isolated incidents. Between 2008 and 2010, the HHS Office of Inspector General (OIG) issued three reports documenting concerns at CDC labs such as ensuring physical security of select agents and ensuring personnel received required training. An audit in 2010 found that a CDC scientist discovered select agents in a drawer in an unsecured lab during a reorganization, and another CDC scientist found 16 vials of a select agent stored in an unsecured freezer that was reportedly left over from an outbreak investigation many years earlier. This is reminiscent of the recent discovery of smallpox vials in a storage room on the NIH campus. The smallpox was undocumented, no one knew it was there, only discovered by accident. In 2011, the OIG found that CDC did not monitor and enforce effectively certain select agent regulations at Federal laboratories, including those at the CDC. In addition to the Inspector General audits, several GAO reports in recent years have raised concerns about oversight of high-containment labs, including those at the CDC.

Despite the number of red flags, these incidents keep happening. We learned last Friday that CDC scientists in March shipped influenza strains to a Department of Agriculture lab that was contaminated with a very deadly flu virus. This cross contamination was discovered on May 23, 2014, but it took six weeks for this to be reported to CDC leadership.

What we have here is a pattern of recurring issues, of complacency, and a lax culture of safety. This is not sound science and we will not tolerate these practices that put the health of the American public at risk. It is sloppy and inexcusable.

Dr. Frieden, I thank you for testifying today. I have questions about whether the corrective actions you have announced will ultimately solve the problem. CDC has already reassigned one lab official from his duties. Taking personnel actions, though, will not address problems that—based on the number of incidents and reports over the years—appear to be systemic. CDC needs to ensure that proper policies are implemented and followed. Dr. Frieden, you said last Friday that you are distressed about the delay in notification about the influenza shipments. I want to know if you are concerned about why CDC workers are not reporting everything and whether you have any reason to believe they may be afraid to report these incidents. Is this going to be like the Veterans Administration, frought with coverups and dependent on whistleblowers, outside investigators, and accidental discoveries.

CDC is not going to solve human errors unless it gets as much information as possible from its own people.

Since 2007, there have been 17 reports at CDC indicating that a worker was potentially exposed to a select agent or toxin. Thankfully, as far as we are aware, no one at CDC has become sick from improper handling of select agents. But CDC should not assume that its luck with these near-miss events will continue. Sooner or later, that luck will run out and someone will die. CDC needs to strengthen its safety procedures. The risks from these deadly pathogens require fail-safe mechanisms and redundancies similar to those used in other contexts such as handling weapons.

The subcommittee will also review the oversight system of Federal laboratories' compliance with select agent regulations, and to explore the possibility of an independent agency to oversee the CDC labs.

I thank all the witnesses for testifying today.

# # #

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

Ms. DEGETTE. Thank you very much, Mr. Chairman. Last month, scientists at CDC's BRRAT Laboratory in Atlanta made a series of mistakes that could have had deadly consequences. They

transferred anthrax spores to two other labs, potentially exposing dozens of individuals to anthrax. Luckily, nobody has yet fallen ill.

Like all of us, I am deeply troubled by what we have learned about this incident. How did it happen? CDC conducted its own internal investigation that identified numerous failures. There was no standard operating procedure for the analysis being conducted by the CDC scientists. There was no approved study plan. The scientists used a pathogenic strain of anthrax when a non-pathogenic strain could have been used. The scientists used unapproved sterilization techniques for pathogenic anthrax, and then proceeded to transfer the material without confirming that it was inactive.

This is obviously an alarming series of failures, but there were other problems at CDC that made this incident worse. CDC has provided to the committee a disturbing report from the U.S. Department of Agriculture Animal and Plant Health Inspection Service, APHIS. After the anthrax incident, APHIS conducted its own inspection of the facility. Inspectors identified serious problems in lab operations and decontamination procedures, but also detailed major problems with the CDC's response to the incident, reporting that the Agency was inadequately prepared to handle the cleanup or to treat those who were potentially exposed.

I think we can all agree the reports on this incident are bad. But what is even more troubling to me is that in context, they reveal a broad problem with the CDC's safety culture. We have received report after report from GAO, the HHS IG, and APHIS offering a multitude of warnings and recommendations on operations of high containment labs. CDC's after action report identified four other cases in the last decade where CDC shipped dangerous pathogens offsite.

The Democratic committee staff prepared a memo describing the results from six different APHIS inspections at the CDC Roybal facility in 2013 and '14. Overall, in the six inspections, APHIS identified dozens of observations of concerns, 29 related to facilities and equipment, 27 related to safety and security, and 39 related to documentation and record keeping. In some cases, the APHIS observations revealed that what appeared to be only paperwork problems, but in other cases, they found many more serious problems. They found reports of scientists using torn gloves and exhaust hoods blowing fumes in the wrong direction. Not one of these six inspections gave the CDC a totally clean bill of health.

Now, I would like to make this memo part of the record, Mr. Chairman. I think your staff has seen it.

Mr. MURPHY. Without objection.

Ms. DEGETTE. The record shows that CDC had ample warnings and should have been focused on the problems in their high containment labs long before the June anthrax release. I just do not understand why they did not heed those warnings. Dr. Frieden has indicated that he was as surprised as anybody by the scope of the problems. And the fact, Dr. Frieden, you were so surprised is a problem in and of itself because what it shows is that there is a fundamental problem with the culture of identifying and reporting safety problems up the chain of command.

Now, I am sorry to say, Mr. Chairman, these lab safety issues are not new to me or the committee. This is one of the detriments

of having been on this committee for 18 years. We have had multiple hearings on this problem at the CDC over the years. In 2006 and 2007, we had terrible problems at the CDC facility in Fort Collins, Colorado just north of my district where we had vector-borne diseases that were being very sloppily handled.

Fortunately, we built a new facility since then up in Fort Collins. It is a beautiful facility, and we are able to handle these diseases. But, you know, these issues are not resolving themselves. And so, Dr. Frieden, you have got a strong record at the CDC. I know you have got answers and recommendations, and you are acting aggressively to make sure this does not happen again. I appreciate that. We all appreciate that. But what we all need to know is what the plan is to change the culture at the CDC. We cannot legislate. We can do a lot, but we cannot legislate a culture change. It has to come from within the Agency.

I am also glad to have GAO and APHIS witnesses here because in retrospect, your warnings were prescient and should have been taken more seriously.

I can assure you these warnings are being taken very seriously right now, not just by the Agency, but by the people here on this panel. Thank you very much, Mr. Chair.

Mr. MURPHY. Thank you. The gentlelady's time has expired. And I will recognize the chairman of the full committee, Mr. Upton, for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman. This is a very serious hearing for sure. 2 years ago after allegations about problems in CDC's Building 18, the home of the world's deadliest agents and pathogens, this committee investigated whether the CDC was complying with Federal safety requirements in the operation of its main lab facilities.

In response to our concerns, CDC Director Tom Frieden sent the committee a letter in September of '12. The CDC letter, which I would like to include in the record, outlined the Agency's efforts to ensure better oversight and safe handling of select agents at CDC labs.

These measures included rigorous training, constant review of safety measures, multiple layers of engineering and operational systems. The letter also stated that a senior official, who was not identified, would be designated to report directly to the CDC director on safety at CDC labs. These measures sound very similar to the corrective actions that Dr. Frieden outlined last week to address the current lab crisis. Why should we believe this time that things are, in fact, going to be different?

We asked CDC 2 years ago to identify each biosafety incident that had taken place at its main lab since January 1st of '05. CDC provided the committee with a list back in 2012, but we now know from CDC's internal investigation released last Friday that, in fact, the list was not complete. Improper shipments of pathogens in '06, including anthrax, were not included in CDC's list of safety incidents that, in fact, was provided to this committee.

CDC staff has now acknowledged to committee staff that the '06 incidents, which were reported to the HHS IG, should have been included. We do not know why they were not. This raises the question of whether CDC leadership is receiving all the information about its own biosafety systems.

Add to the possible anthrax exposure, the delayed notice provided to CDC leadership about Avian flu shipments, and the discovery of smallpox vials in a cardboard box in an FDA storage room on the NIH campus, and these incidents no longer appear isolated. A dangerous, very dangerous, pattern is emerging, and there are a lot of unknowns out there as well.

When dealing with pathogens, such as the ones being discussed today, unknowns are frankly unacceptable. What you do not know can hurt you. Why do these events keep happening? What is going to be next? CDC needs to solve the safety problem now as a team. The Agency needs to get as much info as possible from its workers about the true state of biosafety at CDC, and keep this committee and the American people fully informed. There is zero tolerance for unlocked refrigerators and Ziploc bags. Those days have to be over.

I yield to Marsha Blackburn.

[The prepared statement of Mr. Upton follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Two years ago, after allegations about problems in CDC's Building 18—the home to the world's deadliest agents and pathogens—this committee investigated whether the CDC was complying with federal safety requirements in the operation of its main lab facilities. In response to our concerns, CDC Director Tom Frieden sent the committee a letter in September 2012.

The CDC letter, which I would like to include in the record, outlined the agency's efforts to ensure better oversight and safe handling of select agents at CDC labs. These measures included rigorous training, constant review of safety measures, and multiple layers of engineering and operational systems. The letter also stated that a senior official—who was not identified—would be designated to report directly to the CDC Director on safety at CDC labs. These measures sound very similar to the corrective actions Dr. Frieden outlined last Friday to address the current lab crisis. Why should we believe this time that things will be different?

We asked CDC 2 years ago to identify each biosafety incident that had taken place at its main lab since January 1, 2005. CDC provided the committee with a list back in 2012—but we now know from CDC's internal investigation report released last Friday that the list was not complete. Improper shipments of pathogens in 2006, including anthrax, were not included in CDC's list of safety incidents that was provided to this committee. CDC staff has now acknowledged to committee staff that the 2006 incidents, which were reported to the HHS Inspector General, should have been included. We don't know why they were not. This raises the question of whether CDC leadership is receiving all the information about its biosafety systems.

Add to the possible anthrax exposure the delayed notice provided to CDC leadership about avian flu shipments and the discovery of smallpox vials in a cardboard box in an FDA storage room on the NIH campus, and these incidents no longer appear isolated; a dangerous pattern is emerging, and there are a lot of unknowns out there. When dealing with pathogens such as the ones being discussed today, unknowns are unacceptable.

What you don't know can hurt you. Why do these events keep happening? What will be next? CDC needs to solve this safety problem now, as a team. The agency needs to get as much as information as possible from its workers about the true state of biosafety at CDC, and keep this committee and the American people fully informed on its progress. There is zero tolerance for unlocked refrigerators and Ziploc bags—those days are over.

Ms. BLACKBURN. I thank the chairman for yielding. I want to thank our panel for being here. And as you can hear, on a bipar-

tisan basis we have plenty of questions for you. We are deeply concerned about the incidents that have occurred at the Federal labs that are run by the Department of Health and Human Services, CDC, with the anthrax specimens.

Dr. Frieden, we appreciate the time you spent with us last week, but I think we do have plenty of questions for you about the safety and the carefulness. We would think that the priority would be safety and caring and making certain that you are tending to that culture of safety within these labs.

NIH, with the vials of smallpox, and the fact that this was in an unused portion of a storage room. Who all would have access to that? And then, of course, the cross-contamination of the influenza sample.

We have all talked about these three events. And the fact that they have occurred within this framework of time, the fact that there seemed to be a dismissiveness of the serious nature of these occurrences, the fact that the CDC's own report pointed out some of the contributing factors in this, and the lack of a standard operating procedure, and best practices; and the fact that this is known among the employees at that Agency.

We know that there are some remediation measures that have been implemented, but the culture of safety or lack thereof continues to be a concern to us for public health. I yield back my time.

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

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman, for holding this hearing. I think it is important for us to investigate this incident involving the release of potentially viable anthrax on CDC's campus in Atlanta.

When I was chairman of the Oversight Committee, we held hearings after the 2001 anthrax attacks. We looked at the safety of postal workers and the public in handling mail, and the Postal Service and CDC's response to those attacks. We had hearings again in 2003 and 2005 where we found there were still gaps in biological detection of anthrax and in communicating test results and risks to the public.

Those hearings showed why CDC's work on identifying and containing public health risks from these types of biological agents is so important. But this work can also pose risks, and that is why this oversight hearing is important.

In 2009 when I was chairman of the full committee, we held a hearing on the proliferation of high containment bio labs and the lack of oversight over such facilities. Mr. Dingell also held a hearing in 2007, so this is not our first introduction to this subject.

At our request, GAO, the Government Accountability Office, also looked into lab safety. GAO reported in a number of studies, one as recently as 2013, on the problems associated with the government's fragmented piecemeal approach to these labs. No single agency has oversight over all high containment bio labs. There are

no national standards for operation, and we have no record of how many labs even exist.

The Health and Human Services Inspector General also issued numerous reports on high containment labs and their handling of select agents. The Inspector General identified issues with the treatment of select agents and the safety of the individuals working with these dangerous pathogens. The Inspector General recommended that the Centers for Disease Control labs improve training for individuals handling select agents, improve record keeping, and take appropriate measures to improve safety.

The American people count on the Centers for Disease Control to protect them, and we want to be able to assure them that CDC is conducting its research in safe and secure ways.

I am supportive of Dr. Frieden's efforts at CDC. We have worked with him on numerous issues in the last 5 years, and he has shown himself to be an effective leader and a strong communicator. And I appreciate the quick actions that he has taken in response to this incident. I am encouraged to see that Dr. Frieden has appointed Dr. Michael Bell to oversee laboratory safety protocols and procedures. This investigation has shown us that CDC needs to change its safety culture, and I hope that Dr. Bell can help instill a new mindset at the Agency.

Still, I am concerned that it took the exposure of dozens of CDC staff to anthrax to finally spur CDC to action. So we want answers from the CDC about how this incident was allowed to happen in the first place. And I look forward to hearing from APHIS and GAO about the problems they have identified in the past, how CDC should implement their recommendations moving forward, and what role Congress should play in making sure that happens.

Mr. Chairman, this is not the first hearing on the subject. We have looked at it before. We need now finally to be sure that all the recommendations that we have had are put in place so that we can stop something like this from happening again.

Thank you, and I yield back my time.

Mr. MURPHY. Thank you. I now would like to introduce the witnesses on the first panel for today's hearing. First, Dr. Thomas Frieden is the director of the Centers for Disease Control and Prevention. Today Dr. Frieden is accompanied by Mr. Joseph Henderson, who is the deputy director of the Office of Security and Emergency Preparedness at the Centers for Disease Control. Dr. Jere Dick is the associate deputy administrator of the Animal and Plant Health Inspection Services at the U.S. Department of Agriculture. Dr. Nancy Kingsbury is the managing director of Applied Research and Methods at the U.S. Government Accountability Office. And, Dr. Gingrey, did you want to introduce someone who is from your district?

Mr. GINGREY. Mr. Chairman, thank you very much for giving me the opportunity. I know this witness is on the second panel, and it will be a little while before we will be hearing from the second panel. But it is an honor and a pleasure to introduce off of the second panel Sean Kaufman.

Mr. Kaufman is the president and founding partner of a company called Behavioral-Based Improvement Solutions. His background is long-term employment with the CDC before forming his own com-

pany in my district, the 11th Congressional District of Georgia in Woodstock, Georgia.

And I would encourage all the members on both sides of the aisle, if you have not had a chance—I know we try to read all of the testimony, but sometimes we skip one or two along the way. But I will assure you that the written testimony from Mr. Kaufman really hits the nail right on the head in regard to this overall issue, and I would recommend it to you. And I am proud to introduce him to you in anticipation of the second panel.

Mr. Chairman, thank you very much, and I yield back.

Mr. MURPHY. Thank you, Dr. Gingrey.

To the panel, you are aware that the committee is holding an investigative hearing, and when doing so has the practice of taking testimony under oath. Do any of you have objections to taking testimony under oath?

All the witnesses indicate no.

The chair then advises you all that you are 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 during today's testimony?

All the witnesses indicate no.

In that case, would you all please rise and raise your right hand, and I will swear you in. Stand, please.[Witnesses sworn.]

Mr. MURPHY. Thank you. All the witnesses answered in the affirmative. You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute summary of your written statement. Dr. Frieden, you are recognized.

TESTIMONIES OF THOMAS R. FRIEDEN, DIRECTOR, CENTERS FOR DISEASE CONTROL AND PREVENTION; JERE DICK, ASSOCIATE DEPUTY ADMINISTRATOR, ANIMAL AND PLANT HEALTH INSPECTION SERVICES, U.S. DEPARTMENT OF AGRICULTURE; NANCY KINGSBURY, MANAGING DIRECTOR, APPLIED RESEARCH AND METHODS, GOVERNMENT ACCOUNTABILITY OFFICE

TESTIMONY OF THOMAS R. FRIEDEN

Dr. FRIEDEN. Chairman Murphy, Ranking Member DeGette, members of the subcommittee, thank you very much for this opportunity to appear before you. I am Dr. Tom Frieden, director of the CDC. With me is Mr. Joe Henderson, who heads our Office of Security, Safety and Asset Management.

I will review the problems that have come to light in the past month and tell you what we are doing now to address improving lab safety. The fact that it appears that no one was harmed and that there were no releases does not excuse what happened. What happened was completely unacceptable. It should never have happened.

If I leave you with just one thought about today's hearing as it relates to CDC, it is this. With the recent incidents, we recognize the pattern at CDC where we need to greatly improve the culture of safety, and I am overseeing sweeping measures to improve that culture of safety.

CDC works 24/7, and our scientists protect Americans from threats, including naturally-occurring threats, like Ebola, and MERS, and drug-resistant bacteria, and manmade threats, such as anthrax. But we must do that work more safely, and we will.

There is a recap of the recent incidents that are summarized in our report, which has been completed, and we are just at the outset of our investigation of the influenza contamination. I would be pleased to go through the two diagrams that we have provided to the subcommittee which outline what we know to date. But in brief, the anthrax incident shows deeply troubling problems: a lack of proper protocol, incorrect inactivation procedures, failure to ensure that we were transferring materials that were sterile when we thought they were sterile, use of a virulent strain when a non-dangerous form would have been appropriate.

In the influenza cross-contamination, we are still trying to understand how the cross-contamination occurred and investigating how there could have been such a long delay in notification. The risk to employees from the anthrax exposure was at most very small, and the risk of release to the public was non-existent. But that does not change the fact that these were unacceptable events. They should never have happened.

In the past, as the committee has outlined, there were a number of specific incidents, and I do believe that CDC staff worked hard to address the specific findings of past investigations. But I think we missed a critical pattern. Instead of just focusing on those, when we issued the anthrax report, we provided not only these two incidents, but the prior episodes of what has happened because what we are seeing is a pattern that we missed. And the pattern is an insufficient culture of safety.

We are now implementing every step we can to make sure that the problems are addressed comprehensively in order to protect our own workforce, and to strengthen the culture of safety, and to continue our work protecting Americans. I have taken a number of specific steps. I have issued a moratorium on the transfer of all biological materials outside of all BSL–3 and 4 laboratories at CDC. I have closed the two laboratories that were involved in this situation until we are sure that they can be reopened safely. I have appointed Dr. Michael Bell, a senior scientist, to be Director of Laboratory Safety reporting directly to me as the single point of accountability. He will review the moratorium and lift it lab by lab when we are confident that can be done safely. He will also facilitate expansion and use of that safety culture throughout CDC.

CDC scientists are world famous for their rigor in scientific investigation, and we will now apply that same rigor to improving the safety in our own laboratories. I am convening a high-level working group within CDC internally to advise us on every step of the process and an external advisory group of outside experts who are top in the world to take a fresh look and see what we can do to do better.

We will look at every inactivation and transfer protocol and other protocols and improve them as needed. We will look at future incidents, if they occur, with a command structure which should have been used earlier in the anthrax exposure. I will ensure that appropriate discipline is taken as indicated by our investigations, and

will apply lessons learned from this experience to our function as a regulatory agency and our select agents' regulatory program.

In hindsight, we realized that we missed a crucial pattern, a pattern of incidents that reflected the need to improve the culture of safety at CDC. But as with many things, recognition is only the first step, and we are taking a number of additional actions to establish and strengthen a culture that prioritizes the safety of our own staff, encourages reporting of actual and potential situations that may place staff and others at risk, openly assesses those risks, and implements redundant systems to keep risks to the absolute minimum.

Part of that culture will be increased reporting of problems or potential problems. One of the aspects of an effective culture of safety is rapid reporting of problems so if we do uncover problems in the coming weeks and months, this may well be the result of strengthening our culture of safety rather than failing to address it.

We have concrete actions underway to change processes that allowed these incidents to happen, reduce the likelihood of an occurrence in the future, and apply the lessons broadly. We will do everything possible to live up to the high standards that Congress and the American public rightfully expect us to achieve.

I look forward to your questions, and thank you for inviting me to testify today, and for your interest in this important topic.

[The prepared testimony of Dr. Frieden follows:]

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

Review of CDC Anthrax Lab Incident

Thomas R. Frieden, M.D., M.P.H.
Director
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services

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For Release upon Delivery
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Thank you, Mr. Chairman and Members of the Subcommittee. I am Dr. Tom Frieden, Director of the Centers for Disease Control and Prevention (CDC). I appreciate the opportunity to appear before you and to discuss the June 2014 anthrax incident at CDC laboratories, as well as other laboratory safety incidents including the spring 2014 cross-contamination involving the H5N1 influenza virus at the CDC influenza laboratory. Fundamentally, I want to make three points:

First, these incidents should never have happened, and the lack of adequate procedures and oversight that allowed them to happen was totally unacceptable. Although it does not appear that these incidents resulted in any illness, and there was no release of pathogens as a result of either event, this does not excuse what happened.

Second, we will take every step possible to prevent any future incident that could put our laboratory scientists, others in the CDC workforce and the broader community, or the public at risk. CDC's laboratory scientists are a national and global resource. They work 24/7 to keep us all safe, and all of us at CDC share a responsibility to do everything possible to make sure they are safe in their work. I am personally overseeing a series of reforms designed to address these specific incidents – but more broadly, recognizing that our challenge is larger than addressing these two specific incidents, I will oversee the careful and deliberate review of existing, and development of new safety practices at all levels of our Agency. I have implemented a moratorium on transfer of any biological material out of any BSL-3 or BSL-4 laboratory at CDC until processes are reviewed and improved, and this moratorium will be lifted on a lab-by-lab basis once corrective actions have been taken and confirmed.

Third, 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.

As this Subcommittee is aware, we continue to face significant health threats from nature and from man-made releases. In recent months, we have seen a surge of cases of the Middle East Respiratory Syndrome (MERS-CoV), a novel coronavirus with no treatment, and the largest outbreak of Ebola ever, in countries in West Africa. Last year, concern mounted over a new strain of avian flu emerging in China. And it was not long ago that anthrax was used as a weapon here on Capitol Hill. Our most important defense against these threats is our public health scientists – both those who are sent to the front lines, and those in our laboratories who diagnose these conditions, conduct research, and develop medical treatments that allow us to protect public health.

CDC Work with Anthrax and Other Deadly Bacteria and Viruses

I want to begin by focusing on the June 2014 incident regarding anthrax in some detail, as we have completed our internal review and therefore have a detailed understanding of what happened. For context, CDC laboratories are a critical component in our defense against naturally-occurring disease and bioterrorism, including the most deadly biological agents or "select agents" – those agents or toxins that have been determined to have the potential to pose a severe threat to health. CDC laboratories are uniquely capable of identifying these agents and other deadly bacteria and viruses rapidly, and diagnosing the diseases they cause, since these organisms are rarely seen in clinical practice and require skills and protections not routinely available in

clinical laboratories. These capabilities are critical to our ability to identify exposure or illness and intervene to saves lives in a natural or bioterrorist incident. CDC also leads a nationwide network of laboratories – the Laboratory Response Network (LRN) which is on our Nation's first line of defense in the event of an act of bioterror. We also work closely with our colleagues in the Department of Health and Human Services (principally through the National Institutes of Health and the Biomedical Advanced Research and Development Authority) and counterparts in the Department of Homeland Security. This research is conducted in highly-specialized laboratories with protections designated by their Biosafety Level (BSL). The anthrax incident involved CDC BSL-2 laboratories (where access is restricted, and personal protective equipment includes gowns, gloves, and eye protection), and a BSL-3 laboratory, where greater respiratory protections include controls on airflow and the use of respirators.

Bacillus anthracis (the bacteria that causes anthrax), though found in nature, is of particular concern because it can be aerosolized and used as a weapon. CDC, and the U.S. Public Health Emergency Medical Countermeasures Enterprise more broadly, conduct anthrax research in order to: (1) create new tests for rapid identification; (2) help other laboratories test for anthrax quickly, accurately, and safely; (3) evaluate and improve prevention and treatment options including vaccines and antibiotics; and (4) provide support and training to laboratories across the Nation.

The CDC Bioterrorism Rapid Response and Advanced Technology (BRRAT) Laboratory involved in the June 2014 incident has Biosafety Level (BSL)-3 and BSL-2 components. The Laboratory was established in 1999 to provide national laboratory testing and consultative support for the analysis of materials suspected to contain

biothreat agents. The LRN was established in accordance with Presidential Decision Directive 39, which outlined national anti-terrorism policies and assigned specific missions to federal departments and agencies.

June 2014 Laboratory Incident

In the recent incident, research was initiated in the BRRAT laboratory on June 5, 2014, to investigate a method that might allow detection of anthrax more rapidly than with conventional methods, using instrumentation known as the Matrix-Assisted Laser Desorption Ionization – Time of Flight Mass Spectrometry (MALDI-TOF). CDC researchers began with a sample of active (*i.e.,* live, infectious) anthrax bacteria, and sought to render it into an inactive form (*i.e.,* killed) so that it could be evaluated in CDC laboratories where this specialized research equipment was available, with the goal of providing a faster way for emergency response laboratories to detect anthrax.

Believing that the entire anthrax sample had been killed, when no growth was observed on sterility plates after 24 hours of incubation, CDC staff transferred the samples from BSL-3 laboratories to lower-containment BSL-2 laboratories, which is appropriate for an inactivated sample. The sterility plate sample had undergone only 10 minutes of treatment, as compared with the 24 hours of treatment performed on all samples that had been transferred out of the BSL-3 laboratory. Eight days later, on June 13, 2014, a laboratory scientist in the BRRAT laboratory BSL-3 lab observed unexpected growth on the anthrax sterility plate. While this plate had only been treated for 10 minutes as opposed to the 24 hours of treatment of samples sent outside of the BSL-3 lab, this nonetheless indicated that the *B. anthracis* sample extract may not have been sterile when transferred to BSL-2 laboratories. We therefore could not rule out the

possibility that employees in the BSL-2 laboratories that received the samples might have been put at risk.

As soon as the potential for exposure was identified, CDC responded with an intensive effort to identify all individuals who may have been exposed, to ensure that those at potential risk were medically evaluated, and to take appropriate action with those for whom exposure could not be ruled out. In addition, all of the samples were collected and safely transferred back from the BSL-2 laboratories to the BSL-3 laboratory. Risk was evaluated for each individual who was in proximity to the relevant laboratories and potentially exposed. Taking no chances, CDC recommended antibiotics (to prevent any exposure from leading to disease, called post-exposure prophylaxis) for 81 staff potentially at risk, and anthrax vaccine as appropriate. Subsequently, after further investigation and a more refined analysis was conducted, we were able to conclude on June 30, 2014, that only about half of those individuals actually had the potential to have been exposed and we were therefore able to recommend discontinuation of antibiotics to the other staff. We recommended continuation of post-exposure prophylaxis for those individuals for whom we cannot rule out a small increased risk. No employee has presented with symptoms associated with anthrax. Work in these laboratories was halted while further investigation and remedial actions were undertaken

Ultimately, our internal investigation suggests that, while it is not impossible that exposures occurred, there was at most a very small chance that anyone was exposed to live anthrax during this incident. First, experiments conducted after the incident, both within CDC and also by a non-CDC, independent laboratory, suggest that the

disinfection procedure used was likely to have inactivated the samples that were transferred to the BSL-2 containment laboratories. Second, the samples transported to these BSL-2 laboratories sat in an acid bath for 24 hours prior to transfer to the BSL-2 laboratory – while those that later exhibited growth sat in an acid bath for only 10 minutes, increasing the likelihood that those samples were inactive. Finally, sampling of surfaces in the relevant laboratories found no viable anthrax.

I want to be very clear: to outline these results is not to excuse or minimize what happened. First and foremost, our primary concern is the health and well-being of our workforce. As a result of this incident, they had to deal with uncertainty, stress, potential risk, and some had to take preventive medications that can have adverse effects. The incident revealed concerns about the use of inappropriate protocols and lack of adherence to procedure, and points to needed improvements in our oversight systems. Our review of the factors leading to this potential exposure – and other incidents detailed in our July 11, 2014, report and noted below -- revealed troubling breaches of protocol, gaps in our review systems, and errors in judgment.

This is unacceptable. CDC epitomizes the highest quality science critical to protecting Americans from health, safety and security threats, both foreign and in the United States. I am personally overseeing efforts to improve biosafety and biosecurity, and to protect our laboratory workers with the goal of preventing future incidents.

Reviewing the Causes of the Anthrax Incident

We took immediate measures to respond to the June 2014 incident and to provide individuals with appropriate preventive treatment. We also took steps to

reconstruct the laboratory procedures to identify opportunities for improvement. I commissioned an internal review of policies and procedures in the BRRAT BSL-3 laboratory, and also a review of our response and incident management. The results of these reviews and recommendations have been made available to the Subcommittee and the public.

The overriding factor contributing to this incident was the lack of an approved, written plan reviewed by senior staff, such as Laboratory, Branch or Division scientific leadership, to ensure that the research design was appropriate and met all laboratory safety requirements.

The internal review also found that the following contributed to the incident:

- Unapproved inactivation techniques were used in this experiment.
- Anthrax samples were transferred without confirmation that they were inactive.
- A virulent strain of anthrax was used for this research, when less dangerous forms would have been appropriate.
- Laboratory staff directing and performing the work had inadequate knowledge of the peer-reviewed literature, which showed that steps beyond those used were required to inactivate the anthrax.
- Standard operating procedures or processes were lacking for the inactivation and transfer of select agents to other laboratories.

Further, our internal review of the response to this incident identified several issues, including complications in our ability to rapidly identify the full universe of individuals who may have had theoretical risk of exposure; the initial lack of a single, accountable leader of the overall response activity, given that elements of the response involved

multiple organizational units across the Agency, including ensuring sufficient surge capacity in our occupational health clinic; inconsistent use of decontamination practices across laboratories; and employee frustration with our internal communications, as we focused on managing the situation with at-risk staff without making information more widely available to others in the CDC community.

We have accepted the findings of these reviews and outlined below are steps we ar taking to address the recommendations.

As a matter of compliance with the select agent regulations, we reported the incider to the Federal Select Agent Program. In turn the Agricultural Select Agent Services located within the USDA/Animal and Plant Health Inspection Service (APHIS) conducted a two-week investigation. We value the expertise of APHIS and also accept the accountability that comes from inspection by an outside entity. APHIS has completed their on-site inspection in reviewing the June incident, and we will take actio on the specific issues raised in the APHIS report.

Other Related Laboratory Incidents

In our July 11, 2014 report, we noted another troubling incident in the past in CDC BRRAT laboratory, where in 2006 viable anthrax was transferred to two other lab: Also in 2006, DNA preparations shipped from another CDC laboratory were found to contain live *Clostridium botulinum* due to the use of inadequate inactivation procedures. In 2009, newly available test methods showed that a strain of *Brucella*, thought to have been an attenuated vaccine strain and previously shipped to laboratories outside CDC, was not the vaccine strain. And just last week, I was made aware that in March 2014 a culture of non-pathogenic avian influenza was

unintentionally cross-contaminated at the CDC influenza laboratory with the highly pathogenic H5N1 strain of influenza and shipped to a BSL-3, select agent laboratory operated by the United States Department of Agriculture's (USDA) Agricultural Research Service (ARS); ARS discovered the cross-contamination in May 2014 and informed the CDC laboratory, but other necessary notifications were not made. The June 2014 anthrax incident alone was a call to action for changes in CDC's laboratory safety systems, but the larger context of these other incidents reinforces and amplifies that strong, rapid, and comprehensive action is needed.

While specific corrective actions were taken in response to individual incidents in past years, the broader pattern of inadequate laboratory safety was not addressed effectively. Addressing that broader pattern and our safety culture is what we are doing now.

Implementing New Protections for CDC Laboratories

We are committed to implementing the changes identified in these reviews that are needed to protect our staff and the CDC community, to reinforce CDC's practices as an example for other laboratories, and to safely execute critical diagnostic and research work that is essential to protecting Americans. We are already taking the following actions with respect to the BRRAT laboratory, and CDC's laboratories more broadly:

1) At my direction, the BRRAT Laboratory has been closed since June 16, 2014. This action was reinforced by APHIS on July 8, 2014. No work with select agents and toxins will be undertaken in the BRRAT laboratory, pending the completion of a series of steps we outlined in our report and compliance with corrective actions indicated by the APHIS inspection. At

a minimum, we will address staffing (assessment and appropriate remediation of skills, training, supervision, knowledge, and expertise) and assure that procedures are fully implemented to prevent future occurrences.

2) Appropriate personnel action will be taken with respect to individuals who contributed to, were in a position to prevent, or did not appropriately report these incidents.
3) On July 11, 2014, I placed a temporary moratorium on any biological material leaving any CDC BSL-3 or BSL-4 laboratory.
4) We established a high-level working group, chaired by a senior scientist not associated with the reported incidents and reporting to the CDC Director, to, among other duties, accelerate improvements in laboratory safety, review and approve, on a laboratory-by-laboratory basis, resume transfer of biological materials outside of BSL-3 and BSL-4 laboratories, and be the interim single point of accountability on laboratory safety called for in the review of the potential exposure to anthrax incident.
5) All decontamination, inactivation, and transfer procedures of select agents and other dangerous pathogens throughout CDC laboratories will be carefully reviewed and updated as needed. For example, the review will confirm that all CDC laboratories that handle select agents and other dangerous pathogens will have written, validated, and verified procedures to assure materials are non-viable before being removed from

containment — and we will implement redundant systems both in the sending and in the receiving laboratory.

6) More broadly, CDC will establish a permanent CDC-wide single point of accountability for laboratory safety, to establish and enforce agency-wide policies, such as redundant systems and controls for protocols and procedures; and establish an external advisory committee to provide on-going advice and direction for laboratory quality and safety.
7) CDC will initiate an incident command structure early in our response to an incident at CDC when it is suspected that the incident is significant or not well understood. CDC may also leverage the assets of CDC's Emergency Operations Center to help coordinate the event response.
8) Lessons based on this incident will be considered for broader implications. If appropriate, CDC's DSAT program will incorporate findings and recommendations into nationwide regulatory activities to provide stronger safeguards for laboratories across the United States. For example, in its review of biosafety plans with regulated entities, DSAT will emphasize the importance of having validated inactivation protocols and utilizing testing to verify that preparations are inactivated prior to distribution.

Conclusion and Next steps

In closing, I want to emphasize how seriously we have taken these incidents. Though it now appears that the risk to any individual was either non-existent or very small in the June 2014 anthrax incident, and that there was no risk of exposure or release in the spring 2014 H5N1 flu incident, the issues these incidents raise are

significant. While we take action necessary to address these incidents, we will address broader, underlying issues rather than addressing each incident or laboratory in isolation. We also need to encourage a culture of openness and effective reporting of past or future incidents – since a key aspect of effective response is to support rapid reporting of problems. So though I know of no other incidents at this time, and it would be disappointing to learn of any other incident, future reports of problems can reflect an improved culture of safety where monitoring and reporting is valued, rather than lack of progress improving safety. We have concrete actions underway now to change processes that allowed these incidents to happen, prevent an occurrence like this in any CDC laboratory, and to apply the lessons we have learned to inform biosafety and biosecurity procedures at other laboratories across the United States. We will do everything possible to live up to the high standards the Congress and the American public rightfully expect us to achieve.

Mr. MURPHY. Thank you.

Dr. Dick, you are next. Make sure your microphone is on. Push it very close to your mouth. Thank you. It is not on. The green light. There you go.

TESTIMONY OF JERE DICK

Mr. DICK. Thank you. Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify today about the Animal and Plant Health Inspection Service's inspection into the release of possibly live anthrax at the CDC's Roybal campus. I am Dr. Jere Dick, associate administrator for APHIS within USDA.

APHIS conducted a thorough inspection of the incident to learn how it happened and determine appropriate remedial measures. We will continue to monitor the CDC's response to ensure all necessary corrective action is taken, and that when work resumes at the laboratories, it will be done in full compliance with the health and safety of the employees and the public at the forefront.

USDA was designated by Congress as the partner with CDC in the oversight of select agents because of our expertise and experience, safely working with select agents over the past century, through our efforts to prevent dangerous disease agents from impacting U.S. agriculture and the environment. For decades, APHIS has also safely operated high containment laboratories that handle select agents, including those of concern for human health. Our personnel are leading diagnosticians, and experts in the effective working of high containment laboratories.

To ensure objectivity, APHIS and CDC signed a memorandum of understanding in October of 2012, which makes APHIS the lead inspection agency for CDC entities.

Since the MOU was finalized, APHIS has carried out 11 inspections of the four CDC laboratories.

APHIS takes any potential release of a select agent or toxin very seriously, with the goal of quickly ensuring that the release is contained and determining what led to the release to ensure no future incidents. On June 13th, CDC officials discovered a potential release of anthrax and notified APHIS. CDC voluntarily closed impacted labs on June 16th.

APHIS made its inspection a priority and quickly began its work to ensure that all select agents were secured, and that there were no other breaches in biosafety or biosecurity. The specially-trained APHIS inspection team of veterinarians and a plant pathologist spent nearly 2 weeks, beginning on June 23rd, conducting a facility review of the laboratories and interviews with CDC personnel. APHIS briefed CDC officials on July 2nd, outlining deficiencies so that they could immediately begin taking corrective actions.

APHIS found that the laboratory did not use an adequate inactivation protocol and did not ensure that the protocol was, in fact, validated. The initial response to this incident by the CDC laboratories was inadequate both in securing as well as disinfecting laboratories. For example, individuals without approval to handle select agents were able to access space containing or potentially contaminated with anthrax at least 4 days after the incident was discovered. We also found that employees did not have appropriate training in some instances.

We found no clear management oversight of the incident at the labs and no clear single manager overseeing the overall CDC incident response, which resulted in employee confusion about how to respond. In addition, CDC's Occupational Health Clinic was not prepared to respond to the potential exposure of a large number of workers.

APHIS currently has in place a cease and desist order with select agents and toxins at the two impacted select agent laboratories. We will require that corrective actions be taken to ensure the integrity of these research programs. We have directed CDC to provide APHIS with its plan for coming into compliance by July 25th. And before allowing CDC to resume select agent work in the laboratories, APHIS will conduct a re-inspection to ensure that all corrective actions have been taken.

Mr. Chairman, this concludes my testimony. I would be happy to answer any questions that you or the members of the subcommittee have.

[The prepared testimony of Mr. Dick follows:]

Testimony of

Dr. Jere Dick
Associate Administrator
Animal and Plant Health Inspection Service
U.S. Department of Agriculture

Before the House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
July 16, 2014

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to testify today about the inspection conducted by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) into the release of possibly live *Bacillus anthracis* (anthrax) at the Centers for Disease Control and Prevention's (CDC) Roybal campus. APHIS conducted a full and thorough investigation of the incident to learn how it happened and determine appropriate remedial measures. We will continue to monitor the CDC's response to ensure all necessary corrective action is taken and that when work resumes at the laboratories, it will be done in full compliance with select agent and toxin regulations and with the health and safety of employees and the public at the forefront.

APHIS' Agriculture Select Agent Services (AgSAS) and CDC's Division of Select Agents and Toxins (DSAT) jointly operate the Federal Select Agent Program, which oversees the possession, use and transfer of biological select agents and toxins that have the potential to pose a severe threat to public, animal or plant health or to animal or plant products. While CDC authority over select agents dates back to the Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104-132), USDA's Agriculture Select Agent Services was created under authorities granted by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Public Law 107-188).

USDA was designated by Congress as a partner with CDC in the oversight of select agents because of our expertise and experience effectively and safely working with select agents through our domestic pest and disease programs as well as our efforts to prevent dangerous disease agents from impacting U.S. agriculture and the environment—including zoonotic diseases that impact human as well as animal health. These programs and efforts have been in place for over 100 years; in this time, we have had success in completely eliminating high consequence diseases from the United States such as foot and mouth disease and contagious bovine pleuropneumonia. APHIS has also safely operated high containment laboratories for decades, including the Foreign Animal Disease Diagnostic Laboratory on Plum Island, New York, and the United States' animal health reference laboratory, the National Veterinary Services Laboratories, in Ames, Iowa, that handle select agents, including those of concern for human health. Our personnel are leading diagnosticians and experts in the effective working of high-containment laboratories.

Under Public Law 107-188, entities such as private, State, and Federal research laboratories; universities; and vaccine companies that possess, use, or transfer select agents must register these agents with the appropriate federal agency. In the case of select agents that are deemed a threat to animal or plant health, the appropriate agency would be APHIS; select agents deemed a threat to public health fall under CDC-DSAT. Some agents such as anthrax may pose a severe threat to both animal and public health and safety, and are considered overlap select agents that fall under both APHIS and CDC jurisdiction.

In addition to registering with APHIS or CDC, a facility working with select agents or toxins must also meet biosafety requirements that are commensurate with the risk posed by the agents or toxins. Facilities must also establish security measures that provide protection based on the threat of the particular agents or toxins within their possession. Additionally, the U.S. Department of Justice, through the Federal Bureau of Investigation, completes a security risk assessment of the facility owners, the designated responsible official, and all individuals possessing, using, or transferring the agents or toxins. Specially trained APHIS-AgSAS and CDC-DSAT officials also conduct an inspection of the facility prior to granting registration and additional unannounced inspections are conducted to ensure compliance with select agent regulations and policies. Additionally, our agencies review, modify, and republish the list of select agents and toxins on a biennial basis.

To ensure objectivity, APHIS and CDC-DSAT put in place a memorandum of understanding (MOU) in October 2012 which makes APHIS the lead inspection agency for entities that are owned and operated by CDC. This includes the conduct of both select agent registration renewal inspections as well as compliance inspections. Since the MOU was finalized, APHIS has carried out 11 inspections of CDC laboratories.

APHIS Inspection of the CDC Anthrax Incident

APHIS takes any potential release of a select agent or toxin very seriously, with a goal of quickly ensuring that any release is contained and determining what led to the release to ensure no future incidents. On June 13, 2014, CDC officials discovered the potential release of anthrax at CDC's Roybal Campus in Atlanta, Georgia, and CDC voluntarily closed the impacted labs on June 16. CDC notified APHIS-AgSAS on June 19 of the incident.

APHIS made this inspection a priority and quickly began its work to ensure that all select agents were secured and that there were no other breaches in biosafety and security which could impact public safety. The APHIS inspection team was comprised of a team leader and 4 veterinary medical officers. From June 23 through July 3, 2014, the inspection team conducted a facility review of the laboratories involved in the incident followed by interviews with CDC personnel. The AgSAS inspection team provided an exit briefing to CDC officials on July 2, outlining the deficiencies found during the inspection so that CDC laboratories could immediately begin taking corrective actions.

Through our inspection and interviews, we identified lapses in procedures which led to the accidental release and made a number of key findings that we have provided to CDC. Between June 6 and June 13, 2014, a CDC researcher improperly inactivated cultures of *B. anthracis* in a

select agent registered laboratory and moved the cultures to several laboratories on the Roybal Campus that are not approved to work with the live agent. Laboratory workers may have been exposed to live anthrax spores and vegetative cells through incidental contact or movement through seven laboratories in three separate buildings on the CDC Roybal campus. The APHIS inspection team verified that no livestock were exposed.

Our inspection confirmed that this was an unintentional release of anthrax. However, our inspection also found a number of deficiencies in the biosafety, security, incident response, occupational health, and management controls of the incident, which will require corrective actions in order to prevent such incidents from reoccurring in the future.

First, the laboratory that inadvertently transferred the possibly live anthrax did not use an adequate inactivation protocol and did not ensure that the protocol was validated. The initial response to this incident by the impacted CDC laboratories was inadequate, both in fully securing as well as disinfecting exposed laboratory areas and equipment. Individuals without approval to handle select agents were able to access space containing or potentially contaminated with anthrax at least through June 17, or 4 days after the incident was discovered. Additionally, a number of the disinfectants used in the response were expired and impacted laboratories used inconsistent methods of disinfection. We found that employees did not have appropriate training in the application of the inactivation protocol, appropriate disinfection of exposed laboratory areas or actions to take in the event of exposure.

At the management level, we found no clear management oversight of the incident within the various laboratories that were impacted. There also was no clear, single manager overseeing the overall CDC incident response, which resulted in employee confusion about how to manage the response to the incident. In addition, CDC's Occupational Health Clinic was inadequately prepared to respond to the potential exposure of a large number of workers, resulting in some staff not knowing if they were at risk and at least one person who was in contact with contaminated material without proper personal protective equipment not being examined for 5 days.

APHIS currently has in place a cease and desist order for all work with select agents and toxins at the two impacted Roybal campus select agent labs, due to the deficiencies in biosafety and containment procedures we found during our inspection. We have provided a report of the full inspection findings to CDC and will require that a number of corrective actions be taken to ensure the integrity of its select agent research programs. We have directed CDC to provide APHIS with its plan for coming into compliance no later than July 25, 2014. Prior to allowing CDC to resume select agent work in the laboratories, APHIS will conduct a reinspection to ensure that all corrective actions have been taken.

APHIS Inspection of the CDC Avian Influenza Incident

APHIS learned on July 9, 2014, of an incident in which CDC sent a low pathogenic H9N2 avian influenza virus sample contaminated with high pathogenic H5N1 avian influenza virus to the USDA, Agricultural Research Service, Southeast Poultry Research Laboratory in Athens, Georgia. APHIS quickly dispatched a team of inspectors during the week of July 14, 2014, to

lead the compliance inspections at both the CDC and USDA-ARS laboratories and determine any needed corrective actions.

Mr. Chairman, this concludes my testimony. I would be happy to answer any questions that you or the members of this Subcommittee may have.

Mr. MURPHY. Thank you, Dr. Dick.

Ms. Kingsbury, you are recognized for 5 minutes. Please point that microphone very close to your mouth. A lot closer than that.

Ms. KINGSBURY. Thank you, Mr. Chairman, for inviting——

Mr. MURPHY. Bring it really—ma'am. Dr. Kingsbury?

Ms. KINGSBURY. Pardon me?

Mr. MURPHY. Bring the mic really close, please.

Ms. KINGSBURY. Really close.

Mr. MURPHY. Really close. Thank you.

Ms. KINGSBURY. Is that better? Yes. OK.

TESTIMONY OF NANCY KINGSBURY

Ms. KINGSBURY. Thank you very much for inviting us to come to talk to you about some of our past work on biosafety issues. As Mr. Waxman noted in his statement, we have been doing this work for quite a while. We started with the original anthrax attacks, and we have gone on to a number of other issues over the years.

Basically, our past work has a couple of major themes. One of them is a lack of strategic planning and oversight of the whole picture of biosafety laboratories. APHIS and CDC are only a part of that picture, and since 2001, there have been an increasing number of biosafety laboratories both within that sector, but also across the whole government. There are six or seven different agencies involved, and no one entity has been charged with developing a strategic plan.

We became particularly concerned about that as budgets began to shrink, recognizing that the management and operation of these laboratories is an expensive venture. And if they are not properly maintained, other kinds of problems can arise.

We have also observed that there is a continued lack of national standards for designing, constructing, commissioning, and operating these laboratories. There is guidance. The biosafety and microbiological and biomedical laboratories guidance is available, but it is not required, and there is no process by which an entity needs to make sure that they are following that guidance. We think this broader government perspective about both how many of these laboratories we need and for what purpose, and also a better framework for oversight is still needed.

We have done some work since the most recent episode became public. We did take a team to Atlanta. I want to thank Dr. Frieden for his staff's cooperation with us when we were there. Coming together with something I am prepared to sit here and talk about on something like 10 days' notice is a bit of a challenge for us, but his staff was very good at providing everything we asked for.

I am not going to add very much to that debate. I think the two previous witnesses have covered the details pretty well. The one thing I would add, however, is while we agree that there is a requirement to have standard operating procedures that are reviewed at appropriate levels for biosafety, we believe it is also important that those procedures be validated. And by that we mean independently tested so that we can be assured that if these procedures are followed, there will be no further episodes. So I will just add that one thought to the debate about the incident itself.

Thank you very much, Mr. Chairman. That concludes my statement.

[The prepared testimony of Ms. Kingsbury follows:]

92323.018

GAO Highlights

Highlights of GAO-14-785T, a testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

Recent biosecurity incidents—such as the June 5, 2014, potential exposure of staff in Atlanta laboratories at the Centers for Disease Control and Prevention (CDC) to live spores of a strain of anthrax—highlight the importance of maintaining biosafety and biosecurity protocols at high-containment laboratories. This statement summarizes the results of GAO's past work on the oversight of high-containment laboratories, those designed for handling dangerous pathogens and emerging infectious diseases. Specifically, this statement addresses (1) the need for governmentwide strategic planning for the 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 oversight of biosafety and biosecurity at high-containment laboratories. In addition, it provides GAO's preliminary observations on the potential exposure of CDC staff to anthrax. For this preliminary work, GAO reviewed agency documents, including a report on the potential exposure, and scientific literature; and interviewed CDC officials.

What GAO Recommends

This testimony contains no new recommendations, but GAO has made recommendations in prior reports to responsible agencies.

View GAO-14-785T. For more information, contact Nancy Kingsbury at (202) 512-2700 or kingsburyn@gao.gov.

July 16, 2014

HIGH-CONTAINMENT LABORATORIES

Recent Incidents of Biosafety Lapses

What GAO Found

No federal entity is responsible for strategic planning and oversight of high-containment laboratories. Since the 1990s, the number of high-containment laboratories has risen; however, the expansion of high-containment laboratories was not based on a government-wide coordinated strategy. Instead, the expansion was based on the perceptions of individual agencies about the capacity required for their individual missions and the high-containment laboratory activities needed to meet those missions, as well as the availability of congressionally approved funding. Consequent to this mode of expansion, there was no research agenda linking all these agencies, even at the federal level, that would allow for a national needs assessment, strategic plan, or coordinated oversight. As GAO last reported in 2013, after more than 12 years, GAO has not been able to find any detailed projections based on a government-wide strategic evaluation of research requirements based on public health or national security needs. Without this information, there is little assurance of having facilities with the right capacity to meet the nation's needs.

GAO's past work has found a continued lack of national standards for designing, constructing, commissioning, and operating high-containment laboratories. As noted in a 2009 report, the absence of national standards means that the laboratories may vary from place to place because of differences in local building requirements or standards for safe operations. Some guidance exists about designing, constructing, and operating high-containment laboratories. Specifically, the Biosafety in Microbiological and Biomedical Laboratories guidance recommends various design, construction, and operations standards, but GAO's work has found it is not universally followed. The guidance also does not recommend an assessment of whether the suggested design, construction, and operational standards are achieved. As GAO has reported, national standards are valuable not only in relation to new laboratory construction but also in ensuring compliance for periodic upgrades.

No one agency is responsible for determining the aggregate or cumulative risks associated with the continued expansion of high-containment laboratories; according to experts and federal officials GAO interviewed for prior work, the oversight of these laboratories is fragmented and largely self-policing.

On July 11, 2014, the Centers for Disease Control and Prevention (CDC) released a report on the potential exposure to anthrax that described a number of actions that CDC plans to take within its responsibilities to avoid another incident like the one in June. The incident in June was caused when a laboratory scientist inadvertently failed to sterilize plates containing samples of anthrax, derived with a new method, and transferred them to a facility with lower biosecurity protocols. This incident and the inherent risks of biosecurity highlight the need for a national strategy to evaluate the requirements for high-containment laboratories, set and maintain national standards for such laboratories' construction and operation, and maintain a national strategy for the oversight of laboratories that conduct important work on highly infectious pathogens.

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

I am pleased to be here today to participate in today's hearing to address recent biosecurity incidents. On June 5, 2014, staff in Atlanta laboratories at the Centers for Disease Control and Prevention (CDC) were potentially exposed to live spores of the Ames strain of anthrax (*Bacillus anthracis or B. anthracis*). On July 1, 2014, at the Bethesda, Maryland, National Institutes of Health (NIH), vials of potentially live smallpox (*variola*) virus were unexpectedly discovered. Public attention is once again focused on the importance of maintaining biosafety and biosecurity protocols at high-containment laboratories.[1]

My statement summarizes the results of our past work on the oversight of high-containment laboratories and our preliminary assessment of the recent incident in Atlanta. Since 2007, we have reported on several issues associated with the proliferation of high-containment laboratories and risks posed by past biosafety incidents. The public is concerned about these laboratories because exposing workers and the public to dangerous pathogens, whether deliberate or accidental, can have disastrous consequences. Highly publicized laboratory errors and controversy about where high-containment laboratories should be located have raised questions about whether the governing framework, standards, and oversight for biosafety and biosecurity measures are adequate.

This testimony is primarily based on GAO's past work on high-containment laboratories. The issues in this work covered (1) the need for governmentwide strategic planning for the 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 oversight of

[1]High-containment laboratories—commonly referred to as biosafety level (BSL)-3 and BSL-4 laboratories—are designed for handling dangerous pathogens (which might accidentally or intentionally be released into the environment) and emerging infectious diseases for which risks may not be clearly understood. Some use "high- and maximum-containment laboratories" to refer to BSL-3 and BSL-4 laboratories. "Animal biosafety level (ABSL)-3 and ABSL-4" mean laboratories that work with animals infected with indigenous or exotic agents. "BSL-3 Ag" describes laboratories where studies employ large agricultural animals. In this statement, "high-containment laboratories" refers to all these types of laboratories.

biosafety and biosecurity at high-containment laboratories. Each report cited in this statement provides detailed information on our work's objectives, scope, and methodology (the reports are listed at the end of this statement). For our preliminary observations, on the June 5–13, 2014 biosafety incident at CDC's laboratories we interviewed CDC officials and reviewed agency documents and scientific literature. We provided a draft of this statement to CDC for technical review and addressed their comments in the body of our statement where appropriate. We also reviewed CDC's July 11, 2014, *Report on the Potential Exposure to Anthrax*. The work this statement is based on was conducted 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 the evidence obtained provided a reasonable basis for our findings and conclusions based on our audit objectives.

No Federal Entity Is Responsible for Expansion and Oversight of High-Containment Laboratories

The number of biosafety level (BSL)-3 and BSL-4 laboratories (high-containment laboratories) began to rise in the late 1990s, accelerating after the anthrax attacks throughout the United States. The laboratories expanded across federal, state, academic, and private sectors. Information about their number, location, activities, and ownership is available for high-containment laboratories registered with CDC's Division of Select Agent and Toxins (DSAT) or the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) as part of the Federal Select Agent Program. These entities register laboratories that work with select agents that have specific potential human, animal, or plant health risks.

Other high-containment laboratories work with other pathogens that may also be dangerous but are not identified as "select agents" and therefore these laboratories are not required to register with DSAT or APHIS.[2] We reported in 2009 that information about these non-select agent laboratories is not known.

[2]A select agent is a biological agent or toxin that (1) potentially poses a severe threat to public health and safety, animal or plant health, and animal or plant products and (2) is regulated by select agent rules for possession, use, and transfer (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73). CDC and USDA maintain a list of select agents and toxins.

Our work has found that expansion of high-containment laboratories was not based on a government-wide coordinated strategy. The expansion was based on the perceptions of individual agencies about the capacity required for their individual missions and the high-containment laboratory activities needed to meet those missions, as well as the availability of congressionally approved funding. Decisions to fund the construction of high-containment laboratories were made by multiple federal agencies (e.g., Department of Health and Human Services (HHS), Department of Defense, USDA), in multiple budget cycles. Federal and state agencies, academia, and the private sector (such as drug companies) considered their individual requirements, but as we have previously reported a robust assessment of national needs was lacking.

Since each agency or organization has a different mission, an assessment of needs, by definition, was at the discretion of the agency or organization. We have not found any national research agenda linking all these agencies, even at the federal level, that would allow for a national needs assessment, strategic plan, or coordinated oversight. As we last reported in 2013, after more than 12 years, we have not been able to find any detailed projections based on a government-wide strategic evaluation of research requirements based on public health or national security needs. Without this information, there is little assurance of having facilities with the right capacity to meet our national needs. This deficiency may be more critical today than 5 years ago when we first reported on this concern because current budget constraints make prioritization essential.

National Standards for Designing, Constructing, Commissioning, Operating, and Maintaining High-Containment Laboratories Are Needed

Our work on this issue has found a continued lack of national standards for designing, constructing, commissioning, and operating high-containment laboratories. These laboratories are expensive to build, operate, and maintain. For example, we noted in our 2009 report that the absence of national standards means that the laboratories may vary from place to place because of differences in local building requirements or standards for safe operations. In 2007, while investigating a power outage at one of its recently constructed BSL-4 laboratory, CDC determined that construction workers digging at an adjacent site had some time earlier cut a critical grounding cable buried outside the building. CDC facility managers had not noticed that cutting the grounding cable had compromised the electrical system of the facility that housed the BSL-4 laboratory. It became apparent that the building's integrity as it related to the adjacent construction had not been adequately supervised. In 2009, CDC officials told us that standard procedures under local building codes did not require monitoring of the new BSL-4 facility's electrical grounding.

This incident highlighted the risk of relying on local building codes to ensure the safety of high-containment laboratories in the absence of national standards or testing procedures specific to those laboratories.[3]

Some guidance exists about designing, constructing, and operating high-containment laboratories. The Biosafety in Microbiological and Biomedical Laboratories guidance, often referred to as BMBL recommends various design, construction and operations standards, but our work has found it is not universally followed.[4] It also does not recommend an assessment of whether the suggested design, construction, and operations standards are achieved. As we have recommended, national standards would be valuable for not only new laboratory construction but also periodic upgrades. Such standards need not be constrained in a "one-size fits all" model but could help specify the levels of facility performance that should be achieved.

Risks Associated with Expanding High-Containment Laboratories and Oversight Challenges

Our work has also found that no executive or legislative mandate directs any federal agency to track the expansion of all high-containment laboratories. While federal agency officials and experts agree that operating high-containment laboratories is always associated with some risk, no one agency is responsible for determining the aggregate or cumulative risks associated with the continued expansion of these laboratories. According to the experts and federal officials we have interviewed for our prior work, the oversight of these laboratories is fragmented and largely relies on self-policing. For example, if an entity is registered under the Federal Select Agent Program, CDC DSAT or APHIS provides oversight. However, if an entity receives federal funding from the National Institutes of Health for recombinant deoxyribonucleic acid (rDNA) research, the NIH Office of Biotechnology Activities provides oversight. DOD also separately funds and inspects high-containment laboratories. These agencies assume that risks will be dealt with by the entities' self-regulation, consistent with the laboratory practice guidelines

[3] GAO recommended in our 2013 report that the Executive Office of the President, Office of Science and Technology Policy (OSTP) examine the need to establish national standards relating to designing, constructing, commissioning, maintaining, and operating high-containment laboratories. OSTP concurred.

[4] Department of Health and Human Services (Washington, D.C., 2007), *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed. HHS has developed and provided biosafety guidelines outlined in this manual.

developed by the funding or regulatory agencies. In 2013, we reported that another challenge of this fragmented oversight is the potential duplication and overlap of inspection activities in the regulation of high-containment laboratories.[5] We recommended that CDC and APHIS work with the internal inspectors for Department of Defense and Department of Homeland Security to coordinate inspections and ensure the application of consistent inspection standards.

According to most experts that we have spoken to in the course of our work, a baseline risk is associated with any high-containment laboratory. Although technology and improved scientific practice guidance have reduced the risk in high-containment laboratories, the risk is not zero (as illustrated by the recent incidents and others during the past decade). According to CDC officials, the risks from accidental exposure or release can never be completely eliminated and even laboratories within sophisticated biological research programs—including those most extensively regulated—has and will continue to have safety failures. Many experts agree that as the number of high-containment laboratories has increased, so the overall risk of an accidental or deliberate release of a dangerous pathogen will also increase.[6]

Oversight is critical in improving biosafety and ensuring that high-containment laboratories comply with regulations. However, our work has found that aspects of the current oversight programs provided by DSAT and APHIS 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 us, citing the June 2014 updated guidance, that "the burden

[5]*High-Containment Laboratories: Assessment of the Nation's Need Is Missing*, GAO-13-466R (Washington, D.C.: February 25, 2013).

[6]The Office of Science and Technology Policy (OSTP), Executive Office of the President, disagreed with our assessment in our 2013 report of the increased overall risk associated with the expansion of high-containment laboratories. Officials did not agree that there was an increased risk. Our assessment is based on probability theory, and we make no assumptions about the magnitude (size or extent) of the increase. The risk associated with any single laboratory is nonzero, for example, as laboratory accidents happen. Even where newer safety controls reduce the risk of an accident for any individual laboratory, and even if the number of accidents at any laboratory is small, when the number of laboratories increases, each laboratory's risk adds to the overall risk of an accident's happening nationwide. Because laboratories operate independently, the risk is not increased for each laboratory. The risk at each laboratory leads to an overall increased risk with expansion.

of validating non-viability and non-functionality remains on the individual or entity possessing the select agent, toxin, or regulated nucleic acid." [7] While DSAT does not approve each entity's scientific procedure, 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." Biosafety select agent regulations and oversight critically rely on laboratories promptly reporting any incidents that may expose employees or the public to infectious pathogens. Although laboratories have been reasonably conscientious about reporting such incidents, there is evidence that not all have been reported promptly.

The June 2014 Incident at the CDC Laboratories and GAO's Preliminary Observation

The June 2014 incident in which live anthrax bacteria were transferred from a BSL-3 contained environment to lower-level (BSL-2) containment laboratories at CDC in Atlanta resulted in the potential exposure of tens of workers to the highly virulent Ames strain of anthrax. According to CDC's report, on June 5, a laboratory scientist in the BSL-3 Bioterrorism Rapid Response and Advanced Technology (BRRAT) laboratory prepared protein extracts from eight bacterial select agents, including *Bacillus anthracis*, under high-containment (BSL-3) conditions.[8] These samples were being prepared for analysis by matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, a relatively new technology that can be used for rapid bacterial species identification. Also, according to CDC officials that we spoke to this protein extraction procedure was being evaluated in a preliminary assessment of whether MALDI-TOF mass spectrometry could provide a cheaper and faster way to detect a range of pathogenic agents, including anthrax, compared to conventional methods and thus could be used by emergency response laboratories. According to CDC officials, the researchers intended to use the data collected in this experiment to submit a joint proposal to CDC's Office of Public Health Preparedness and Response to fund further evaluation of the MALDI TOF method

[7] National Select Agent Registry. "Non-viable Select Agents and Nonfunctional Select Toxins and Rendering Samples Free of Select Agents and Toxins." June 16, 2014. It is guidance for the inactivation of select agents and toxins.

[8] CDC." Report on the Potential Exposure to Anthrax." July 11, 2014.

because MALDI TOF is increasingly being used by clinical and hospital laboratories for infectious disease diagnostics.

The protein extraction procedure was chemically based and intended to render the pathogens noninfectious, which alternative extraction procedures would have done using heat, radiation, or other chemical treatments that took longer. The procedure that was used to extract the proteins was not based on a standard operating procedure that had been documented as appropriate for all the pathogens in the experiment and reviewed by more senior scientific or management officials. Rather, the scientists used a procedure identified by the MALDI TOF equipment manufacturer that had not been tested for effectiveness, in particular, for rendering spore-forming organisms such as anthrax noninfectious. Following that procedure, the eight pathogens were exposed to chemical treatment for 10 minutes and then plated (spread on plates to test for sterility or noninfectious status) and incubated for 24 hours. According to CDC, on June 6, when no growth was observed on sterility plates after 24 hours, the remaining samples, which had been held in the chemical solution for 24 hours, were moved to CDC BSL-2 laboratories for testing using the MALDI TOF technology. Importantly, the plates containing the original sterility samples were left in the incubation chamber rather than destroyed as would normally occur because of technical problems with the autoclave that would have been used for destruction.

According to CDC officials, on June 13, a laboratory scientist in the BRRAT laboratory observed unexpected growth on the anthrax sterility plate, possibly indicating that the sample was still infectious. (All the other pathogen protein samples showed no evidence of growth.) That scientist and a colleague immediately reported the discovery to the CDC Select Agent Responsible Official (RO) in accordance with the BRRAT Laboratory Incident Response Plan. That report triggered a response that immediately recovered the samples that had been sent to the BSL-2 laboratories and returned them to BSL-3 containment, and a response effort that lasted a number of days was implemented to identify any CDC employees who might have been affected by exposure to live anthrax spores. (The details of the subsequent actions and CDC's lessons learned and proposed actions are described in CDC's July 11, 2014, *Report on Potential Exposure to Anthrax*. That report indicates that none of the potentially affected employees experienced anthrax-related adverse medical symptoms.)

Our preliminary analysis indicates that the BRRAT laboratory was using a MALDI-TOF MS method that had been designed for protein extraction but

not for the inactivation of pathogens and that it did not have a standard operating procedure (SOP) or protocol on inactivation. We did not find a complete set of SOPs for removing agents from a BSL-3 laboratory in a safe manner. Further, neither the preparing (BRRAT BSL-3) laboratory nor the receiving laboratory (BRRAT BSL-2) laboratory conducted sterility testing. Moreover, the BRRAT laboratory did not have a kill curve based on multiple concentration levels.[9]

When we visited CDC on July 8, it became apparent to us, that a major cause of this incident was the implementation of an experiment to prepare protein extractions for testing using the MALDI TOF technology that was not based on a validated standard operating procedure.[10] CDC officials acknowledged that significant and relevant studies in the scientific literature about chemical procedures studied for preparing protein samples for use in the MALDI TOF technology, were successful in rendering tested pathogens noninfectious, except for anthrax. The literature clearly recommends an additional filtering step before concluding that the anthrax samples are not infectious. Our preliminary work indicates that this step was not followed for all the materials in this incident.

In response to a 2004 inadvertent exposure to anthrax spores at Children's Hospital Oakland Research Institute in California, where laboratory workers were evaluating the immune response of mice to *B. anthracis*, CDC conducted an investigation along with the California Department of Health Services. This investigation found that workers in a research laboratory unknowingly received and used a suspension from a contract laboratory that likely contained viable B. anthracis organisms, although the pathogen was supposed to have been inactivated. CDC's investigation report of that incident stated that inactivated suspensions of *B. anthracis* should be cultured both at the preparing laboratory before shipment and at the research laboratory receiving the suspension before use to ensure sterility (that the material is noninfectious). The hospital

[9]A kill curve is a graph in which the number of viable organism is plotted against time. A kill curve's shape depends on the concentration of chemicals that the organisms are exposed to.

[10]Validating a procedure or method provides a defined level of statistical confidence in the results of the procedure or method.

staff did not perform sterility testing on the suspension received in March 2004.

CDC's 2004 report further stated that "Research laboratory workers should assume that all inactivated *B. anthracis* suspension materials are infectious until inactivation is adequately confirmed [using BSL-2 laboratory procedures]." These recommendations are relevant to the June 2014 incident in Atlanta but were not followed. The laboratories receiving the protein extractions were BSL-2 laboratories, but the activities associated with testing with the MALDI TOF technology were conducted on open laboratory benches, not using biocontainment cabinets otherwise available in such laboratories.

CDC's July 11, 2014, *Report on the Potential Exposure to Anthrax* describes a number of actions that CDC plans to take within its responsibilities to avoid another incident like the one in June. However, we continue to believe that a national strategy is warranted that would evaluate the requirements for high-containment laboratories, set and maintain national standards for such laboratories' construction and operation, and maintain a national strategy for the oversight of laboratories that conduct important research on highly infectious pathogens.

This completes my formal statement, Chairman Murphy, Ranking Member DeGette and members of the committee. I am happy to answer any questions you may have.

GAO Contact and Staff Acknowledgments

For future contacts regarding this statement, please contact Nancy Kingsbury at (202) 512-2700 or at kingsburyn@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this statement. Sushil Sharma, Ph.D., Dr.PH, Assistant Director; and Elaine L. Vaurio also made key contributions to this statement.

Related GAO Products

High-Containment Laboratories: Assessment of the Nation's Need Is Missing. GAO-13-466R. Washington, D.C.: February 25, 2013.

Biological Laboratories: Design and Implementation Considerations for Safety Reporting Systems. GAO-10-850. Washington, D.C.: September 10, 2010.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-1045T. Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-1036T. Washington, D.C.: September 22, 2009.

High-Containment Laboratories: National Strategy for Oversight Is Needed. GAO-09-574. Washington, D.C.: September 21, 2009.

Biological Research: Observations on DHS's Analyses Concerning Whether FMD Research Can Be Done as Safely on the Mainland as on Plum Island. GAO-09-747. Washington, D.C.: July 30, 2009.

High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland. GAO-08-821T. Washington, D.C.: May 22, 2008.

High-Containment Biosafety 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.: October 4, 2007.

Biological Research Laboratories: Issues Associated with the Expansion of Laboratories Funded by the National Institute of Allergy and Infectious Diseases. GAO-07-333R. Washington, D.C.: February 22, 2007.

Homeland Security: CDC's Oversight of the Select Agent Program GAO-03-315R. Washington, D.C.: November 22, 2002.

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Mr. MURPHY. Thank you, Dr. Kingsbury. I will now recognize myself for 5 minutes.

Dr. Frieden, is anthrax a biological agent that has been or could be used in warfare?

Dr. FRIEDEN. Yes.

Mr. MURPHY. And the mishandling of anthrax can have some real consequences. If someone were sickened by anthrax, what would some of the symptoms be?

Dr. FRIEDEN. Anthrax can cause a variety of symptoms, but the most severe forms are respiratory anthrax, which can cause severe illness or death.

Mr. MURPHY. I have an image here of some workers handling testing for anthrax, et cetera. One sees that generally you're—this is not in a lab, but some other workers investigating. When I tour labs, and thank you for this slide, the number of levels there of what is required for breathing, for covering clothes before and after is pretty severe.

I have got to ask this question. Now, these are lined, but this is a Ziploc bag. And I haveto think what in heaven's name would go through the minds of some scientists thinking a Ziploc bag is enough to protect someone from anthrax when we have other instances of all that paraphernalia someone has to wear when they are dealing with anthrax. Have you talked to these personnel involved with transporting anthrax and asked them why?

Dr. FRIEDEN. I have been directly involved in the investigation. I will be directly involved in the remediation of the problems that we find. Many of the issues that are mentioned in the APHIS findings relate to what was done with the material that was believed to have been inactivated. So once the laboratory had said here is killed anthrax, it was handled by the staff in those lower containment laboratories as if it were not infectious.

Our subsequent studies suggest that it is likely that it was not, but the core error there was the failure to——

Mr. MURPHY. But, Dr. Frieden, this is like saying I did not know the gun was loaded, but somebody got shot. But you should always assume it is. For someone to say, well, I did not think the anthrax was live is not acceptable. And quite frankly, I wonder if you have the ability to not only reprimand such personnel, but to fire them, to suspend them from working with pathogens that are deadly.

Quite frankly, do they understand that the extent to which this went could have left them in a condition where they were charged with criminal negligence, or negligent homicide, or reckless endangerment? Do they understand the seriousness of this to the American public health?

Dr. FRIEDEN. I think, first, your idea, Mr. Chairman, of a two-key system as is used in other circumstances is quite appropriate here both within the high containment laboratories and to verify that stuff coming out is safe if it does come out, because stuff has to come out of those laboratories to be tested or worked with elsewhere.

In terms of disciplinary proceedings, what we want to do is strike the right balance. On the one hand, we recognize the need to make sweeping improvements in our culture of safety, and part of that means that staff need to feel comfortable any time saying, "hey,

there may be a problem here," coming forward. At the same time, if our investigation finds that there is negligence, that people knowingly failed to report, or took actions that were likely to or should have been known to endanger themselves or others, then we will take appropriate action.

Mr. MURPHY. Well, I am looking at Dr. Dick, who has said that people who were not approved were able to handle select agents, were able to access space containing or potentially contaminated with anthrax at least through June 17th, 4 days after the incident was discovered. Now, my assumption is these scientists and their aides are pretty smart people, but it is extremely disturbing to think that they are not thinking of this.

But let me ask this. It has been a week since you learned about the March 2014 CDC shipment of H5N1 influenza. And there was a 6-week delay in notifying. Have you found out why there was a 6-week delay, and was there a cover-up involved in that, or are the bureaucratic hurdles too high? What was the cause?

Dr. FRIEDEN. I have only gotten some very preliminary information on that. I will make a general point, however. When we look at emergencies in emergency departments or intensive care units in the healthcare sector, the biggest problem is not usually a failure to respond effectively when people recognize there is an emergency. It is a failure to recognize that the situation is an emergency or something that requires immediate attention. But we have not completed our investigation of that, and we will look at all possibilities.

Mr. MURPHY. Is there any kind of notification or alarm system that lets people know when there has been a release or a problem there?

Dr. FRIEDEN. There are multiple alarm systems within CDC. In this case, it was a cross-contamination of a culture, so somehow, and we have not figured out how yet, a relatively low virulence Avian influenza was cross-contaminated in our laboratory with the high pathogenic H5N1.

Mr. MURPHY. I get more alarms going off when you try and walk out of Walmart with a shirt that has not been paid for. You see those happening all the time. Is there any evidence of cover-up here from employees not wanting to let someone else know that somebody else——

Dr. FRIEDEN. No. We have seen at this point no evidence of a cover-up, but we do see the need to strengthen the culture of safety that encourages reporting any time there is a problem or a potential problem so that we can assess it and take rapid and prompt action.

Mr. MURPHY. Thank you. I now recognize Ms. DeGette for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. Dr. Kingsbury, let me just make sure that I heard your testimony right. You testified that there is an increasing number of labs that are handling these bioagents, correct?

Ms. KINGSBURY. Correct.

Ms. DEGETTE. And you said that there is really no one agency in charge, is that correct?

Ms. KINGSBURY. Correct.

Ms. DEGETTE. Now, you said that today, but in 2007, the GAO testified before this committee the same thing, no single government agency was responsible for tracking all of these labs.

Ms. KINGSBURY. That is correct.

Ms. DEGETTE. That is correct, too. Dr. Frieden, are you aware of this finding by the GAO going back all the way to 2007?

Dr. FRIEDEN. Yes, I am.

Ms. DEGETTE. And do you agree with Dr. Kingsbury that there are an increasing number of labs handling these bioagents?

Dr. FRIEDEN. If we look over the past 10 years or so, it is my understanding that there is an increasing number.

Ms. DEGETTE. And do you agree with her that there has never been one agency in charge despite the red flags going up all of these years?

Dr. FRIEDEN. There is a clear division of responsibilities between CDC and APHIS in terms of select agent oversight, inspection, and enforcement. Several years ago at my direction, we turned over the inspection of CDC's select agent laboratories to APHIS, which has conducted them since that point. But the overarching issue of laboratory safety is one that does touch many parts of both the public sector and the non-governmental sector.

Ms. DEGETTE. So are you saying that APHIS is in charge now since you put that into effect the last few years?

Dr. FRIEDEN. In terms of the inspection of laboratories which are working with select agents, there is a clear division of responsibility between ourselves and APHIS.

Ms. DEGETTE. Does that mean APHIS is in charge, yes or no?

Dr. FRIEDEN. APHIS is in charge of investigating CDC's select agent laboratories. APHIS is not in charge of the overall enterprise.

Ms. DEGETTE. So do you think we need to clarify who is going to be in charge of the overall enterprise?

Dr. FRIEDEN. We are certainly willing to look at every suggestion to improve laboratory safety and biosecurity.

Ms. DEGETTE. Do you think it would be useful if we had one agency in charge of all of the inspections and making sure people were doing things in the right way?

Dr. FRIEDEN. I have seen several suggestions for how we could improve the process BSL–3 oversight and select agent oversight. And my sense is that each of these ideas is certainly worth exploring.

Ms. DEGETTE. What do you think about that, Dr. Kingsbury? Do you think it would be useful to have one agency in charge?

Ms. KINGSBURY. Well, we have said for a number of years, as you know, that there needs to be some entity in charge of a national strategy, not necessarily in charge of every laboratory in the country. The other thing I would point out——

Ms. DEGETTE. So you are saying an agency in charge of developing the protocols and how you are going to do this?

Ms. KINGSBURY. And ensuring biosafety and biosecurity. But the more important issue, and from a strategic point of view, is how many of these laboratories do we really need, for what purpose, against what threat. One of the interesting things that I have become a little bit more sensitive to in the last few weeks is that the whole structure we have that CDC and APHIS are involved in is

around the select agent agents, and there are a lot of other bugs out there in other laboratories that are not select agents that also need to be protected. And there is very little visibility about that sector of this enterprise.

Ms. DEGETTE. And, Dr. Frieden, I am going to assume that you are going to agree with Dr. Kingsbury that it would be very useful to have national safety and security standards that would apply to everybody. Is that correct?

Dr. FRIEDEN. I am not sure I understood the question. I am sorry.

Ms. DEGETTE. OK. Well, what GAO says is that we do not have one single agency developing national biosafety and security standards, and as a result, we have all these labs doing this type of research, a proliferating number of labs. But there is nobody developing standards across all those agencies.

Dr. FRIEDEN. I think there are many aspects of both biosafety and biosecurity which merit careful investigation. And if we can figure out better ways to do them, we are certainly completely open to that——

Ms. DEGETTE. And do you think the protocol should apply to everybody?

Dr. FRIEDEN. The protocols may be very specific for the different situations, but they should all adhere to the highest standard of safety.

Ms. DEGETTE. Dr. Dick, what is your opinion of this?

Mr. DICK. I think that there should be a single oversight body. Right now for the Select Agent Program, there is a single oversight body made up of the Division of Select Agents and Toxins at CDC. There is a single oversight body in Agriculture that makes up the other half of that Select Agent Program.

Together we meet on a monthly basis. We have the directors and assistant directors of the programs that are in the two programs, and we have OGC and other counsel present.

Ms. DEGETTE. But if that is the case, why are we having all these problems then?

Mr. DICK. And so, what we need, what we have is a single set of biosafety and biosecurity regulations that are followed by both sides.

Ms. DEGETTE. But we do not have that now, is that what you are saying?

Mr. DICK. No. What I am saying is that I think we currently do have that. I do agree with Dr. Frieden that eventually after we get done with this investigation, we should take a very close look at all of the issues and see if there are updates that need to be made to biosafety and biosecurity.

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

Mr. GINGREY. Mr. Chairman, thank you. And I am going to address my questions of this panel to Dr. Frieden. Dr. Frieden, thank you very much for being here and providing the subcommittee with your testimony. I actually have a number of questions for you, in fact four, and I will get right to those since time is of the essence.

Firstly, can you please describe the policies and procedures CDC has in place to handle biosafety issues that may arise from human

error like what happened in the Bioterrorism Rapid Response and Advanced Technology Laboratory in Atlanta on June the 5th?

Dr. FRIEDEN. We have extensive policies and procedures. But what we are doing now is implementing a moratorium on all transfers out of BSL–3 and BSL–4 laboratories while we review each laboratory's policies and procedures to ensure that there is appropriate inactivation before any materials are transferred out.

Mr. GINGREY. And I appreciate that answer, and you explained that to us I think last week in an informal setting, and I think that is a good thing. That leads to my second question. What is the impact and the cost of the BRRAT Laboratory shut down? You shut down those two laboratories for X number of days. Do you have a cost estimate in regard to them being offline for a period of time?

Dr. FRIEDEN. I do not have a cost estimate for that. The impact of the moratorium is potentially significant, and so we are working rapidly to rigorously assess protocols and where there are situations such as the diagnosis of drug resistant tuberculosis, or helping to control the Ebola outbreak, or beginning work on next year's flu vaccine. We will work to ensure that we can do that safely in time, but there are real challenges with this moratorium.

One of the things that the BRRAT Lab does, the lab that was associated with the anthrax incident, is to provide to the Laboratory Response Network, a network of over 150 laboratories, proficiency testing to make sure that they can rapidly identify anthrax and other dangerous pathogens safely. So we will figure out a way to do that safely in time.

Mr. GINGREY. Well, I would think time is of the essence in regard to cost. But as you say, safety is the most important factor. You got to get it right, and I certainly agree with that.

Should inactivated select agents be added back to the select agent list?

Dr. FRIEDEN. I think that what we need to ensure is that any inactivation is done completely because once something is inactivated, it may be able to be used. It may be necessary to use that, for example, to diagnose it. And you would not want to have to follow select agent requirements without diagnosing something in a hospital lab, or a clinical lab, or even in the field.

But the key point here is to have that two-key system that the chairman mentioned in that meeting, that two-key system to make sure that when an inactivation is undertaken, it is validated and verified that the materials are inactive.

Mr. GINGREY. The last question, Dr. Frieden. In your testimony, you noted you only learned of the March 13th, 2014 shipment from the CDC influenza lab of a virus that was cross-contaminated with H5N1 to a USDA laboratory on July the 9th. So that is from March 13th when it actually occurred to when you were informed or learned of it July the 9th.

Can you please describe how you are going to improve communications of these incidents up and down the chain of command?

Dr. FRIEDEN. Thank you. In fact, it was the afternoon of our meeting, which was in the morning, when I learned about this, if I remember correctly. What your question gets to is really the crux of the matter, which is how do we improve the culture of safety at

CDC? And I think that is going to involve a number of steps that we think will succeed, but will take time.

We need to encourage reporting. We need to encourage all staff to take responsibility in addition to having a single point of accountability for laboratory safety. We need to have a clear vision of working safely. We are, after all, the prevention agency, and we want to apply that same rigor that we apply to our work in the field and in disease control to preventing any incident from happening in our laboratory.

We also want to build on many of the organizational strengths and identify the laboratories that are doing this very well within CDC and identify the practices that they are taking that will prevent these incidents.

And finally, I think coming up with ways to monitor progress and track progress, and identifying what are called the critical control points. What are the flashpoints? What are the areas where problems may occur, and then developing redundant, effective, validated, monitored ways to address those critical control points, whether it is inactivation, or transfer of materials, or making sure that materials transferred only contain those materials.

We have terrific scientists at CDC, and they are now focusing their creativity, their energy, their commitment on improving our culture of safety.

Mr. GINGREY. Dr. Frieden, thank you very much. And, Mr. Chairman, I will yield back my 30 seconds.

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

Mr. WAXMAN. Thank you, Mr. Chairman. Dr. Frieden, last Friday when you released the CDC report on the anthrax incident, you announced you were imposing a moratorium on CDC transferring any biological samples out of any BSL–3 or BSL–4 labs until they had conducted a lab-by-lab assessment. Additionally, you closed the Bioterrorism Rapid Response and Advanced Technology, or the BRRAT Laboratory, and announced that it will remain closed until it is approved to reopen under safer conditions. These seem like appropriate interim steps until CDC can undertake a comprehensive safety review and ensure that the proper procedures and protocols are in place moving forward.

Dr. Frieden, how long do you anticipate this moratorium lasting and the BRRAT lab being closed?

Dr. FRIEDEN. The short answer to your question is as long as it takes to ensure that they can open safely. The longer answer is that there are some things that need to resume, for example, proficiency testing for select agents in the Laboratory Response Network. And that is something that we will look at very carefully. But I am committed that we will not open them until we can open them safely.

Mr. WAXMAN. What steps are you taking to lift the moratorium and reopen the facilities? When will you know or how will you know when it is safe to do so?

Dr. FRIEDEN. I have appointed Dr. Michael Bell, who is a top expert at CDC not only in laboratory science, but also in safety. He works within the hospital infection control and safety unit of CDC to oversee a high-level working group reporting to me. And they

will develop in the next day or so, finalized criteria by which they will assess each of the laboratories.

And then each laboratory will look at its own protocols and practices and determine whether they are validated, effective, and scientifically proven, and implemented in a way that we can be sure they will be applied. And then each laboratory will apply to him for resumption and lifting of the moratorium. I will review his recommendations and ultimately approve laboratory-by-laboratory a reopening of this process.

I would just mention this is not a small thing because many of our laboratories that have BSL–3 laboratories have adjacent BSL–2 laboratories. And much of their work has to be done in the BSL–2, so they inactivate in the BSL–3 and then move it to the BSL–2. That work has all stopped at this point until we can ensure that we are doing it safely. And this is one of the things that really is a tipping point for improving the culture of safety at CDC.

Mr. WAXMAN. One of the more disturbing findings of CDC's own report on this incident is that scientists use a pathogenic strain of anthrax when they could have used a non-pathogenic strain, is that not correct?

Dr. FRIEDEN. Yes, that is.

Mr. WAXMAN. Well, when the moratorium is lifted and the BRRAT Lab is reopened, will you have clearer standards and protocols to make sure scientists are not unnecessarily using potentially dangerous strains of bacteria when it is not necessary?

Dr. FRIEDEN. Yes.

Mr. WAXMAN. GAO and APHIS both conducted investigations of the BRRAT Laboratory following the June anthrax exposure. Dr. Kingsbury and Dr. Dick, you believe the moratorium and lab closure an appropriate response to this incident, do you not?

Mr. DICK. Yes, I do.

Mr. WAXMAN. OK. We should not forget today that the reason CDC conducts their special agent research is to help keep the American public safe. CDC serves a critical role for studying dangerous pathogens and finding cures and vaccines for deadly diseases. These labs are critical to our Nation's response to bioterrorism threats. So I am interested in learning about how this moratorium and the lab closures are affecting the critical research that these labs were conducting.

Dr. Frieden, how do the moratorium and lab closures limit CDC's research capabilities? What happens to the studies, some of which I am guessing were operating on detailed schedules that were being conducted in the labs?

Dr. FRIEDEN. We are looking at the moratorium now in detail and identifying any laboratories which need to resume transfers for individual patient care or for public health response with highest priority. And we expect that those laboratories we will be able to get reopened for transfer very soon.

But we have already heard from, for example, the laboratory that deals with drug-resistant tuberculosis, the laboratory that deals with Ebola, and the laboratory that deals with Avian influenza, that they have deadlines coming up for either patient care or public health response. And we will address that very quickly. But we will always put safety first.

Mr. WAXMAN. How do the closures and moratorium affect research occurring at other labs outside of the Roybal campus?

Dr. FRIEDEN. We provide proficiency testing and other materials to laboratories, and so there may be impacts on some of our partners. But the one that we are most aware of now and we will work to address before the deadline is provision of materials that companies need to make next year's flu vaccine. And we anticipate being able to do that on time.

Mr. WAXMAN. My time has expired, but it seems to me that protecting the safety and health of your scientists, the moratorium, and the lab closures appear to be the appropriate response. Thank you, Mr. Chairman.

Mr. MURPHY. Thank you. The gentleman's time has expired. I now recognize Mr. Barton for 5 minutes.

Mr. BARTON. Thank you, Mr. Chairman. In answer to a previous question, Dr. Kingsbury raised the point about how many laboratories there are. The GAO has indicated that there are probably too many laboratories.

My first question would be to you, Dr. Frieden. Why do we have so many laboratories, and are they all necessary?

Dr. FRIEDEN. I do not know that there is a right number of laboratories out there. Our job within CDC is to make sure that we only work with dangerous pathogens where it is necessary to do that and that we do so safely. And we will be taking a fresh look everywhere we work with these pathogens internally at CDC to make sure that it is kept to the minimum necessary to serve the function of responding to infectious disease outbreaks.

We still have anthrax in nature and respond to events like that. We still have Ebola with the largest outbreak in history now in West Africa. So the challenges we have are substantial.

In terms of outside laboratories, our function in the Division of Select Agents and Toxins is to ensure that the laboratories that are there are operating safely.

Mr. BARTON. Well, it would seem that one way to increase security would be to have fewer locations and fewer laboratories. I mean, if you are only using the extreme case, if you are trying to protect a hundred, that is going to be more difficult than if you are just trying to protect one.

I do not know what the magic number is, but I think especially since the GAO has said there are probably too many, that would be worthy of a look-see. Dr. Kingsbury, do you have an opinion on that?

Ms. KINGSBURY. Well, I am not sure we have actually said there may be too many. I think what we have actually said is nobody knows how many there are, and nobody knows how many we need. And that goes beyond the scope——

Mr. BARTON. Well, that is even worse in a way.

Ms. KINGSBURY. Yes. That goes beyond the scope of CDC and APHIS. And until there can be some kind of strategic look at what our requirements actually are, and they may be changing because of things like the Ebola outbreak and so forth. But somebody ought to be thinking about this, I think, a little bit more broadly than a single agency at a time. And that is basically our point.

Mr. BARTON. Well, I am going to ask the question. Why are there 435 members of Congress? What is magic about 435? And the answer is that is as many seats or desks at the time they could put on the House floor. When they got 435, they could not put anymore, and so it is an odd number, and they just stopped. But there is nothing magic about it.

Ms. KINGSBURY. That is correct.

Mr. BARTON. And the same thing with the laboratory situation. I think there should be a strategic review, and the sooner the better.

The staff has asked me to ask this question. It concerns the fact that beginning in 2012, the United States Department of Agriculture and the Centers for Disease Control entered into a memorandum of understanding that allows the USDA Animal and Plant Health Inspection Service to inspect the CDC laboratories for compliance with the Federal Select Agent Program. Since the Select Agent Program was authorized in 2002, the CDC had been inspecting its own laboratory. Why did CDC decide to turn its inspection process over to the Department of Agriculture? Was that because CDC did not think that it could do the job itself? I will ask Dr. Frieden that.

Dr. FRIEDEN. We have made a number of improvements both in our own laboratories and in our regulatory function through the Division of Select Agents and Toxins. And as I looked at this issue, I was concerned that there was at least the appearance that we could not be objective in inspecting our own laboratories.

I did not believe that was the case. I believed that one part of CDC which has no organizational affiliation with another could do that objectively, but I did not think the appearance was a good idea. So I requested and APHIS graciously agreed to take over inspections of our own campus so that there would not be that appearance of a problem.

Mr. BARTON. If you had to do it over again, would you do the same thing? Was it a good decision to let USDA do the inspection?

Dr. FRIEDEN. Yes. I believe that decision was appropriate. If I had it to do over again, I wish I had recognized the pattern of incidents that we now recognize, which is why we put those prior incidents into our July 11th report.

Mr. BARTON. OK. With that, Mr. Chairman, I yield back, or I can tell an Aggie joke. I yield back, Mr. Chairman.

Mr. MURPHY. OK. Thank you. He yields back. Now, I will recognize Ms. Castor for 5 minutes.

Ms. CASTOR. Thank you very much, Mr. Chairman and the ranking member, for calling this hearing today. I had the opportunity to visit the CDC last spring, and on the surface they appear very serious about laboratory security. And yet every few years there are these lapses, and now an anthrax scare, and an Avian flu issue that was not reported in a timely manner.

And we have very high expectations for everyone at the CDC. I am impressed with everything that is happening there, but for the high containment biological laboratories, to have these lapses is not acceptable.

So it is really troubling that although numerous government agencies over the past few years have warned CDC about problems

at the high containment labs, it appears CDC has not heeded those warnings. We know of at least 14 separate reports, letters, and lab investigations from GAO, the U.S. Animal and Plant Health Inspection Service, and HHS Inspector General that documented a series of safety lapses and lack of oversight at CDC high containment labs.

Dr. Kingsbury, your testimony is invaluable here. Can you tell us more about the concerns GAO has identified with regard to safety lapses at the high containment labs? You have said now someone has got to look at the number of labs across the country as well. Who is that? What entity is that? What are your recommendations there?

Ms. KINGSBURY. I wish I was in a position to say I know the answer to that. One of the difficulties that we faced in making that suggestion is that when you look around the government, because they are being built and managed across multiple agencies and each agency has its own mission and its own focus, it is difficult to think about who would be the single agency.

We have discussed the issue with the Office of Science and Technology Policy at the White House, but while they have some overarching responsibilities, they do not have staff and management officials that would permit actually doing it that way.

So we do not really have a good answer to that question, but we think it is worth just keeping the issue on the table, particularly in tight budget times.

Ms. CASTOR. You mentioned in your opening statement that you have heightened concerns because of budget cuts. Talk a little bit about that. Is there a particular area we should be focused on?

Ms. KINGSBURY. Well, it is just that, as I said in my statement, the building, and management, and upgrade of these kinds of laboratories is relatively expensive compared to just building ordinary buildings. And so, if we are going to have X number of laboratories, I would like to see the strategy that was going to permit us even in tight budget times to continue to fund them, to continue to upgrade them when necessary, and to manage the biosafety and biosecurity programs that are necessary to keep them safe. So that total picture just is not available now, and that worries us.

Ms. CASTOR. OK. Dr. Dick, do you think this has anything to do with budget cuts?

Mr. DICK. I do not believe that it has anything to do directly with budget cuts. We have been able to accomplish our mission in support of the Select Agent Program over the recent years and provide the funding that is necessary.

Ms. CASTOR. OK. And before the June anthrax incident, APHIS conducted at least six separate investigations at CDC's Roybal campus facilities in 2013 and 2014. Can you summarize your findings in those investigations?

Mr. DICK. Yes. I think there were a number of findings, some of which were found in the recent finding, some of which were not. Simple things that people maybe think are simple, unlocked refrigerators, those kinds of things, up to and including more serious incidents, if you will around inactivation protocols not being up to date.

Ms. CASTOR. And, Dr. Frieden, it is troubling. I mean, this has gone on for years now with GAO, APHIS, the Inspector General, outside experts calling attention to these issues. And I am encouraged because you have been forthcoming in your statements. You have not been defensive. But what is your current action plan now going forward in detail? Is there a culture among researchers? What is it, and get specific for us from this day forward with these recommendations, what are you going to do in the timeframe? Thank you.

Dr. FRIEDEN. Well, first, I think for path incidents, the staff at CDC and the scientists did take the reports seriously and did respond to those individual reports. What we missed was a pattern. And you are absolutely right that that pattern was an inadequate culture of safety. So the overarching challenge now is to ensure that we establish and strengthen a culture of safety in all of our laboratories throughout all of CDC. And there are a number of steps that we are doing to begin to do that.

The first is the moratorium so that we can stop and think about that particular procedure of inactivation, make sure it is done right, the appointment of a single point of accountability for laboratory safety throughout CDC, the establishment of a working group that that person and Mr. Henderson will lead. The invitation to an external advisory group, and I intend to invite some of the leading independent experts of the country by the end of this week to serve on that advisory group for CDC. A hard look at all of the critical control points where there may be a problem with lab safety, and reviewing to make sure that we have protocols in place that are validated and verified. It gets back to that trust but verify approach.

We need to make sure that we are empowering our laboratory staff to report and to identify ways to improve safety and security. We also need to verify that that is happening.

Mr. MURPHY. OK, thank you. The gentlelady's time has expired. I will now recognize Ms. Blackburn of Tennessee for 5 minutes.

Ms. BLACKBURN. Thank you, Mr. Chairman. Dr. Frieden, I want to come back to you. And if you will go to tab 15, the USDA APHIS investigation, and let us look at that. This started 10 days after the event. There were 18 days after possible exposure, and you had a lot of really awful basic errors. Even you admit there is not a culture of safety. There is not that double check system.

And it is something that when you look at worker safety, how it was compromised, and then the management lacking the basic information on what substances to use to have the contamination cleaned up.

So looking at this tab and that investigation, I want you to detail for the committee what new policies have been designed as a result of this and how did CDC guarantee that the new policies are followed, effective immediately.

You know, our hospitals and organizations get all sorts of new rules from HHS on Friday afternoons at 4:00. They are effective immediately. So I want you to detail for us how you implemented that and what the new policies are.

Dr. FRIEDEN. So effective immediately, all transfers not just from these two laboratories, but from every single BSL–3 and BSL–4

laboratory at CDC have been stopped. Effective immediately, these two laboratories, the BSL–3 part of the influenza laboratory, and the BRRAT Lab for the bioterror response, have been closed. Those two laboratories will not be reopened until both APHIS and I are confident that they can be reopened safely.

We have also appointed a single point of accountability to look at this and to review before we reopen, before we begin any more transfers, procedures that are in place to ensure that they can be done safely.

Ms. BLACKBURN. How could it possibly have transpired that your management team could not even decide on the formula of bleach to use to clean up the contamination or to see whether the on-site clinic was thorough and consistent in examining the staff potentially exposed to the anthrax?

Dr. FRIEDEN. In the first week after the anthrax potential exposure was identified, we did not respond in the way that we would respond to an outside emergency. And that is one of our after action findings that when we deal with emergencies, whether it is Ebola, or fungal meningitis, or another problem, we activate our Emergency Operations Center. Or even if we do not activate it, we utilize the resources of that center to have a systematic, structured, intensive, immediate response. That was not done for the first week after the anthrax potential exposure, and that is something that we will be sure to do in the event of any such internal event in the future.

Ms. BLACKBURN. Let me ask you this. Did the management team get preferential treatment to the point that they were unaware that the staff was turned away?

Dr. FRIEDEN. No. Absolutely not.

Ms. BLACKBURN. OK. And then why did the staff not feel confident in expressing their worries to their managers so that they could get adequate treatment?

Dr. FRIEDEN. I am not certain what is behind that. I do know that part of encouraging and strengthening the culture of safety is making sure that people are encouraged and, in fact, reinforced and rewarded for bringing forth problems if they think there are problems and potential problems.

Ms. BLACKBURN. Do you think it had to do with the existing work culture that was there at the CDC?

Dr. FRIEDEN. I think at CDC scientists are so used to risk, they go out into dangerous places where they are not sure what the risks are going to be. But sometimes if you work year in and year out with pathogens that are scary, you can get inured to that danger.

Ms. BLACKBURN. OK. Let me ask you another question. Once the June incident was discovered, why? Why did it take you so long to track down the anthrax, and why was there not a record of where this was stored?

Dr. FRIEDEN. Well, on June 13th, as soon as we identified that there was the potential that any of the plates that were sent out of the containment lab were not sterile, we immediately recovered those plates and put them back in the secure facilities. That is the best of my understanding.

Ms. BLACKBURN. Why was there not a record of where it was stored, and why was it stored in unlocked refrigerators, stuck in an un-posted room or in hallways?

Dr. FRIEDEN. My understanding, and we will have to confirm that in the coming days, is that those findings relate to primarily the materials that were believed to have been sterile and sent out of the laboratory. It is not as if there were anthrax cultures being kept in an unlocked, unsecured place.

I think the point there was there was that once that initial error was made of thinking something had been inactivated when it had not been or may not have been inactivated, then that material was then out of the containment space. That is my understanding.

Ms. BLACKBURN. Thank you. Mr. Chairman, I yield back.

Mr. MURPHY. All right. I now recognize Mr. Green of Texas for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman. First, for all of our panel, there are a number of Federal agencies that handle some of these substances, not just CDC. Is there a general protocol that all the agencies look at and coordinate handling these substances? Dr. Frieden?

Dr. FRIEDEN. When it comes to select agents, then both CDC and APHIS establish standards and then inspect and enforce those standards. Other than select agents, there are agency-by-agency or entity-by-entity approaches that may be specific to the type of research or to the type of agent.

Mr. GREEN. OK. So there is some umbrella type standard for all Federal agencies.

Dr. FRIEDEN. For select agents there is.

Mr. GREEN. OK. Dr. Kingsbury, can you summarize your recommendations for us, and can you elaborate on which of these recommendations would require congressional action?

Ms. KINGSBURY. If you are talking about our recommendations, I think that resolving this issue of whether there is a national strategy probably cannot be done without congressional action, and it will take some thought to get us there.

Mr. GREEN. OK. Dr. Frieden, do you agree with these recommendations, and will you be implementing them that you can within your control?

Dr. FRIEDEN. In terms of laboratory safety recommendations for CDC, we will do everything to implement these recommendations. The report that we released on July 11th has a number of steps that we are already beginning to implement.

Mr. GREEN. OK. Any of them require congressional action, or is that something you control within your Agency?

Dr. FRIEDEN. At this point, I am not aware of anything that would require congressional action for us to take appropriate steps.

Mr. GREEN. Dr. Dick, do you have any recommendations for Congress or CDC that Congress needs to deal with?

Mr. DICK. At this point in this investigation, we do not have anything that cannot be controlled through the Select Agent Program and our work with CDC.

Mr. GREEN. OK. Dr. Frieden, does CDC, based on the findings in your report, have any recommendation to Congress? You have none for us?

Dr. FRIEDEN. We are focused at this point on doing our jobs as well as possible, ensuring that we strengthen laboratory safety throughout CDC, and use the findings from this experience to strengthen our regulatory function through our Division of Select Agents and Toxins, which inspects and regulates hundreds of entities around the country that work with these materials.

Mr. GREEN. OK. Let me ask you about the CDC budget. And again, I have heard other questions from my colleagues that this was not a budget issue as much. Has CDC received adequate funding from Congress to conduct its safety mission, period? Obviously you have other missions.

Dr. FRIEDEN. I think the challenges for safety are more than just funding. There are a variety of issues in implementing safety policies and procedures, and I do not think the primary issue here is a lack of funding.

Mr. GREEN. OK. Some of the witnesses we have been hearing from today have stated CDC employees need better training and that there needs to be better standard operating procedures, but overall there is a problem with the culture at CDC. Dr. Frieden, do you agree with these assertions?

Dr. FRIEDEN. I do agree with them. I think that while we have scientists who are the best in the world at what they do, they have not always applied that same rigor that they do to their scientific experiments to improving safety. And that is why we are taking a number of steps to strengthen the culture of safety at CDC.

And part of that is to encourage reporting of potential or actual problems. And because of that it is possible, though I do not know of anything at this point that I am aware of, it is possible that in the coming weeks and months we will hear of other things in the past or that occur. And that may be a reflection that we have strengthened that culture of safety rather than that we failed to address it.

Mr. GREEN. Well, if it is an issue of culture, and again, like you said, you have some great labs, and I am familiar with some of them. Is it just because they deal with these dangerous substances so often they get lax, and they are more interested in what they are working with than maybe the safety of what they are dealing with?

Dr. FRIEDEN. I think that is a significant part of it, that if you work with something, even if it is a deadly microbe, day in and day out, year after year, you get a level of familiarity that may lead to doing things that you really should not do. And that is why we have to have double checks in place, policies, and protocols, training, and a culture of safety with the vision that we will work to minimize risk such that no worker and the public are never exposed to a risk that could have been prevented in our laboratories.

Mr. GREEN. And I guess that complacency, it needs to be monitored literally every day 24/7 because of what you do. Is that part of what you are trying to do at CDC with the guidance for other agencies?

Dr. FRIEDEN. Absolutely. That is what we have done by establishing a single point of accountability for laboratory safety, an empowered working group that will work with that individual, but emphasizing that even with that individual and even with that

group, laboratory safety is really something that everyone who touches a laboratory needs to be conscious of and think of ways to continuously improve.

Mr. GREEN. OK. Mr. Chairman, I would hope that we would have a follow-up in a few months to see the success. And again, it is almost like re-training some of the smartest people in the country to be certain what they are doing with the substance they are dealing with. And I yield back my time.

Mr. MURPHY. I think that is a good idea, but I do want to add also, Dr. Kingsbury, when you were responding to Mr. Green's question about other congressional authorization would be required, can you get this committee details on what that would be?

Ms. KINGSBURY. I do not actually have a basis on which to be specific about what might need to be done. I think we probably need to continue to work with your staff to talk through what some of the options might be going forward.

Mr. MURPHY. Thank you. Mr. Harper is recognized for 5 minutes.

Mr. HARPER. Thank you, Mr. Chairman, and thank you for holding this hearing on a very important issue. And certainly some agencies can be dysfunctional and there is no concern or no real harm in that. But the CDC is one that cannot be dysfunctional, so we are very concerned about safety within the labs for obviously the workers there, and certainly for the public on how we are going to address that.

And if I could, Dr. Frieden, to refer to Tab 7. That is a letter that you sent in September 2012 to the committee responding to concerns about CDC lab safety. In that you stated that a senior official was designated to report directly to you about safety issues and those things there. Who was that senior official?

Dr. FRIEDEN. I will have to get back to you about that to get you the name and the details of what was done pursuant to that letter.

Mr. HARPER. OK. Then obviously the question would be, and I wish you could have answered today, was who was that senior official, and what were the results of that action. And then the question that perhaps you can answer now is how is the appointment of Dr. Michael Bell as the new CDC point person over lab safety when we do not even know who the old point person was, how is that going to be more effective other than we know his name?

Dr. FRIEDEN. What I believe to be the case is that we did in 2012 similar to what we did in other incidents was we did address comprehensively the specific problems that were identified. So there were concerns about some airflow issues. There were concerns about some of the security issues in our laboratories.

And while I would never say that we are 100 percent resolved on those things, we really focused on those particular problems. What we missed was the broader pattern, and that is what Dr. Bell is overseeing now.

Mr. HARPER. So does this mean that there will be always a point person, is that what your plan——

Dr. FRIEDEN. Yes. Dr. Bell is the person now. We will transition that to a single point of accountability for lab safety. And one of the things that Dr. Bell and his group will do is to recommend where that entity should sit within CDC to be most effective.

Mr. HARPER. Dr. Dick, the CDC reported that since 2007 there have been two surprise inspections of CDC, both performed by CDC's Division of Select Agents and Toxins before APHIS took over inspections of CDC labs. Since 2012 I am showing that APHIS has conducted 11 inspections of CDC labs. I would like to know why APHIS has not conducted any surprise inspections of CDC labs, or have they done that?

Mr. DICK. Thank you for the question. We conduct surprise inspections to enforce compliance between renewal inspections, which is every 3 years. As we stated, we came on in late 2012 as the oversight entity for CDC. At the Roybal Lab, we actually have been there six, seven if you include this last incident, times in that year and a half. So we have not had an opportunity to do a surprise inspection since we are there regularly.

Mr. HARPER. So the last time a surprise inspection was done was when?

Mr. DICK. We have not done a surprise inspection prior to taking over in 2012. I am not familiar with before that.

Mr. HARPER. And obviously I will not ruin the surprise by asking when one is planned. But it does seem like we——

Mr. DICK. We intend to follow up on——

Mr. HARPER [continuing]. That that is a great tool to have.

Mr. DICK. Absolutely, and certainly first and foremost we are going to be following up on the current incident with them and making a revisit when CDC indicates that they are ready for us to revisit. And then we will be doing surprise inspections after that point.

Mr. HARPER. Let us say that, and this is for you, Dr. Frieden, or for you, Dr. Dick. If it is determined that a dangerous biological agent has been stolen, who do you report that to?

Dr. FRIEDEN. So we have a protocol for dealing with theft. There has been no theft of a biological agent reported from either CDC or any of the regulated facilities in the 10 years of the program to my knowledge. When there are concerns for potential theft or misplacement, we work with law enforcement, including the FBI, to do a joint investigation. I would just mention that our expansion of surprise inspections was something that we directed over the last few years at CDC because we felt that was very important to do.

Mr. HARPER. So you said there have been no reports of stolen agents.

Dr. FRIEDEN. That is my understanding.

Mr. HARPER. But what about missing biological agents?

Dr. FRIEDEN. There have been losses at certain facilities, and in those circumstances we also coordinate with the FBI. Usually it is an issue of inventory control, so as earlier we were talking about critical control points, such as inactivation of virulent pathogens. Similarly, inventory is a critical control point.

Mr. HARPER. Yield back.

Mr. MURPHY. Thank you. I do want to ask clarification of Mr. Harper's question, though. When he asked about theft of an item, your inventory control is not so tight that someone could not, I mean, someone could take something, replicate it, and walk out with something. Am I correct on that?

Dr. FRIEDEN. Inventory control is one of the critical controls to prevent loss or theft. But there have been to my knowledge no thefts reported from any of the select agent regulated labs, including CDC's, over the past decade.

Mr. MURPHY. Well, there was at the Army one in Texas, I believe, a few years ago.

Dr. FRIEDEN. I am not familiar with that.

Mr. MURPHY. Thank you. Mr. Tonko, you are recognized for 5 minutes.

Mr. TONKO. Thank you, Mr. Chair. Welcome to our panelists. The CDC is responsible for registration and oversight of all laboratories that possess, use, or transfer select agents that could pose a threat to human health, while APHIS is responsible for those select agents that pose a threat to animal or plant health. Select agents that pose a threat to both human and animal health, like anthrax, are regulated by both CDC and APHIS.

So that being said, Dr. Kingsbury, can you tell us what GAO has found with regard to the increase in the number of high containment bio labs?

Ms. KINGSBURY. I have got that on. I am not sure I understand your question. I think within the Select Agent Program, I think there is information about how many laboratories there are, and they are regularly inspected as these gentlemen have just been saying.

Our concern about the national strategy is that there are a lot of other laboratories that deal with highly infectious pathogens that are not considered to be select agents, and nobody knows how many of those laboratories there are.

Mr. TONKO. But with the high containment bio labs, in that given category, is there an increase that has been measured by your review?

Ms. KINGSBURY. I mean, I did not hear the word.

Mr. TONKO. Is there an increase in the number of——

Ms. KINGSBURY. There has been an increase since the anthrax attacks in 2001. The last time we actually tried to count them was 2 or 3 years ago, and I think at that point it looked like there were slightly fewer than there had been the year before, which we sort of think is maybe just a budget problem. But that, again, is the only ones that people are actually aware of.

I think there are private entities and perhaps State government entities that have BSL–3 and BSL–4 laboratories that are not overseen in the same way and that is of a little concern to us.

Mr. TONKO. Well, what accounts for the growing numbers of these labs that you suggested are out there?

Ms. KINGSBURY. Well, following the anthrax attacks in 2001, there are a number of agencies whose missions touched on the issue of biological weapons and whether those pathogens could be used to attack our country. And so each within their own sphere developed a program to counter those possible threats, and each got funded by the Congress to build additional laboratories and so forth. So it is just a fragmented program that had a very strong rationale at the beginning, but right now I think there is perhaps a different rationale that might be articulated. But nobody is in charge of doing that.

Mr. TONKO. So with this increase in the number of labs and these various missions associated, what would your recommendations be to addressing——

Ms. KINGSBURY. Well, we have made recommendations that there should be a single entity that has responsibility for developing a national strategic plan and national standards for the operations of high containment laboratories. The dilemma is figuring out how to do that in the current environment with competing interests among the agencies involved and so forth. There is even a competing interest issue in the Congress since different committees of the Congress have different jurisdictions over these different agencies.

So it is a tough problem to solve, but we think it would be worth spending some time even at a theoretical strategic level to begin to address this issue and think through how we would go about doing it in the future.

Mr. TONKO. And, Dr. Frieden, what are your views here in terms of the growing numbers of these labs and how to move forward with the activity here in the U.S.?

Dr. FRIEDEN. I do think this is a complicated topic for which there is probably not a quick and simple solution. But just logically, the more places work with dangerous pathogens goes on, the more possibility there is of accidents or accidental releases. So ensuring the work that happens is happening in a safe environment is critical.

And the key concept I think we have to apply is risk benefit. I do not think we can ever guarantee zero risk for some of the things that are done, but we can do everything humanly possible to get that risk as low as possible. But we have to ensure that the benefit is something that is reasonably likely to occur.

Mr. TONKO. Thank you. Thank you very much. With that I yield back, Mr. Chair.

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

Mr. GRIFFITH. Thank you, Mr. Chairman. I appreciate that, and I appreciate you all being here today to testify to us.

Dr. Frieden, if I could get you to turn to Tab 5 in the booklet. And as you look at that Tab 5, that is the HHS Inspector General report regarding the CDC Roybal facility, which says it was sent to you. Have you seen this before at some point? The front page says it was sent to you.

Dr. FRIEDEN. I have it.

Mr. GRIFFITH. OK. And then if I could direct you to page 5, and on page 5 it says that the Inspector General's Office could not verify that 10 out of 30 sample-approved individuals for select agents had received the required training. And do you see that on that page?

Dr. FRIEDEN. Yes.

Mr. GRIFFITH. And likewise it says that select agent inventory records are incomplete, and you also acknowledge that that is on that page?

Dr. FRIEDEN. Yes.

Mr. GRIFFITH. And then if go over to page 6, the report says that there were agents stored in areas not listed in the registration. You see that at the top of the page as well, page 6.

Dr. FRIEDEN. Yes.

Mr. GRIFFITH. Thank you. And one example given is that scientists found a vial of select agent in a drawer and another scientist discovered 16 vials stored in an unsecured freezer. Do you see that in that paragraph?

Dr. FRIEDEN. Yes.

Mr. GRIFFITH. Yes. And the report on page 6 also states that there were unauthorized transfers and packages received by unapproved individuals. Now, my concern is this. This is at the Roybal facility. Were these not the same kind of violations that then popped up and were found in subsequent inspections by the USDA in 2013 and 2014, and then revealed again in the matter that brings us here today in the anthrax and influenza incidents of 2014? Are they not the same types of problems?

Dr. FRIEDEN. The answer is yes and no. The specific problems that were found led to a specific response. For example, on security we implemented layers of security. We strengthened the systems. We improved personal background checks and security. So in each of these, we felt——

Mr. GRIFFITH. Let me ask you this question. Did you all do a system-wide after these problems were discovered because we have 2010, and then we have got 2013, and earlier in 2014? Did you all ever do a system-wide re-check?

Dr. FRIEDEN. Not adequately. Not adequately. We addressed the specific problems, I believe, with a sincere effort to rectify them, but what we missed was the broader pattern that we are now addressing by strengthening our culture of safety in our labs.

Mr. GRIFFITH. All right, and I do appreciate that, and I know that you are having to answer a lot of tough questions, and I appreciate your demeanor here today. I do think that is appropriate and appreciated.

That being said, let us look over page 7, and then on top of page 8 there are five recommendations there. If you could read those out loud that take place, and then let me know if they were followed up on.

Dr. FRIEDEN. Well, I can shorten this by saying that the key one is the fifth, and the fifth has to do with confirming that materials are inactive before transferring them. And that was specifically what was not done in the anthrax incident. So if we had applied this broadly, this incident would not have happened.

Specifically, just to give you a sense of it, in 2006, the same laboratory, the BRRAT Lab, had a pretty similar incident, and that is why I directed that it be put into our July 11th report. And after that incident, they implemented a standard operating procedure for that particular type of biological material leaving their laboratory. But when they had a different type of biological laboratory—excuse me—biological material leaving the same laboratory, they did not apply that standard operating procedure that would have inactivated it.

So I do think it is the lack of adequate pattern recognition that has led us until these last few weeks not to undertake the kind of

comprehensive, sweeping change and improvement in our laboratory safety culture that we are now implementing.

Mr. GRIFFITH. Well, I appreciate that. Now, what about the other four? Number five may have been the most important, but could you look at the other four?

Dr. FRIEDEN. The first has to do with physical security measures, and I believe we have taken a number of steps there. There are still steps that we need to do better on in that area having to do with staff coming in and not swiping in every time.

Mr. GRIFFITH. And you have indicated you are going to have training, which is number three. What about number two?

Dr. FRIEDEN. Yes. I think we have made a great deal of progress on ensuring that only approved individuals are allowed access to select agents, and Mr. Henderson can speak more to that.

Mr. GRIFFITH. All right. You have got 20 seconds to do number four.

Dr. FRIEDEN. Inventory is an area where we have done a number of things, but given the recent incident at NIH and the fact that inventory is a flashpoint, we will be reviewing all of our inventory work. It is a massive job to do it right, but we will do that as well.

Mr. GRIFFITH. Well, and I appreciate that. The safety of the American public rests in your hands. Thank you, and I yield back. Thank you.

Mr. MURPHY. Thank you. I now recognize Ms. Schakowsky for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. And I want to thank the witnesses. As you can see from the tone of this hearing, there is complete bipartisan concern about what happened here. And what I wanted to concentrate on is not the incidents themselves, but then the response in particular to the anthrax release.

The CDC report described delays in identification of potentially exposed individuals, and potentially affected lab rooms, and communication of the possible release of anthrax to all CDC staff that may have been exposed, and that there was no clear lead for response to this incident in the first week.

So, I know you have discussed a number of these things, but it is the management piece once a problem was discovered. And so, I wanted to ask you, Dr. Frieden, what was your response to this finding?

Dr. FRIEDEN. This was our finding, and we indicated that when we deal with outside events, and we are currently dealing, for example, with Ebola in West Africa where we have the largest outbreak ever, we activate our Emergency Operations Center, or sometimes we will use the facilities of the Emergency Operations Center to manage our response more effectively.

We should have done that the moment we learned of the potential exposure. What that allows us to do is break down a big problem into smaller problems and address them one by one: communications, employee safety, clinical care, decontamination, scientific evaluation and investigation. And so, instead of doing that in a systematic way, it was done unsystematically, and not as well as it should have been done.

In those first few days, which I remember vividly, we were really focused on the employees who may have been exposed and making sure that they got into care and got on treatment.

Ms. SCHAKOWSKY. But it took a while to even identify who those people were.

Dr. FRIEDEN. Yes. In the effort to do that, we identified that we did not have the kind of systems that were needed or the systems that we had in place were not used promptly, for example, viewing security camera coverage to see who had come into and left the facilities on time. That was not done because one part of the Agency did not know or did not use those resources. The root cause of that problem was not activating our Incident Command System.

Ms. SCHAKOWSKY. OK. Dr. Dick, can you elaborate on that finding about response?

Mr. DICK. Yes. I think our findings were very similar to Dr. Frieden's. We had an independent team that came in during. There was still an ongoing investigation by CDC and their staff, and our Select Agent Group was interviewing employees and workers from the various sections that were responding to this.

We found very similar findings to those that he just indicated.

Ms. SCHAKOWSKY. You know, I wanted to follow up for a second on what the chairman was saying about the possibility of even stealing something that is a threat. You know, in the smallpox incident, it turned out that the vials were discovered at NIH, but they could have been somewhere else. Nobody seemed to know. And that is really disturbing, too, that, you know, who knows? Somebody could have taken them out. So I am not sure when you say that nothing has been stolen, that it also says that nothing could have been stolen. Respond to that, Dr. Frieden?

Dr. FRIEDEN. Well, we have taken a number of steps to strengthen the security aspects of select agent registration. Those steps include suitability assessments for all people who work with tier one agents. They include looking at cyber security issues and personnel reliability, ongoing access of personnel who have access to tier one agents, increased physical security standards, incident response plans, and ongoing training. So I do think that the concern for theft is real.

Some of these organisms still occur in nature and ensuring that where there are laboratories not just in this country, but around the world, that you test on them.

Ms. SCHAKOWSKY. Well, let us worry about this country right now, and smallpox, of course, would be a big concern. Let me just end with this, if I could, Mr. Chairman. Whenever I hear the word "culture," and a "cultural problem," I know we have a real challenge on our hands, you know. Hand washing change the face of medicine. It is not sexy, and people do not win Nobel Prizes over that kind of thing. But it really as part of the culture has made our medical system much more successful, huge advance.

And so, these kinds of small things that deal with culture, and attitude, and awareness of these kinds of very simple things, we need to really figure out, you need primarily to figure out how to make them part of the everyday thinking of your staff. And, you know, we are willing participants here. And I yield back.

Dr. FRIEDEN. Thank you.

Mr. MURPHY. Thank you. I now recognize Mr. Johnson of Ohio for 5 minutes.

Mr. JOHNSON. Thank you, Mr. Chairman. And I, too, want to thank our witnesses for joining us today. Dr. Frieden, it looks like you are the guy on the hot seat. You are getting peppered with all the questions, and I have got a few for you as well.

You know, the mission of CDC laboratories, as you well know, includes carrying out work to protect the American public against bioterrorist activities. Now, critical lab activities are shut down pending the outcome of your remedial evaluation and reform. So how will CDC be able to address any bioterrorism or other emergencies which might occur before they reopen?

Dr. FRIEDEN. There is just one particular laboratory that is shut. There are multiple other laboratories at CDC that continue their operation that would be able to respond to bioterrorist and a potential bioterrorist incident.

Mr. JOHNSON. OK. So there is no concern on your part that because of these CDC errors that we may be limiting our ability to protect the public.

Dr. FRIEDEN. No, I am confident that the incidents that we saw did not cause any release of agents into the community. They most likely did not cause any actual exposure to CDC staff. But they really are a tipping point in our recognition of the need to improve our laboratory safety. But we are still fully functional in terms of being able to respond to an event.

It is just that step of sending something out of a high containment space into a lower containment space that I have issued a moratorium on, and we will lift that laboratory by laboratory as soon as we are confident we can do that safely.

Mr. JOHNSON. OK. Is the CDC planning to use the National Science Advisory Board for Biosecurity as the external committee to advise CDC on laboratory quality and safety?

Dr. FRIEDEN. What I intend to do is to invite an external advisory group specific to look at CDC and specific to tell us every way they think we can do better in——

Mr. JOHNSON. But what about the National Science Advisory Board for Biosecurity? Are you going to be using them?

Dr. FRIEDEN. That is not our current plan to the best of my understanding.

Mr. JOHNSON. OK, because NIH on Sunday purged almost half of the members from that board, and I was inquisitive about whether you knew about this, why the Administration took this action, and whether or not NIH consulted. Do you use that advisory board for anything?

Dr. FRIEDEN. I would have to get back to you. It is primarily managed by NIH, so I would have to defer to them for the management of that group.

Mr. JOHNSON. All right. Well, that is good. That eliminates one question for you then. For Dr. Dick, in light of the anthrax incident investigation APHIS recently completed, do you think that prior inspections of CDC laboratories were sufficient?

Mr. DICK. I do.

Mr. JOHNSON. OK. Well, given the fact select agents were stored in undesignated places, should such problems have come to light fully as a result of prior inspections?

Mr. DICK. Yes. I think the important thing to recognize is that when we review their protocols, the protocols were in place. And because of the primary cause of this incident, and that was that this bacteria was not inactivated, it was transferred to a laboratory that would not necessarily have to have a locked cabinet. And so, therefore, when we provide our report on select agents, as was indicated earlier, we also report on those laboratories where that select agent went, in this case not deactivated.

Mr. JOHNSON. OK. All right. Well, that concludes my questions, Mr. Chairman. I yield back the balance of my time.

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

Mr. LONG. Thank you, Mr. Chairman. Dr. Frieden, are you familiar with this picture?

Dr. FRIEDEN. I certainly am.

Mr. LONG. Well, I am going to turn 59 years old in less than a month, and this vial is dated 17 months before I was born. And apparently it was located in a cooler where?

Dr. FRIEDEN. On the NIH campus.

Mr. LONG. Last week.

Dr. FRIEDEN. A little over that.

Mr. LONG. In recent——

Dr. FRIEDEN. Yes.

Mr. LONG. Recently.

Dr. FRIEDEN. Yes.

Mr. LONG. So this vial of smallpox that is older than I am had been in a cooler, am I given to understand, in one location? I cannot even imagine a cooler running for 60 years, 61 years.

Dr. FRIEDEN. My understanding is that it was a walk-in cold room that was used for storage.

Mr. LONG. And someone walked in and discovered this smallpox.

Dr. FRIEDEN. What happened was that that laboratory, as I understand it, was transitioned from NIH to FDA many years ago when FDA took over some of those functions. FDA is moving into its new facilities. In the course of moving, it was doing a complete inventory of everything in its facility, and the workers there discovered a large box that had this vial and others in it.

Mr. LONG. Workers like moving workers?

Dr. FRIEDEN. No, laboratory scientists.

Mr. LONG. Lab workers.

Dr. FRIEDEN. Sorry, laboratory scientists, yes.

Mr. LONG. OK. Well, recently there was a case of someone that wanted to remove information from NSA, and he got in a position to do that. And with a $1,500 thumb drive, he was able to take all kinds of severe government secrets with him out of his position he had worked in. Does it bother you at all that people could, if they had cruelty and meanness in mind, that they could get into a cooler like this and take a 61-year-old vial of smallpox?

Dr. FRIEDEN. We are certainly concerned that smallpox, which should not have been there, was there for many years. And we want to ensure that on our campus, and NIH is looking at their

campus, and FDA at theirs, there are not other examples of collections because this was a collection of organisms that are in place and in places where they should not be.

This particular box was clearly created by a scientist who was very experienced or a group of scientists. The materials were essentially freeze dried, or lyophilized is the scientific term for it, and then sealed in that ampule that you held up the picture of. And that was done before smallpox eradication was undertaken, so it was not done with malicious intent. It was done just to preserve something for future——

Mr. LONG. No, no, I know that, but just the fact that this could lay around for 61 years. I cannot even conceive of that thought. But let me take you to a press conference last Friday now that we have moved from 61-plus years ago. At a press conference last Friday, you indicated that the CDC does research to figure out how better to treat people if they are exposed and prevent it, if they are exposed, and how better to prevent it through vaccination. You also stated the fact that anthrax continues to occur in nature, that anthrax has been used as a weapon.

My question is this. How many CDC laboratory workers received the FDA licensed anthrax vaccine prior to the anthrax incident last month as recommended by the CDC, its Advisory Committee on Immunization Practices committee for lab workers since 2002?

Dr. FRIEDEN. I would have to get back to you on the exact number, but we offer anthrax vaccine to anyone for whom anthrax vaccine is indicated. We do not require people to get vaccinated, but we offer it to anyone who might be exposed through their laboratory or epidemiologic work.

Mr. LONG. So you think that is a pretty active program?

Dr. FRIEDEN. Oh, yes.

Mr. LONG. Do you have any idea? I mean, you say you have to get back to me, which is fine if you will. I appreciate it.

Dr. FRIEDEN. I would have to get back to you.

Mr. LONG. OK, because it is reported that you told Reuters on June 30th the fact that anthrax exposure was even a concern or that it might have happened is unacceptable. Employees should never have to be concerned about the safety from preventable exposures. And as you note, to date more than 12 million doses of BioThrax, the FDA licensed anthrax vaccine, have been administered to more than 3 million individuals. So if you can get back to me with that, I would appreciate it.

Dr. FRIEDEN. I will.

Mr. LONG. And with that, Mr. Chairman, I yield back.

Mr. MURPHY. Thank you. I now recognize Ms. Ellmers of North Carolina for 5 minutes.

Ms. ELLMERS. Thank you, Mr. Chairman, and thank you to our panel. This is a very good discussion, and I appreciate your candid responses. I think that at this point the most important thing that we all can do is get to the bottom of it and correct the issues at hand so that these things do not happen again.

I did want to clarify something. Dr. Frieden, there was a question posed to you about the number of missing possible toxic substances. And I know you had acknowledged that over time there has been an account of some missing, but not stolen, correct? If

something is missing, how do you determine that it absolutely was not stolen? And if anyone else on the panel would like to comment on that, I would appreciate it as well.

Dr. FRIEDEN. So to give you an example, there may have been a package that was sent from one location to another and had a select agent in it. It did not arrive at the second location. The FBI was involved in that investigation, and the FBI concluded in one particular case as an example that the package had been inadvertently destroyed, but it had not been stolen or lost. Is there anything you would like to add to that?

Mr. HENDERSON. Just one thing I think is important is we take the notion of chain of custody very seriously, so we are always trying to be mindful of where the select agents are stored, and if they are in transport, we have eyes on them or somebody trusted to be with them as much as possible. Occasionally, Dr. Frieden is correct, there could be an accounting issue where something has been destroyed and they did not complete the paperwork, and then we have to go and try to understand what happened. And there have been a couple of instances like that.

Ms. ELLMERS. OK. Thank you for clarifying that for me. And again, getting back to just some of the toxic substances that have been found in boxes that may not have stated what they were in a refrigerated walk-in storage or otherwise. When the NIH ran across their most recent problem, they put in place what they call a clean sweep. And I know you had said that there was a transition between NIH and FDA. Were they already in the process? I mean, is that what the clean sweep is that you were talking about, or did they institute the clean sweep afterwards?

Dr. FRIEDEN. My understanding is that both NIH and FDA are doing complete inventory checks and follow-up to the discovery of the smallpox vials.

Ms. ELLMERS. OK. So once that happened— So I guess my question for you is, is the CDC doing the same?

Dr. FRIEDEN. Yes. We will undertake a comprehensive inventory review at all of our facilities.

Ms. ELLMERS. At all the facilities.

Dr. FRIEDEN. That is my understanding.

Ms. ELLMERS. Including the one that is shut down now obviously.

Dr. FRIEDEN. Yes. Yes.

Ms. ELLMERS. But all of them.

Dr. FRIEDEN. All of our lab facilities.

Ms. ELLMERS. Great. Well, thank you. I have time if anyone wants to use it, Mr. Chairman. But I yield back right now if no one else wants my time.

Mr. MURPHY. Right. I believe that concludes our first panel. So I thank all the witnesses for coming today, and we will just let you step away while we prepare the second panel.

I would also remind everybody that we will have some follow-up questions for you, so please get back to us quick.

Ms. DEGETTE. Mr. Chairman, will you yield for one second?

Mr. MURPHY. Yes, I will be glad to.

Ms. DEGETTE. I would just hope that we would have this panel back in the fall after Dr. Frieden completes his investigation and puts his controls in place. I think it is really important for us to

know what they are doing, and I know they are working hard on this.

Mr. MURPHY. I agree with that, and we would like to hear again, so we will have you back.[Recess.]

Mr. MURPHY. Well, while they are getting ready, I will get the next panel introduced. We will have Mr. Sean Kaufman, who is the President and Founding Partner of Behavioral-Based Improvement Solutions, LLC. We also have Dr. Richard Ebright, who is a Board of Governors Professor of Chemistry and Chemical Biology at Rutgers University, and Laboratory Director at the Waksman Institute of Microbiology.

While the witnesses are stepping up here, I will be swearing them in. Are you sitting in your right seats there? I am sorry, I do not know what the means. Mr. Kaufman, are you ready? Where is Dr. Ebright? The witness is AWOL I guess.

What we may do to get going here, Mr. Kaufman, let me swear you in so you can get started on your testimony, and then we will swear in Dr. Ebright when he returns.

So you are aware the committee is holding an investigative hearing and doing so has a practice of taking testimony under oath. Do you have any objections to testifying under oath?

Mr. KAUFMAN. No.

Mr. MURPHY. And advise you under the rules of the House, you can be advised by counsel. Do you have a desire to be advised by counsel during testimony today?

Mr. KAUFMAN. That is correct.

Mr. MURPHY. You do have counsel with you?

Mr. KAUFMAN. I do not.

Mr. MURPHY. OK, thank you. Could you please raise your right hand and I will swear you in.[Witness sworn.]

Mr. MURPHY. Thank you very much. You are now under oath subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute summary of your written statement. Go ahead.

TESTIMONIES OF SEAN KAUFMAN, PRESIDENT AND FOUNDING PARTNER, BEHAVIORAL-BASED IMPROVEMENT SOLUTIONS, LLC; RICHARD EBRIGHT, RUTGERS UNIVERSITY, BOARD OF GOVERNORS, PROFESSOR OF CHEMISTRY AND CHEMICAL BIOLOGY

TESTIMONY OF SEAN G. KAUFMAN

Mr. KAUFMAN. Fantastic. Thank you. Chairman Murphy, Ranking Member DeGatte, and the members of the subcommittee, thank you for the opportunity to be here to testify on the Centers for Disease Control and Prevention anthrax laboratory incident.

Let me begin by commending the CDC, specifically the actions taken to protect the workforce and inform the general public during this very serious issue. I stand by my belief that when someone does something wrong, we cannot forget what they have done right, and in general we must not forget that CDC has an outstanding history of service.

For over 10 years I have been providing biosafety training programs for individuals working in high containment laboratories.

My background is in behavioral science, and I specialize in motivating individuals to behave to mitigate risks associated with infectious diseases.

There are three main challenges we face when doing scientific research: the agent, the people working with the agent, and the organization where the work is being done. The first challenge of working safely with infectious agents has been for decades, and can be, appropriately mitigated. Effective engineering controls, personal protective equipment, and standard operating procedures are already in place. However, it is important to recognize that one person and one error, whether it is unintentional or intentional, can negate all these controls in an instant.

This leads me to the second challenge we face when looking at safe science, and that is the people working with the agent. Human risk factors, such as risk perceptions, attitudes, behavior, complacency, outrage, apathy, and perceived mastery must be addressed to sustain optimal performance of the scientific workforce.

We must accept and learn from and control for human error in the laboratory environment. In other words, we must stop focusing on the who and start focusing on the why, how, and what went wrong, passing no judgment other than we are all human, which would lead to solutions minimizing further human error.

Our final and greatest challenge is the existing social norms or safety culture within an organization. Let me repeat myself. The greatest challenge we face specific to safe science is not the agent. It is not the worker. It is the culture of the organization. The culture of an organization permits norms to be developed, and it is within these norms that behavior is either deemed acceptable or unacceptable.

As a former proud CDC employee, I am very, very disappointed by what I am hearing. It has been and remains very clear that this issue is a systemic one or an organizational issue rather than an issue of a laboratory director and two scientists. I have become irritated by the unnecessary finger pointing and statements surrounding disciplinary actions of scientists who worked in parallel with the culture of the organization and made an unintentional error.

The incident highlights the need for scientific protocols to be reviewed and verified, ensuring they work and they can be done by those working in a laboratory. This incident highlights the need to ensure those protocols are followed, and if they are not, consequences aimed at minimizing future failures are immediately applied.

This incident calls for more evidence-based biosafety research to determine what specifically works and minimize risks associated with the challenges that we face, which again are the agent, the people, and the organization.

In the years I have been doing training, I have been forced to speak a common language around the world. No matter where you are in the United States of America or around the world, people can relate to the concept of neighborhood, house, and family. I have used a home, sweet home approachfor establishing a healthy culture in my laboratory trainings.

Please consider this analogy. A laboratory is a home. The scientists working within the laboratory are a family. The scientific protocols are the house rules. If one member of the family breaks the house rules, it puts the whole family at risk. If breaking the rules is not addressed, the whole house is at risk and begins to affect other houses in the neighborhood.

Let me clarify. If scientists do not follow their house rules, it impacts other laboratories within the organization. CDC is a neighborhood that houses hundreds of houses or actually has hundreds of labs. If the neighborhood does not establish a set of ground rules for all the houses, then each house begins to do their own thing, and inevitably the neighborhood is at risk.

Building a culture of safety starts with establishing a commitment to the residents, or the scientists, of that neighborhood or that organization. We do not banish family members for unintentional errors. We encourage homeowners or labs directors to come together and find solutions. We establish consequences for neighborhood members, scientists who blatantly choose to break neighborhood rules. We support each other, especially when unintentional accidents occur.

We talk about incidents, not hide them, so the whole neighborhood learns and grows from them. We recognize that together we are safer. This commitment is contagious and spreads to homes throughout the neighborhood, and that includes laboratories throughout an organization. This is just the start of culture change, folks. The seed we plant today is what we will reap 5 years from now.

Somewhere out there may be a scientist or an organization who finds something unexpected in a freezer, or as a human being makes an unintentional error. A choice has to be made. Do I report this or not? I ask this committee to facilitate a process which encourages organizations to report incidents and accidents rather than punishing them for doing so.

CDC remains a national treasure, and the United States of America remains the land of opportunity for scientists and biological research. Placing untested mandates as a result of this incident on scientists and institutions of research may not only push science and innovation outside of infectious disease research, but worse, it could shift it to other regions of the world.

I ask this committee to continue to take a leadership role while considering the implications of this hearing and future legislation. I look forward to your questions.

[The prepared testimony of Mr. Kaufman follows:]

Sean G. Kaufman

President and Founding Partner
Behavioral-Based Improvement Solutions

July 14, 2014

Written Testimony

Review of CDC Anthrax Lab Incident

INTRODUCTION

Chairman Murphy, Ranking Member DeGette and members of the Sub-Committee – I am pleased to have the opportunity to appear before you today in regards to the recent CDC Anthrax Lab Incident.

I am Sean Kaufman, President and Founding Partner of Behavioral-Based Improvement Solutions, a small business providing professional development programs for individuals working in high-containment facilities (BSL3 and BSL4). I have trained thousands of individuals in biosafety related topics, offering insights and increasing skills needed to operate safely in high-containment laboratory environments.

I am a former employee of CDC and was involved in the Amerthrax response in Trenton, New Jersey. During this detail, I worked directly with postal employees exposed to Anthrax and provided the information and resources needed for the successful completion of their prophylactic treatment. During the past 10 years, I developed and directed the Emory University BSL3/BSL4 Science and Safety Mock Training Laboratory – a program providing simulation-based training for those working in high-containment facilities.

My background is in behavioral science and infectious diseases. I have always approached biosafety training from the belief that training is only effective if there is change in the thinking and behavior of those I train. Biosafety involves taking a plan, integrating human behavior, and achieving a consistent

desired outcome among individuals with different backgrounds, educational levels, and experiences. I continue to assist laboratory staff with their desire to go home at the end of the day - healthy and disease free, rather than presenting a hazard to their family, friends, and the general public.

OBSERVATIONS

To date, I wish to commend the transparency, communication, and investigative response of the Centers for Disease Control and Prevention (CDC). The protection of the workforce and communication with the general public has been a priority and demonstration of outstanding leadership. There is no doubt that the Centers for Disease Control and Prevention is a United States of America national treasure. Research done within the CDC laboratories assist frontline public health labs with the identification of and response to bioterrorism threats. The research which led to this incident requires interaction between research scientists and dangerous infectious diseases. Unfortunately, the risk of this work can never be completely eliminated. However, with a combination of biosafety controls, policies, oversight and workforce preparedness strategies - risks can be mitigated to acceptable levels.

Biosafety is a strategy aimed at minimizing the unintentional release of a biological agent during the interaction between a scientist and infectious diseases. Although most people spend their lives running away and avoiding infectious diseases, research scientists spend their lives running to and investigating how infectious diseases work. This does not make scientists adrenaline junkies. This makes scientists unique and difficult for the general population to understand. Many individuals cannot grasp the concept of why or how someone could work safely with dangerous infectious diseases – but it has and can be done effectively.

I have provided training to individuals (politicians, first responders, community leader) and know there is a great misunderstanding between what they think and what really happens in a high-containment

laboratory. Work within high-containment (BSL3 and BSL4) facilities is very strategic and deliberate. Millions of dollars are spent on engineering equipment designed to keep the agents scientists are working with contained within the laboratory environment. Thousands of dollars are spent on personal protective equipment designed to protect all portals of entry (not allowing the agent to enter the human body) should there be an unexpected incident (spill or BSC failure). Hundreds of hours are spent developing standard operating procedures (SOPs) which are designed to strategically mitigate risks associated with the laboratory work. Additional programs ensure scientists are trained, that compliance with SOPs occur, and that incidents are documented. Scientists also participate in medical surveillance programs and receive background checks to ensure security of the agents they work with. The magnitude of system failures that lead to a laboratory caused illness (or LAI) are great and uncommon.

It is my belief the general public is safer as a result of the research being done within the high-containment laboratories at CDC. However, no system is 100% fail safe. In an instant, one person can negate all controls mentioned above with a small deviation of behavior. This fact is something which has been and will remain the greatest challenge to safety in science.

The observations included in this testimony come from over 10 years of providing biosafety and leadership training to scientists working in multiple high-containment facilities in the United States of America and around the world. I have also trained all of the scientists involved in the CDC Anthrax Laboratory Incident on biosafety.

The Laboratory Director and two scientists involved in this incident are hardworking and accomplished scientific professionals. It is my belief this incident did not occur as a result of incompetence. I also believe this is not a problem of one or two scientists, it is a problem of a culture which exists within a specific organization.

The culture of an organization permits norms to be developed and it is within those norms that behavior is either deemed acceptable or not acceptable. All scientists involved in this incident sought counsel from manufacturers and leaders in other laboratories at CDC before and during the work leading to this incident. They did not act alone, irresponsibly, belligerently, carelessly, or with any intent to hurt themselves or others. At no time did any of these scientists believe they were doing anything wrong. They were operating at a professional standard, in an organization which had developed few controls surrounding the approval, adaptation, review, verification, and implementation of SOPs.

It is very clear to many that the greatest risk in a biological laboratory is not the agent, it is the people working with the agent. However, this incident along with other recent incidents has identified an even greater risk. The safety culture of the organization establishes performance expectations of scientists interacting with dangerous infectious diseases.

It is my belief the CDC high-containment laboratory safety culture largely contributed to this incident. The rush to discipline scientists who make unintentional errors is an indicator that leadership within CDC continues to look at who made the error instead of looking at what caused the error to occur in the first place. I believe CDC sets the standard and should spend more time reviewing organizational systems, controls, policies, cultural issues and attitudes toward safety.

Currently, the CDC Select Agent Program regulates many private, academic, and state laboratories working with biological agents found to be a serious risk to human health. Additional regulations are required for Tier 1 Agents.

It is my belief that the "Actions Already Underway and Plans for the Future" noted in the CDC Report on the Potential Exposure to Anthrax are actions which could have been implemented several years ago – after similar events had occurred. If implemented, these actions may have prevented the recent incident from occurring because they may have established a process for reviewing and approving

scientific inactivation protocols – increasing organizational performance expectations among CDC scientists.

At no time during this incident were the scientists or laboratory director doing anything that would put themselves or others at unnecessary risk (including the work with virulent agents). Decisions (specific to this incident) were made by intelligent and competent individuals for good reasons. An unintentional human error occurred. Hindsight is always 20/20 and moving forward, identifying solutions to effectively prevent this kind of event from happening again is essential.

Though individual actions must be assessed (to determine what happened), we must also include an assessment of the organizational culture which not only permitted but allowed for these actions to occur. This assessment will assist in determining if this incident is an isolated (blame falls on the individuals involved) issue and/or a systemic (organizational) issue. That being said, there is clear evidence with the recent reports of new and past CDC incidents, this incident is a systemic issue and not an isolated one.

When reviewing the incident details, this incident occurred as a result of many reasons in addition to problems with the organization's safety culture. The CDC Anthrax Lab Incident was also a result of a training failure. Biosafety training for scientists working in high-containment facilities consists of multiple phases. It is my belief the individuals involved in this incident were appropriately trained in biosafety. However, before working with a specific agent and in a high-containment laboratory - scientists must have a deep understanding of the agent they are working with and receive on-the-job training which would include the mastery of inactivation protocols.

It is my belief the scientist involved in this protocol did not receive adequate job specific training. This is a systemic problem not only for this laboratory at CDC but for the majority of research laboratories around the world. SOPs are written and passed on to scientists with the expectation that it can be

followed and reproduced with great consistency. Unfortunately, it is my observation that SOPs alone dc not produce consistent results among different individuals. Therefore, it is critical that organizational leaders verify laboratory staff have the ability to demonstrate scientific SOPs as intended by the author of the SOP rather than the reader of it.

Another systemic issue which goes beyond the walls of CDC is the lack of continued professional development of those working in high-containment laboratories. Organizational safety requires frequent investment in the workforce instead of a "one and done" investment philosophy. Most scientists spend less than 1% of the total on-the-job time (40 hours a week x 46 weeks = 1840 hours x .01 = 18 hours per year) in professional development. These development opportunities play a critical role in controlling human risk factors related to this work by increasing situational awareness, which counters issues of perceived mastery, complacency, apathy, and outrage.

Assessing organizational culture, ensuring the workforce is adequately trained, and providing frequent professional development programs for scientists are great starts, but much more is needed.

I have never met a scientist who comes to work to intentionally infect themselves or others around them. However, one scientist behaving in a bubble among other scientists can produce unacceptable results. It is the responsibility of the organization to ensure SOPs are being followed. There must be accountability for scientists choosing not to follow SOPs. SOPs must be considered house rules and those working in the house (laboratory) are only as safe as the weakest family member (scientist choosing not to follow SOPs). Unfortunately, many organizations struggle to ensure the house rules are followed, as there are no regulatory actions for handling willfully non-compliant scientists. As a result, scientists start doing their own thing which then puts everyone in the laboratory at risk. Laboratory SOPs must be followed and consequences should be identified for when they are not.

As stated before, this incident did not involve scientists who intentionally chose not to follow SOPs. This incident also occurred because a process to review protocols for safety issues was not utilized.

When scientific protocols are not reviewed and vetted by peers to ensure all issues have been considered, things can be overlooked and incidents like this one can occur. In this case, not only was the scientist not SOP verified (meaning had not demonstrated the ability to follow the inactivation SOP as the author intended) but differences between the biological agents being worked on in one laboratory (*Brucella*) versus the other laboratory (*B. anthracis*) were not considered, and the SOP was not modified accordingly - leading to a sterility test being administered prior to complete inactivation of a biological agent.

Another systemic issue is the lack of communicated expectations from organizational leadership to research scientists. It is my belief that scientists be asked to formally agree to a set of behavioral expectations, established from previous laboratory incidents leading to illnesses or deaths. During the past five years, I have been successful in motivating many scientists to annually sign behavioral expectation contracts for working in biological laboratories.

The difference between a lesson learned and lesson ignored is change – and if CDC does not change as a result of this incident – the message will have been ignored and this incident could happen again. If change does occur, we must make sure it enhances safety and does not lead to a reverse safety issue (an action taken to increase safety but leads to an increase in risk instead).

I believe science has an outstanding safety record, however I cannot point to data or baseline information because it does not exist. We don't know how safe science is - primarily because there is an enormous need for the funding of research in biosafety – ensuring that what we are asking scientists to do (from a safety perspective) is effective and not wasteful of limited research dollars.

If there is any good coming out of this incident, it is the fact that others are learning from it. There is no doubt scientists and biosafety officers across the country are checking their freezers as a result of the recent Smallpox Incident. They are reviewing their chemical inactivation procedures as a result of this incident. Along with the issues identified above, there is a great need for the reporting, collection, and sharing of all laboratory incidents and accidents. This data base should be readily accessible so scientists and biosafety officers have an opportunity to learn from others instead of repeating the same errors.

CONCLUSIONS

It cannot be disputed research in biological laboratories has contributed to the reduction of mortality caused by infectious diseases. It also cannot be disputed that biological research is still greatly needed, not only for bioterrorism preparedness, but for newly emerging and existing infectious diseases.

It is my hope the CDC leadership accept responsibility for the safety culture which exists within the organization they are leading. I believe CDC has responded exceptionally well during this incident. Staff at CDC have communicated honestly, openly, and with great integrity. The steps which have been identified to move forward are a great start and if implemented will have a profound impact on safety within all laboratories at CDC. However, why these steps were not implemented earlier (as a result of previous incidents) is a question this committee should explore.

There will always be a risk when scientists interact with infectious diseases. However, risks can be adequately mitigated to ensure the health and safety of the scientist and general public. Science has been done safely for many years – and we are getting better with every year that passes. Though this incident did not pose a direct risk to scientists or the general public, it is an important wake up call.

I ask this committee to consider the message this hearing is sending to those watching. Somewhere out there may be a scientist or organization who finds something unexpected in a freezer or as a human-being makes an unintentional error. A choice will have to be made. Do I report this or not? I ask this committee facilitate a process which encourages organizations to report incidents and accidents – rather than punishing them for doing so.

It is my hope that any disciplinary measure taken by the scientists includes the opportunity to be a part of the solution. Organizations must defer from finding fault in who and instead begin focusing on what went wrong. Disciplinary actions which tarnish, damage, or terminate any future opportunity of scientists who make unintended errors as a result of the social norms (culture) within an organization – will do little in preventing this problem from occurring again.

In short, we must begin establishing an effective safety culture. A culture which 1) establishes expectations among scientists, 2) allows peers to review laboratory protocols, 3) holds scientists accountable to their SOPs, 4) provides continued development opportunities which minimize human risk factors, 5) implements validated safety methodologies, and 6) learns from outside laboratory incidents.

The United States of America remains the land of opportunity for scientists and biological research. Placing additional unfunded mandates and administrative tasks on scientists may push science and innovation outside of infectious disease research or worse – to other regions of the world.

I ask that this Committee continue to take a leadership role while considering the implications of this hearing and future legislation.

SUMMARY OF MAJOR POINTS

1. There is no doubt the Centers for Disease Control and Prevention (CDC) remains a national treasure and that research which increases the capacity of frontline public health laboratories to respond to bioterrorism events and newly emergency diseases must continue.

2. During this incident, CDC responded quickly and appropriately – protecting the workforce and informing the general public – demonstrating true leadership during a tough situation.

3. As long as scientists are human and humans are interacting with infectious diseases – science will never be 100% risk free. Human risk factors which include perceived mastery, complacency, apathy, and outrage will continue to pose a challenge to safety.

4. The biological agents and those working with the agents do not pose the greatest risk to safety. The safety culture within the organization (meaning the established social norms and performance expectations of the organization onto the scientists) poses the greatest risk to safety. The organizational safety culture sets parameters of what is defined as acceptable and unacceptable behavior.

5. This incident, along with other similar incidents - provides strong evidence that this issue a systemic (organizational) one throughout CDC high-containment laboratories rather than an isolated one (specific solely to this laboratory and scientists).

6. Preparing a scientist to work in high-containment laboratory consists of multiple phases of training (general risk, biosafety, agent specific, and job specific). This incident occurred as a result of a failure in job specific training with inactivation protocols.

7. The SOP which was used during this incident was not a new one. The SOP had been used in other laboratories at CDC and outside organizations. Additionally, the protocol was recommended by a manufacturer and validated by other scientists prior to being utilized in this incident. The failure to modify and approve the protocol from one laboratory to another led to this incident.

8. An effective safety culture includes the establishment of expectations among scientists, allowing for the peer review of all scientific protocols, holding scientists accountable for **intentional** SOP compliance violations, providing continued professional development opportunities (minimizing human risk factors), implementing validated safety methodologies, and accepting incidents as opportunities to learn (rather than restrict).

9. I believe science has an outstanding safety record, however I cannot point to a central database to prove this belief. Biosafety research funding is desperately needed to ensure what is being recommended to scientists is effective and not wasteful of limited research dollars.

10. Somewhere out there may be a scientist or organization who finds something unexpected in a freezer or as a human-being makes an unintentional error. A choice will have to be made. Do I report this or not? I ask this committee facilitate a process which encourages organizations to report incidents and accidents – rather than punishing them for doing so.

Mr. MURPHY. Thank you, Mr. Kaufman.

Dr. Ebright, you were not available when I swore him in, so I am going to have to swear you in. But first ask you when we are doing an investigative hearing, we take testimony under oath. Do you have any objection to testifying under oath?

Mr. EBRIGHT. I do not.

Mr. MURPHY. And the chair advises under the rules of the House and the rules of the committee you are entitled to be advised by counsel. Do you desire to be advised by counsel today?

Mr. EBRIGHT. I do not.

Mr. MURPHY. In that case, would you please rise and raise your right hand, and I will swear you in.[Witness sworn.]

Mr. MURPHY. Thank you. You are now under oath and subject to the penalties set forth in Title 18, Section 1001 of the United States Code. You may now give a 5-minute verbal summary of your written statement.

TESTIMONY OF RICHARD EBRIGHT

Mr. EBRIGHT. Mr. Chairman, members of the committee, thank you for inviting me to discuss the 2014 CDC anthrax incident and its implications. I am a Board of Governors professor of chemistry and chemical biology at Rutgers University and laboratory director at the Waksman Institute of Microbiology. I will discuss three topics: first, the 2014 CDC anthrax incident; second, broader biosafety and biosecurity issues in CDC bioweapons agent laboratories, also known as select agent laboratories; and, three, broader biosafety and biosecurity issues at the more than 1,000 other government, academic, and corporate select agent laboratories across the U.S. that are regulated by the CDC.

My assessments are based on information in published CDC, HHS OIG, USDA OIG, GAO documents, published press reports, and on my knowledge of biosafety and biosecurity standards for work with bacterial pathogens. I turn first to the 2014 CDC anthrax incident.

I note that the 2014 CDC anthrax incident did not involve one violation in one laboratory, but instead involved an entire series of violations. The 2014 CDC anthrax incident involved multiple violations of biosafety and biosecurity recommendations in each of three different CDC laboratories. There were at least seven distinct violations in total. Had any of three violations in one CDC laboratory not occurred, the incident would not have occurred. Had any of four violations in two other CDC laboratories not occurred, the impact of the incident would have been mitigated.

I note further that the incident reprised nearly exactly a 2004 incident. In the 2004 incident, workers at Southern Research Institute in Frederick, Maryland used an inappropriate procedure to inactivate a sample of anthrax bacteria, used an inappropriate procedure to verify inactivation, and sent putitatively inert, but actually viable, anthrax bacteria to Oakland Children's Hospital, where eight persons were exposed before learning that the anthrax bacteria were viable.

The CDC, as the agency with regulatory responsibility for select agent work relevant to human health, investigated the 2004 Oakland anthrax incident, and in 2005 issued a report on the incident.

The 2005 CDC report included revised biosafety and biosecurity recommendations both for laboratories that prepare and provide inactivated anthrax bacteria and for laboratories that receive and use those inactivated anthrax bacteria.

Had the CDC implemented the recommendations in its own 2005 report, the 2014 CDC anthrax incident could not have occurred. But the CDC did not implement the recommendations in its 2005 report. The fact that the CDC in 2014 made exactly the same errors that had been made in the 2004 Oakland anthrax incident shows that the CDC did not learn from that incident.

I turn now to biosafety and biosecurity in CDC's select agent laboratories. I submit that the 2014 CDC anthrax incident is not an isolated incident, but it is instead part of a pattern, and a pattern that could have been recognized a half decade ago, and should have been. Last week, a CDC report listed multiple other incidents, none previously disclosed to the public, in which CDC laboratories sent putitatively inactivated or attenuated, but actually viable and virulent select agents to other laboratories. These previously undisclosed CDC select agent incidents are fundamentally similar to the 2014 incident. In particular two previously undisclosed incidents from 2006 involved anthrax and appeared to be essentially identical to the current incident. All of these incidents raise both safety and security concerns.

I note further that HHS OIG audits have documented further biosafety and biosecurity violations in CDC select agent labs. HHS OIG audits of the CDC select agent labs in 2008, 2009, and 2010 reported major violations. These violations included failures to ensure physical security, failures to restrict access, and failures to document inventories. They also included the failure to provide required training to workers with training being unverifiable for fully one in three workers in the most recent available report. Perhaps most egregiously, the violations included unauthorized transfers to select agent labs to other laboratories or individuals.

I note further that press reports from 2007 to the present have documented further biosafety and biosecurity deficiencies in CDC select agent laboratories. Examples just to summarize include inadequate provisions for emergency backup power, failure to maintain negative pressure airflow in bio containment areas, non-functioning doors, non-functioning door seals, jury-rigged repairs with duct tape, failure to close entry doors, failure to latch entry doors, failure to assign distinct key codes to the key cards for select agent laboratories, and in at least one case, the discovery of an unescorted, unauthorized person in a restricted area. Taken together, the available documents indicate that the CDC has not adequately ensured biosafety and biosecurity in its own labs, and are consistent with pervasive and systematic violations of biosafety and biosecurity in its own labs.

I turn now to biosafety and biosecurity at CDC.

Mr. MURPHY. Could you summarize the rest of your statement here because we are——

Mr. EBRIGHT. Regulated select agent labs. The CDC and the USDA have regulatory responsibility for biosafety and biosecurity in the approximately 1,000 other U.S. select agent labs: government, academic, and corporate. There is no basis for confidence

that biosafety and biosecurity standards are higher or that select agent inspections are more stringent at CDC regulated, non-CDC select agent labs, than in CDC select agent labs. There also is no basis for confidence that biosafety and biosecurity standards are higher or that select agent inspections are more stringent at USDA regulated select agent laboratories than CDC select agent laboratories.

Deficiencies in select agent standards at these CDC regulated and USDA regulated other laboratories are amply documented in an HHS and USDA OIG audits.

Mr. MURPHY. Doctor, we are over time. I will give you 15 more seconds.

Mr. EBRIGHT. One final point, which is I note that the CDC and USDA not only performed and fund select agent work, but also regulate biosafety and biosecurity for select agent work. This represents a clear conflict of interest. This systematic clear conflict of interest may at least partly account for the deficiencies that I have mentioned. Thank you.

[The prepared testimony of Mr. Ebright follows:]

Written Testimony of Richard H. Ebright

Board of Governors Professor of Chemistry and Chemical Biology, Rutgers University

Laboratory Director, Waksman Institute of Microbiology

Submitted for the Record to the House Energy and Commerce Committee

Subcommittee on Oversight and Investigations

For the Hearing "Review of CDC Anthrax Incident"

July 16, 2014

Mr. Chairman and members of the Committee:

Thank you for inviting me to discuss the 2014 Centers for Disease Control (CDC) anthrax incident and its implications. I am Board of Governors Professor of Chemistry and Chemical Biology at Rutgers, The State University of New Jersey, and Laboratory Director at the Waksman Institute of Microbiology. I direct a biomedical research laboratory and serve as project leader on four National Institutes of Health biomedical research grants. I conduct research on the mechanism of bacterial RNA synthesis and on the development of new antibacterial therapeutic agents able to treat bacterial infections resistant to current drugs. My research involves both priority public health bacterial pathogens (e.g., the pathogens responsible for Staph infections, Strep infections, and tuberculosis) and priority biodefense bacterial pathogens (e.g., the pathogens responsible for anthrax, plague, and tularemia). I am a member of the Institutional Biosafety Committee of Rutgers University and have been a member of the Working Group on Pathogen Security of the state of New Jersey, the Controlling Dangerous Pathogens Project of the Center for International Security Studies, and the Biosecurity Advisory Board of the Center for Civilian Biodefense. Here, I discuss (1) the 2014 CDC anthrax incident, (2) broader biosafety and biosecurity issues at CDC select-agent biocontainment laboratories, and (3) broader biosafety and biosecurity issues at the more than one thousand other government, academic, and corporate bioweapons-agent (select-agent) biocontainment laboratories that are regulated by the CDC and the USDA. My assessments are based on information in published CDC, Health and Human Services Office of Inspector General (HHS OIG), United States Department of Agriculture Office of Inspector General (HHS OIG), and Government Accounting Office (GAO) documents, on published press reports, and on my knowledge of biosafety and biosecurity standards for work with bacterial pathogens.

2014 CDC anthrax incident

The 2014 CDC anthrax incident involved multiple biosafety and biosecurity violations.

The 2014 CDC anthrax incident involved *multiple* violations of biosafety and biosecurity recommendations in each of *three* CDC laboratories (at least seven distinct violations in total). Had any of three violations in one CDC laboratory not occurred, the incident would not have occurred. Had any of four violations in two other CDC laboratories not occurred, the impact of the incident would have been mitigated.

The CDC Bioterrorism Rapid Response and Advanced Technology laboratory (BRRAT) inappropriately chose to use a virulent strain of anthrax bacteria for a project that did not require a virulent strain, inappropriately used a non-standard procedure to inactivate the anthrax bacteria, inappropriately used a non-standard procedure to verify inactivation, and may inappropriately have handled the resulting material in procedures potentially able to aerosolize anthrax bacteria (i.e., preparing and processing a MALDI-TOF plate) without the engineering controls, operating procedures, and personal protective equipment required for a procedure potentially able to aerosolize anthrax bacteria (i.e., level-II or higher biosafety cabinet, gloves, and gown).

BRRAT then distributed samples of the putatively inert, but actually viable, anthrax bacteria to each of two other CDC laboratories (Bacterial Special Pathogens Branch laboratory, BSPB, and Biotechnology Core Facility Branch laboratory, BCFB). Workers in BSPB and BCFB inappropriately assumed, without verification, that the samples were inert and inappropriately handled the material in procedures potentially able to aerosolize anthrax bacteria (i.e., placing a sample under a stream of compressed gas in BSPB and placing a sample on a vortex mixer in BCFB) without the engineering controls, operating procedures, and personal

protective equipment required for procedures potentially able to aerosolize anthrax bacteria (i.e., level-II or higher biosafety cabinet, gloves, and gowns).

As a result, more than 80 individuals were potentially exposed to anthrax bacteria, more than 40 individuals were deemed potentially at risk of infection with anthrax bacteria, and multiple laboratory rooms required closure and decontamination.

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The 2014 CDC anthrax incident reprised, nearly exactly, a 2004 incident.

The 2014 CDC anthrax incident reprised, nearly exactly, a 2004 incident in which workers at Southern Research Institute (SRI) in Frederick MD used an inappropriate procedure to inactivate a sample of anthrax bacteria, used an inappropriate procedure to verify inactivation, and sent the putatively inert, but actually viable, anthrax bacteria to Children's Hospital Oakland Research Institute (CHORI), in Oakland CA, where eight persons were exposed before learning the anthrax bacteria were viable.

The CDC, as the agency with regulatory responsibility for US work with select agents relevant to human health, investigated the 2004 SRI-CHORI anthrax incident. An article in the June 11, 2004 Washington Post quotes CDC spokesperson Karen Hunter as stating "All I know is that we're working with all the institutes involved to find out what happened and make sure it doesn't happen again."

The CDC published its report on the 2004 SRI-CHORI anthrax incident in 2005.

The 2005 CDC report included revised biosafety and biosecurity recommendations for laboratories preparing inactivated anthrax bacteria ("preparing laboratories") and laboratories using samples of inactivated anthrax bacteria ("research laboratories").

The 2005 CDC report stated that:

"Inactivated suspensions of B. anthracis should be cultured both at the preparing laboratory

before shipment and at the research laboratory several days before use to ensure sterility. Sensitivity of sterility testing might be enhanced by increasing the inoculum size and incubation time, and by inoculating in multiple media, including both solid and broth media. Such procedures would increase the probability of detecting even a small number of viable *B. anthracis* spores.

The 2005 CDC report further stated that:

"Research laboratory workers should assume that all inactivated *B. anthracis* suspension materials are infectious until inactivation is adequately confirmed. BSL-2 procedures should be applied to all suspension manipulations performed before confirming sterility. After sterility is confirmed, laboratory personnel should continue to use BSL-2 procedures while performing activities with a high potential for expelling aerosolized spores."

The 2005 CDC report further stated that:

"The Advisory Committee on Immunization Practices recommends routine anthrax vaccination of persons who work with production quantities or concentrations of *B. anthracis* cultures or perform other activities with a high potential for producing infectious aerosols (8). Facilities performing such work should have appropriate biosafety precautions in place to prevent exposure to *B. anthracis* spores; however, anthrax vaccination can be an additional layer of protection in the event of an unrecognized breach in practices or equipment failure. Because of the small potential for inadvertent exposure to aerosolized *B. anthracis* spores before or after sterility testing, vaccination might also be considered for researchers who routinely work with inactivated *B. anthracis* suspensions."

Had the CDC implemented the recommendations in its 2005 report on the 2005 SRI-CHORI anthrax incident, the 2014 CDC anthrax incidents would not have occurred.

But the CDC did not implement the recommendations in its 2005 report.

Contrary to the guidance in the 2005 CDC report:

(1) The CDC preparing laboratory (BRRAT) did not perform the standard sterility testing (reducing the incubation time from the standard 48 hours to a non-standard 24 hours), much less the recommended enhanced sterility testing entailing "increasing the inoculum size and incubation time, and by inoculating in multiple media, including both solid and broth media."

(2) The CDC research laboratories (BSPB and BCFB) did not perform any form of sterility testing, much less the recommended enhanced sterility testing entailing "increasing the inoculum size and incubation time, and by inoculating in multiple media, including both solid and broth media."

(3) The CDC research laboratories (BSPB and BCFB) did not "assume that all inactivated *B. anthracis* suspension materials are infectious until inactivation is adequately confirmed."

(4) The CDC research laboratories (BSPB and BCFB) did not, "use BSL-2 procedures [which minimally include class-II biosafety cabinet, gloves, and gown] while performing activities with a high potential for expelling aerosolized spores."

(5) The CDC research laboratories (BSPB and BCFB) appear not to have provided workers with anthrax vaccination as "an additional layer of protection in the event of an unrecognized breach in practices or equipment failure."

The 2014 CDC anthrax incident shows the CDC did not learn from the 2004 incident.

The fact that the CDC in 2014 made the same errors that had been made by SRI-CHORI in 2004 shows that the CDC did not learn from the 2004 SRI-CHORI anthrax incident. The fact that the CDC had investigated the 2004 SRI-CHORI anthrax incident, had issued biosafety and biosecurity recommendations that would have prevented the repetition of such an incident, but then ignored recommendations, makes the repetition of such an incident even more egregious.

Biosafety and biosecurity at CDC select-agent laboratories

The 2014 CDC anthrax incident is not an isolated incident, but is part of a pattern.

The July 11, 2014 CDC report listed multiple other incidents--none previously disclosed to the public--in which CDC laboratories sent putatively inactivated or attenuated, but actually viable and virulent, select agents to other laboratories:. The incidents included:

(1) Shipping DNA from anthrax bacteria that contained viable anthrax bacteria in 2006 (at least two shipments);

(2) Shipping DNA from botulinum-toxin-producing bacteria that contained viable botulinum-toxin-producing bacteria in 2006;

(3) Shipping putatively attenuated, but actually virulent, brucellosis bacteria in 2001-2009 (multiple shipments, starting in 2001 and continuing until at least 2006 and possibly until 2009).

(4) Shipping low-pathogenicity influenza virus contaminated with highly pathogenic avian influenza virus H5N1 in 2014.

These previously undisclosed CDC select-agent incidents are fundamentally similar to the 2014 CDC anthrax incident. In particular, the previously undisclosed 2006 CDC anthrax incidents may be essentially identical to the 2014 CDC anthrax incident..

All of these incidents raise both safety concerns (potential for accidental exposure) and security concerns (potential for unauthorized and undocumented access to select agents). All of these incidents can be inferred to entail similar errors (inappropriate procedures for sample preparation and/or inappropriate procedures for sample verification).

Press reports document engineering flaws and equipment failures.

Press reports from 2007 through the present have described biosafety and biosecurity engineering flaws and equipment failures at CDC select-agent laboratories, including inadequate provisions for emergency backup power (essential to maintain safety and security containment in the event of a power outage), failure to maintain negative-pressure airflow in biocontainment areas (essential to ensure safety and security containment at all times), non-functioning doors between biocontainment areas and corridors, non-functioning door seals between biocontainment areas and corridors, and jury-rigged repairs to door seals with duct tape.

Press reports also have described perceptions of CDC staff that issues were not promptly corrected after informing CDC management.

Press reports document security violations.

Press reports from 2012 through the present have described security violations in CDC select-agent laboratories, including failure to close secure entry doors to select-agent laboratories, failure to latch secure entry doors to select-agent laboratories, failure to assign distinct key codes to key cards for select-agent laboratories, and, in one case, the discovery of an unescorted unauthorized person in a select-agent laboratory..

Press reports also have described perceptions of CDC staff that issues were not promptly corrected after informing CDC management.

HHS OIG audits document procedural and training lapses.

HHS OIG audits of CDC select-agent laboratories in 2008, 2009, and 2010 (the most recent audits released to date) reported substantive violations. The violations included failures to ensure physical security, restrict access, and document inventories. The violations also included

failure to provide required training to workers (with training being unverifiable for 1 in 3 workers in the most recent available report). Perhaps most egregiously, the violations included unauthorized transfers of select agents to other labs or individuals.

The 2008, 2009, and 2010 HHS OIG audits provide no evidence of improvement. Some of the same kinds of violations occurred repeatedly over the three-year period. The most, and the most serious, kinds of violations appear to have occurred in the most recent year of the three-year period,

Highlights 2008, 2009, and 2010 HHS OIG audits are as follows:

(1) 2008 HHS OIG audit

p8: Did not ensure security during transfers to other labs.

(2) 2009 HHS OIG audit

p6: Did not consistently ensure physical security.

p6: Did not consistently ensure required training.

p11: Did not provide required training before access for more than 1 in 2 select-agent workers.

p12: Entered authorization codes that overrode and defeated electronic access controls.

(3) 2010 HHS OIG audit

p5: Did not consistently ensure physical security, restrict access, provide training, document inventories, and ensure security during transfers to other labs.

p13: Required training unverifiable for 1 in 3 select-agent workers.

p13: Even minimal training unverifiable for 1 select-agent worker.

p14: Unauthorized transfers to other labs.

The evidence indicates that the CDC does not adequately ensure biosafety and biosecurity.

The July 11, 2014 CDC report; 2008, 2009, and 2010 HHS OIG audits; and 2007-2014 press reports indicate that the CDC has not adequately ensured biosafety and biosecurity in CDC select-agent laboratories and are consistent with pervasive and systematic violations of biosafety and biosecurity standards in CDC select-agent laboratories.

Biosafety and biosecurity at CDC- and USDA-regulated select-agent laboratories

The CDC and the USDA have regulatory responsibility for biosafety and biosecurity in US select-agent laboratories.

The CDC has regulatory responsibility for biosafety and biosecurity in all US government and non-government laboratories that possess select agents relevant to human health--including CDC select-agent laboratories.

The USDA has regulatory responsibility for biosafety and biosecurity in all other US government and non-government laboratories that possess select agents relevant to agriculture--including USDA select-agent laboratories.

A 2009 GAO report states that, as of 2008, there were 1,362 registered US select-agent high-level biocontainment laboratories:

(1) 395 federal-government select-agent high-level biocontainment laboratories.

(2) 295 state/local-government select-agent high-level biocontainment laboratories.

(3) 474 academic select-agent high-level biocontainment laboratories.

(4) 125 private non-profit select-agent high-level biocontainment laboratories.

(5) 73 private for-profit select-agent high-level biocontainment laboratories.

A 2013 GAO report states that, as of 2010 (the most recent registration data released to date), there were 1,495 registered US select-agent high-level biocontainment laboratories.

The 2009 and 2013 GAO reports note that the number of US select-agent high-level biocontainment laboratories has increased dramatically since 2001.

The CDC and the USDA do not adequately ensure biosafety and biosecurity in US select-agent laboratories.

2006 and 2012 USDA OIG audits documented flaws in biosafety and biosecurity at non-CDC, non-USDA US select-agent laboratories and also documented flaws in the procedures for, and the reliability of, USDA inspections of non-CDC, non-USDA US select-agent laboratories.

The 2012 USDA audit documented four categories of violations that occurred at US select-agent labs and that had not been detected by USDA select-agent inspections:

(1) Transferring select agents, including anthrax bacteria and plague bacteria, to laboratories not authorized to possess select agents.

(2) Allowing access to select agents by persons lacking current security risk assessments.

(3) Allowing persons lacking documented biosafety/biosecurity training to access select agents.

(4) Allowing persons lacking documented biosafety/biosecurity training to oversee institutional select-agent biosafety/biosecurity.

The violations are significant. The first category of violations is especially significant., in that violations in this category allowed access to select agents by unauthorized institutions and individuals and provided opportunities for theft, loss, or release of select agents.

The failure of USDA select-agent inspections to detect the violations also is significant.

The data presented in the 2012 USDA OIG audit suggest that undetected violations at US select-agent institutions are numerous. The USDA OIG audited only seven US select-agent institutions (a very small fraction of all US select-agent institutions). Nevertheless, for just seven audited institutions, the audit identified multiple previously undetected example of violations in each of the above four categories of violations.

The data presented in the 2012 USDA OIG audit further suggest that undetected violations are widespread. All seven audited institutions were found to have previously undetected violations involving access by persons lacking the required training. Four of the seven audited institutions were found to have previously undetected violations involving oversight of institutional select-agent programs by persons lacking the required training. Four of the seven audited institutions were found to have previously undetected violations involving access by persons lacking current security risk assessments.

The data presented in the 2006 and 2012 USDA OIG audits preclude confidence that the Select Agent Rule is being effectively monitored and enforced.

The 2012 USDA OIG report documented multiple instances in which the USDA OIG recommended corrective measures to the USDA Animal and Plant Health Inspection Service (APHIS), the entity that carries out USDA select-agent inspections, but was rebuffed by APHIS. (The report contains a veritable litany of "APHIS does not concur with the recommendation....APHIS does not concur with the recommendation....APHIS does not concur with the recommendation....APHIS does not concur with the recommendation....") The refusal of APHIS to correct, or even to acknowledge, flaws in its inspection process indicates that APHIS does not prioritize ensuring that the Select Agent Rule is being effectively monitored and enforced.

As described in the preceding sections, available evidence indicates that the CDC has not adequately ensured biosafety and biosecurity standards in CDC select-agent laboratories. There is no basis to believe that biosafety and biosecurity standards are higher, or that select-agent inspections are more stringent, at CDC-regulated, non-CDC select-agent laboratories than in CDC select-agent laboratories. There also is no basis to believe that biosafety and biosecurity standards are higher, or that select-agent inspections are more stringent, at CDC-regulated, non-CDC select-agent laboratories than at the USDA-regulated, non-USDA select-agent laboratories analyzed in the 2006 and 2012 USDA OIG audits.

The fact that the CDC and the USDA not only perform and fund select-agent work, but also regulate biosafety and biosecurity for select-agent work, represents a clear conflict of interest. This conflict of interest may at least partly account for the failure of the CDC and the USDA--evident from the data in the HHS OIG and USDA OIG audits--to ensure adequate biosafety and biosecurity in CDC-regulated and USDA-regulated select-agent programs.

Recommendations

- **Laboratories that send or receive inactivated or attenuated anthrax bacteria should implement the recommendations in the 2005 CDC report.**

- **Laboratories that send or receive inactivated or attenuated select-agent pathogens other than anthrax bacteria should implement recommendations analogous to those in the 2005 CDC report.**

- **The CDC should conduct a systematic review of biosafety and biosecurity engineering controls, operating procedures, personal protective equipment, training, and management in CDC select-agent laboratories; (2) report identified deficiencies; and (3) resolve identified deficiencies.**

- **The CDC should require formal risk-benefit assessments--in which biosafety and biosecurity risks are enumerated, benefits are enumerated, benefits are concluded to outweigh risks, and methods to mitigate risks are identified--before authorizing new projects or new protocols in CDC select-agent laboratories.**

- **Regulatory responsibility for biosafety and biosecurity of US select-agent laboratories should be re-assigned from the CDC and the USDA to an independent entity (an entity that neither conducts nor funds select-agent research).**

- **The number of US select-agent laboratories should be sharply reduced (preferably to fewer than 25-50).**

Appendices

Appendix 1: 2014 CDC Report on 2014 CDC Anthrax Incident

Appendix 2: 2005 CDC Report on 2004 SRI/CHORI Anthrax Incident

Appendix 3: 2008 HHS OIG Audit of CDC Select-Agent Programs

Appendix 4: 2009 HHS OIG Audit of CDC Select-Agent Programs

[The appendices to Mr. Ebright's testimony have been retained in committee files and can be found at http://docs.house.gov/meetings/IF/IF02/20140716/102479/HHRG-113-IF02-Wstate-EbrightR-20140716-SD001.pdf.]

Mr. MURPHY. I thank the two witnesses. I will now recognize myself for 5 minutes.

Mr. Kaufman, you specialize in the area of behavior and behavioral change, along those lines. We have heard from you and other witnesses today this culture of complacency is a concern. Congress has investigated at length problems at the Veterans Administration. We are outraged because of the care we have for our veterans. But we saw that there were cash incentives for people to cover things up, to shred them, to hide waiting lists.

We also had in this committee hearings with Mary Barra, the CEO of General Motors. Americans were outraged about this, and it was described as the culture of complacency or the GM nod. Now we see this behavior problem getting into an area of which before if you were not a veteran or if you did not buy those Chevy cars, you were at least not at risk. But this, when you release a pathogen, it is pretty indiscriminate around anybody who is exposed to it.

So does this routine familiarity around pathogens tend to lead people to cut some corners and just get complacent about this?

Mr. KAUFMAN. I think that there is a—and I believe you know this, too. I think that there is an inherent risk in behavior in general. You over-behave, you run the risk of becoming complacent. You under-behave, you run the risk of being under-prepared. I think it is a very, kind of a balance, and that, in essence, is really, in essence, what professional development, and training, and assessments can be used for to keep that healthy balance in check.

In this case, though, if we are talking about the anthrax incident in the laboratory, I do not believe that this was a complacency issue or even an incompetency issue. I believe this was a scientist that implemented a protocol from another laboratory where it was used for good purposes, and I would love to share what those purposes are. And unfortunately there was no process to vet that protocol.

And so, when it was adapted from one laboratory to another, the inactivation time it takes to kill one agent versus another is a lot more with the spore forming BA or bacillus anthracis than it was with the brucella.

Mr. MURPHY. But we heard so many things that Dr. Ebright was just saying, too, the way the doors were handled, that we have heard about people being in an area that they were not authorized to be there, that a key was left in a refrigerator. It seems to me there are several other elements here where rules are in place and people are just downright sloppy.

Mr. KAUFMAN. Yes. Chairman Murphy, I think the things that you are saying are very true, and they actually must be addressed and concerned. But I think they also have to be put into perspective. You know, this key in a freezer is almost like, and you used a loaded gun or a gun earlier in the session. It is almost like saying that I have a house, and inside my house I have a gun, and my house has a door with locks, and it also has a house alarm. And

upstairs in the master bedroom is hidden a safe, and inside that safe is a gun with a trigger lock that has a key in it.

Mr. MURPHY. But that is not the case here. If a key was left in the refrigerator and people can come into that area, too, if people were all piggybacking on each other's card here, those are violations of rules.

Mr. KAUFMAN. Chairman Murphy, like I said, I am not going to argue the fact that it is a problem because it is. But I am discussing the perspective, and I am telling you I have seen those refrigerators. They are not common practice refrigerators that people just go walking by. These refrigerators are in places where you actually have to have access.

I came in as a civilian. I am not related to CDC. I have been to the laboratory. I have seen these freezers. They are not——

Mr. MURPHY. Well, but the issue is how people behaved, and that is a question I had for Dr. Frieden before is should someone be required to use their actual card so only certain persons can get in, whoever has authorization. It records when they were in there. And in some cases the deadly pathogens require two sets of eyes in there.

Mr. KAUFMAN. Absolutely.

Mr. MURPHY. But part of this, too, I mean, I am not clear on what you are saying, Mr. Kaufman. I want to be clear on that that in some cases, are you making excuses for the persons and saying that there was not enough protocol? I am not sure what you are saying.

Mr. KAUFMAN. No. No, sir. I am not making excuses. What I am saying is that there is a healthy respect for what truly is going on here, and I think we have to look at the spectrum. We cannot be arrogant and say this is just what happens in science, but we also cannot be living in an illusion where this is the end of the earth. We have got to stop all research. We have got to minimize and cut things down to a certain number of laboratories as a result of what happens here.

I think we have to take a balanced approach and take a look at really what happened, and in the culture in which it happened. That is what I am saying.

Mr. MURPHY. Dr. Ebright, do you concur?

Mr. EBRIGHT. I disagree.

Mr. MURPHY. Can you please explain?

Mr. EBRIGHT. So these are problems of individuals, but they are problems of individuals acting in a context. That context has two components. The one is the laboratory culture, and we have talked several times or heard several times today about a culture of lax attitude towards safety. That is part of the problem. We have also heard several times today about researchers becoming inured to working with dangerous or hazardous materials. That is part of the problem.

What has not been mentioned before with respect to culture is hubris, and hubris is fundamentally part of the problem here, a sense of the scientist that he or she should be able to proceed without restriction and without management. So these are all issues with the culture.

But in addition to that culture, you have an institutional structure. You have institutional management, and then you have the oversight of that institution. I think these are even bigger problems that are even more significantly responsible for the issues that I described.

I mentioned the fact that CDC and USDA regulate their own biosafety and biosecurity. They perform the work. They fund the work. That is an inherent conflict of interest. Until that regulatory responsibility is moved out of those two agencies and out of any agency that performs select agent research and funds select research, I believe you can predict with high confidence the same types of problems, the same patterns, and the same cultures will remain in place in CDC labs, in USDA labs, and in the approximately 1,000 other labs they regulate.

Mr. MURPHY. Thank you. My time is way over. I am going to now to recognize Ms. DeGette for 5 minutes.

Ms. DEGETTE. Thank you, Mr. Chairman. I will follow up on your questions. Mr. Kaufman, I have no doubt that these individuals have no ill motives. They are well motivated. They are trying to do their research. And, Dr. Ebright, I think you would agree with that as well.

Mr. EBRIGHT. I would.

Ms. DEGETTE. But let me just put this in context. I do not know if you were here when we gave our opening statements. I have been on this subcommittee since 1997, and I have got to tell you that the reason why we are so concerned here is because this kind of practice keeps happening over and over again. It is not just one isolated incident.

As our memo that I put into the record said, there were six inspections. APHIS identified 29 observations of concerns of facilities and equipment, 27 related to safety and security, and 39 on documentation and record keeping. And a lot of times what we are dealing with in this situation is very, very extreme bioagents that could kill a number of people. And you are nodding your head, so I am assuming you understand this, yes or no?

Mr. KAUFMAN. Yes, I do.

Ms. DEGETTE. OK. So what we are trying to figure out, and like I say, I think the people are trying to do their job. I think they are well motivated. But with all due respect, we are not overreacting here. This has got to be solved.

So what I want to ask you since you were here is, did you hear Ms. Kingsbury's testimony where she said that we need to have one agency at least in charge of developing national standards?

Mr. KAUFMAN. Yes, I did.

Ms. DEGETTE. And what do you think of that? And she admitted that it is going to be difficult to do that because of overlapping jurisdictions. But would you agree that it is worth an effort to try to do that?

Mr. KAUFMAN. I know you like yes and no answers, and I am trying to think. I agree that we should explore what we are doing today and where we could go in the future, yes.

Ms. DEGETTE. OK. Dr. Ebright, what do you think about that suggestion?

Mr. EBRIGHT. There definitely should be a single national agency that sets policy recommendations, policy standards, and advises on needs and how those needs should be met. There also should be a national entity that regulates and oversees the select agent work. They need not be the same, but they both need to be there.

Ms. DEGETTE. And let me just say that we have seen this in this subcommittee, not just at CDC. We have also seen it in the labs. And we saw it at Los Alamos some years ago where some very highly confidential nuclear data disappeared because a researcher took it home to his house. It is the same kind of, you call it hubris or whatever. It is an assumption that there is important research going on, and that nothing bad is going to happen.

Mr. EBRIGHT. Correct.

Ms. DEGETTE. And so, what I think is that, and in fairness I think what Dr. Frieden thinks, too, is you need to put systems in place so that it is not relying on somebody to have that kind of judgment where really you should have a system. Would you agree with that?

Mr. EBRIGHT. Absolutely.

Ms. DEGETTE. And, Mr. Kaufman, would you also agree with that?

Mr. KAUFMAN. Absolutely.

Ms. DEGETTE. OK, great. Thanks, Mr. Chairman. I do not have anything further. Thank you for clarifying, and I will yield back.

Mr. MURPHY. Thank you. The gentlelady yields back. I will now recognize Ms. Blackburn of Tennessee for 5 minutes.

Ms. BLACKBURN. Thank you, Mr. Chairman. I think we are all kind on the same path here with our questions.

Dr. Ebright, I want to come to you. Let us go back to the CDC report from the 2004 anthrax incident, and you mentioned that. And that incident stated "inactivated anthrax should be cultured both at the preparing lab before shipment and at the research lab several days before use to ensure sterility." So did CDC follow their own advice in this? OK, go ahead.

Mr. EBRIGHT. No, they did not. Apparently not in 2006. Definitely not in 2014.

Ms. BLACKBURN. OK. So what we have is a continued pattern of refusing to learn from their past mistakes.

Mr. EBRIGHT. Indeed refusing to read their own reports and follow their own recommendations.

Ms. BLACKBURN. OK. You are the director of a biomedical research lab.

Mr. EBRIGHT. Yes.

Ms. BLACKBURN. And you do some of this same work with dangerous pathogens. And how important is it to you that all personnel in your lab strictly follow your biosafety protocols, and that in order to follow those biosafety protocols, they have an understanding that they have culture of safety that is lacking at CDC?

Mr. EBRIGHT. I think it is critically important. And for biosafety working with biohazardous organisms at any level—one, two, three, or four—that message of safety has to come first. That safety training has to come first. And before any experiment is even begun, there has to be a process of risk benefit assessment in which the investigator enumerates the risks, enumerates the bene-

fits, weights the risks against the benefits, assesses that the risks are outweighed by the benefits. And that process needs to be reviewed by another set of eyes.

Ms. BLACKBURN. Do you follow this as standard operating procedures?

Mr. EBRIGHT. Yes we do for our biological, biohazard research.

Ms. BLACKBURN. Yes. Is it clearly understood from all of your personnel, do they see this as written best practices, and do they understand that they are expected and required to follow?

Mr. EBRIGHT. They understand that they are expected and required to follow these practices. They are monitored in these practices, and the message consistently is that these agents require respect, and they must be handled with respect. And before any experiment, that risk benefit assessment must occur.

Ms. BLACKBURN. And if one of your personnel failed to follow those protocols, what would you do to them?

Mr. EBRIGHT. Depending on the nature of the failure, they would face consequences up to and including termination.

Ms. BLACKBURN. OK. And we do not see that pattern taking place at CDC.

Mr. EBRIGHT. We have not seen evidence for it.

Ms. BLACKBURN. OK. Do you think that CDC is in need of a major correction, and do you have advice for CDC on what that correction would be?

Mr. EBRIGHT. Many of the things that we heard Dr. Frieden suggest will be undertaken at the CDC are precisely the steps that are required at the CDC. The question is whether this time will be different from the previous time, and the time before that, and the time before that.

Ms. BLACKBURN. And if they did not do that, I think probably according to what you have said, you would terminate the whole bunch.

Mr. EBRIGHT. Again, in this particular case, personnel action will not be sufficient to resolve the issue. This issue is institutional and organizational.

Ms. BLACKBURN. Correct.

Mr. EBRIGHT. They cannot have the regulatory authority to regulate themselves. It simply does not work. It does not work in many areas of human endeavor, and it definitely does not work in this area.

Ms. BLACKBURN. Mr. Kaufman, anything to add to that?

Mr. KAUFMAN. I continue to stand by my belief and my conviction, because over the last 10 years I have traveled the world, including several Federal labs in the United States, and I have asked scientists to please report laboratory accidents and incidents so we have a chance to learn from them. And if we take this chance now and turn it into a punitive aspect against scientists that make unintentional injuries, it is well-known that punishment does three things. It builds resentment, it teaches no new behavior, and it hides true behavior.

And so, if we are going to make decisions that are going to decrease risk in science, we had better consider how we address incidents and accidents before doing so. Punitive actions, in my opin-

ion, are not a way to go, certainly not against the scientists that unintentionally makes a mistake.

If a scientist willingly, and there are scientists that do that, go against SOPs, that is a completely different job issue than a scientist that is doing their job within a culture and does not go outside of the SOP that is provided to them.

Ms. BLACKBURN. Thank you. Mr. Chairman, I yield back.

Mr. MURPHY. I got a comment to that, Mr. Kaufman. It builds resentment. You got to be kidding me. You are telling me these people with Ph.D.s do not understand that anthrax is dangerous? Are you kidding me? They need more training? You are making your statement that CDC anthrax lab incident was all a result of training failure, safety training for scientists working at high containment facilities consistent multiple basis, blah, blah, blah. Are you kidding me? Are you making excuses for these scientists?

If they do not understand that anthrax is used for a weapon, its spores can kill people, it killed people and harmed people at the U.S. Capitol, then they should not be working there. And it sounds like you are saying they need more training. Boo hoo.

This is a bad situation. And I do not think you understand the seriousness of this, and it sounds like you are making excuses. Look at this. The Washington Post. Today's cartoon. Do you think the employees at CDC are proud of this? Ha ha ha. It is funny. No, it is not. This is tragic. It could have been lethal for people.

And I hear you telling Ms. Blackburn that we are going to build resentment. I am sorry, I do not buy that at all.

Mr. KAUFMAN. May I comment? Thank you. Thank you, Chairman Murphy. I again am not defending what is going with CDC. In fact, I have said that I am disappointed even as a former CDC——

Mr. MURPHY. Disappointed is not the right word. You should find this to be abhorrent. Any words other than yes or no, was it wrong or not wrong. We can make excuses for—Mary Barra sat here from GM, and she said this was wrong. There is no question about it. Dr. Frieden said this was wrong. There is no gray zone in this. I do not get it. I will let you respond to that.

Mr. KAUFMAN. I appreciate that. I know the individuals involved, and when I say training is needed and training is a solution, there are several phases of training, and on-the-job specific training, which includes SOP verification, is needed for scientists, which has been mentioned in previous panel aspects as well.

I am not making light of this situation. I am not making light of this situation at all. I am simply saying that if we choose to punish people who come forward when they make a mistake——

Mr. MURPHY. That is different. I am not talking.

Mr. KAUFMAN. That is what I am saying.

Mr. MURPHY. That is different. We want people to be willing to do that.

Mr. KAUFMAN. Thank you. That is what——

Mr. MURPHY. But I thought that you were saying here, and I think it is in your statement here, too, they need more training.

Mr. KAUFMAN. They need on-the-job——

Mr. MURPHY. They do not training to know that this is bad. When you put anthrax in a Ziploc bag or any pathogen, you do not

training to know that. So I have gone over. Mr. Griffith, you are recognized.

Mr. KAUFMAN. That is subjective.

Mr. GRIFFITH. Well, and I guess my concern is that what we have here is a series of reports that Dr. Ebright has brought out some of the questioning that I did and others did earlier. We have had a series of reports that date back a good period of time, and yet the changes have not been made. And so, it is a concern.

A mistake is one thing. Having a standard operating procedure which is so flawed that you have repeated mistakes is something that I have to agree with the chairman on. That is our problem. And I agree with you, Mr. Kaufman, you do not want to punish somebody who merely makes a mistake. You want him to come forward as quickly as possible and let us fix it. But you got to stop the same mistake happening over and over again.

Dr. Ebright, how do we make these reforms happen this time?

How do we do that because while CDC has to protect the American public from anthrax and other things, our job is to do oversight and make sure that they are doing their jobs. So how do we make it happen?

Mr. EBRIGHT. I think the two steps that Congress and the Administration could follow to reduce the probability that this happens again in CDC's own labs and in the labs that CDC and USDA regulate outside those facilities, the two most important steps are, first, to reduce the number of select agent laboratories. The number of select agent personnel, the volume of select agent research, increased by a factor of 20 to 40 over the last decade.

That volume of registered individuals, that volume of activity needs to be rolled back to close to the level of where it was at the beginning of that increase. That would represent taking the current 1,000, or more than 1,000 select agent labs in the U.S. and reducing it to 50.

Mr. GRIFFITH. All right. Let me ask you a question real quick. High containment select agent, are those interchangeable terms or they different?

Mr. EBRIGHT. They are very close to interchangeable.

Mr. GRIFFITH. OK.

Mr. EBRIGHT. Most select agent research, particularly most research, are consequences done at Biosafety Level 3. Biosafety Levels 3 and 4 are considered high level containment.

Mr. GRIFFITH. So your first recommendation is let us squeeze it back down to 50 instead of a thousand of these select agent——

Mr. EBRIGHT. Roughly. The increase was a factor of 20 to 40. I would recommend we roll back a factor of 20 to a factor of 40. A thousand divided by 20 is 50. A thousand divided by 40 is 25.

Mr. GRIFFITH. All right.

Mr. EBRIGHT. So that, I believe, is the single easiest, single fastest, and certainly most economical approach

Mr. GRIFFITH. All right. And you had a second because obviously my time is limited.

Mr. EBRIGHT. OK. Last one is independent entity that carries out the regulation and oversight of biosafety and biosecurity in those labs, not an agency that performs the work, not an agency that funds the work.

Mr. GRIFFITH. OK. Now, you said we need to scale back, but let me ask you. Why has there been an expansion? And the phrasing I have is the high containment laboratories, you said they are closed. Why has there been such a great expansion?

Mr. EBRIGHT. So it was in large measure, essentially in whole, a response to the 2001 anthrax mailings. At the time of 2001 anthrax mailings, it was understandable because it was expected here and elsewhere that the U.S. was under attack with a biological weapon from a foreign source. It was expected that biology would be put on a mobilization footing to address this threat. We expanded by a factor of 20 to 40.

Now, more than a decade later, more than a decade after it has become absolutely clear that the 2001 anthrax mailings did not come from a foreign source, and after it has become clear that the investigation believes it came from within the U.S. biodefense establishment, we have the strange situation that we have expanded that establishment by a factor of 20 to 40 without reason and without reassessment.

Mr. GRIFFITH. And the risks are self-evident?

Mr. EBRIGHT. The risks follow mathematically. When you increase the number of personnel by a factor of 20 to 40, particularly when you recruit people without prior experience, new to the field, you increase risks, and you increase those risks by a factor of 20 to 40 or more.

Mr. GRIFFITH. On those points, Mr. Kaufman, are you in agreement that we need to scale it back some?

Mr. KAUFMAN. I am not. I agree with GAO. I think that there is not enough information to make the decision to either back off or go up. We do not have a baseline. And I also would like to say that the capacity of high containment laboratories are not built for the threats we just see today. They are built for the threats that we do not see coming around the corner tomorrow.

Mr. GRIFFITH. Let me switch gears and ask about the research implications or the implications from research of re-engineering pathogens such as the experiments by the University of Wisconsin scientists that generated a virus similar to the 1918 influenza outbreak that killed tens of thousands, maybe hundreds of thousands worldwide, and other ways to make H5N1 Avian flu virus more contagious in ferrets. I mean, is this part of the expansion or is this——

Mr. EBRIGHT. This is part of the expansion. This is work that is funded as biodefense research. And this is a prime example of the culture of hubris. This is work that should not be performed. Flat and blank, should not be performed.

In those cases where elements of this work are deemed essential, when the research information could be obtained in no other way, then this work should only be performed in a very limited number of institutions, perhaps one or two nationally, and only after extensive review of risk benefit weighing at the national level, and only under the most stringent safety and security standards.

Mr. GRIFFITH. I appreciate that very much. I appreciate both witnesses being here. Mr. Chairman, I appreciate having the hearing. I like the opportunities to learn, and I have learned a great deal from this hearing. Thank you so much.

Mr. MURPHY. I thank the gentleman for yielding back, and I certainly would encourage all members of this committee to go visit some of the labs around the country. Particularly, go to CDC headquarters and see for their own eyes how this works. And certainly for members of the CDC who may be listening, I hope they understand the seriousness of what Congress views today on this.

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

I also ask unanimous consent to put the document binder in the record subject to redactions by staff*.

In conclusion, I want to thank all the witnesses and members who have participated in today's hearing, and remind members they have 10 business days to submit questions for the record. I would ask that all the witnesses agree to respond promptly to the questions.

Thank you very much. And with that, this hearing is adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. PHIL GINGREY

Mr. Chairman, I want to thank you for calling today's hearing to review the incident of potential exposure of 84 CDC staff to anthrax on June 5th at the Bioterror Rapid Response and Advanced Technology (BRRAT) laboratory in Atlanta. I want to thank Dr. Thomas Frieden, Director of the CDC, for being forthcoming in his written testimony as to the problems that occurred and how the agency has already taken steps to address them.

I would also like to welcome a constituent of mine who will be testifying on the second panel, Sean Kaufman from Woodstock Georgia in Cherokee County, who was previously employed by the CDC and has unique knowledge on the inner workings of high-containment laboratories.

Mr. Chairman, the CDC main research facility in Atlanta is incredibly important for the region and the local economy. I hope that we can use today's hearing to learn more about how the agency can improve upon safety measures so that we can ensure that incidents that put employees in harm's way can be avoided in the future.

I yield back.

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*The information has been retained in committee files and is also available at http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=102479.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

SUPPLEMENTAL MEMORANDUM

July 16, 2014

To: Subcommittee on Oversight and Investigations Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: U.S. Department of Agriculture's Animal and Plant Health Inspection Service Inspection Reports of the CDC Roybal Campus

I. INTRODUCTION

In June 2014, Centers for Disease Control (CDC) employees at the agency's Bioterrorism Rapid Response and Advanced Technology (BRRAT) lab transferred potentially live samples of anthrax to two other labs, exposing dozens of CDC employees to this public health threat. The Committee is holding a hearing on this incident today.

A CDC after-incident report that was released to the public identified a series of failures that caused the exposure.[1] Another report on the incident, prepared by the USDA Animal and Plant Health Inspection Service (APHIS), was conducted in June 2014; it has not been released to the public, but its findings have been publicly reported.[2]

The June inspection was not the only recent APHIS inspection at the CDC Robyal facility. As part of their joint oversight of select agents that pose a threat to both human and animal health, CDC's Division of Select Agents (DSAT) and APHIS conduct inspections of

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[1] Centers for Disease Control and Prevention, *Report on the Potential Exposure to Anthrax* (July 11, 2014).

[2] Memorandum from Republican Staff to Members of the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, *Hearing on Review of CDC Anthrax Lab Incident* (July 14, 2014).

facilities that handle select agents to evaluate whether they meet the regulatory requirements.[3] APHIS conducted six of these inspections at the CDC Roybal campus facilities between January 2013 and March 2014.[4]

The Committee requested and obtained copies of these inspections reports, which are summarized in this memorandum.

II. SUMMARY OF FINDINGS OF 2013-2014 APHIS INSPECTIONS AT CDC's ROYBAL CAMPUS

The APHIS reports show that in the 18 months prior to the June Anthrax release, inspectors identified numerous safety problems in CDC laboratories. Many of these safety problems were paperwork violations, such as the failure to provide appropriate documentation of staff training or missing signatures on biosafety plans . Others involved potentially more significant problems, such as a malfunctioning exhaust systems on biosafety cabinets.

- **Problems with facilities or equipment were observed 29 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** Equipment failures included broken or nonfunctioning machinery, the failure to use filters or replace filters on a regular basis, the use of equipment that was not sufficient to contain the select agent or toxin (e.g., equipment used on a laboratory bench top instead of in a biosafety cabinet), and biosafety cabinet grilles obstructed with pens or other items. During one inspection, APHIS inspectors smoke-tested the exhaust flow on the biosafety cabinets in laboratory rooms and discovered the exhaust flowing into the laboratory instead of being safely sucked away.

- **Safety and security problems were observed 27 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These included failures by lab workers to wash their hands after working with potentially hazardous materials and a case where the outermost of two gloves a lab worker handling vials of select agents and toxins was wearing had a tear across the palm. Other observed safety concerns included failures to post entrance and exit procedures for some rooms and failures to post appropriate signage (such as signs indicating toxins or biohazards in use) in laboratories. Observed security failures included unauthorized access to laboratories and the failure to properly document entry and exit from laboratories. In two inspections, APHIS inspectors noted security failures, particularly with regard to recording entry into labs (e.g., recording only the first names or initials of visitors and escorts).

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[3] Letter from Robbin S. Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, and Freeda E. Isaac, Director, Agriculture Select Agent Program, Animal and Plant Health Inspection Service, to Joanne Jones, Responsible Official, Centers for Disease Control and Prevention (June 14, 2013).

[4] The APHIS inspections occurred on January 14-17, 2013, April 24, 2013, August 19-23, 2013, September 30, 2013, January 6-13, 2014, and March 3-12, 2014.

- **Problems with the failure to use or denote appropriate procedures were observed 25 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These failures included the absence of or inconsistent procedures in connection with safety, security, and documentation. These included cases where a biosafety plan did not contain decontamination procedures for a gross contamination incident, the absence of procedures to inform law enforcement or the CDC's designated responsible official of potentially criminal suspicious activities in labs, and the failure to include written procedures to be followed to test and treat workers in the event of a biohazard incident.

- **Problems with documentation and recordkeeping were observed 39 times by APHIS inspectors in the six inspections between January 2013 and March 2014.** These were the most common types of problems observed by APHIS inspectors. They included 11 instances in which written inventories of select agents were inconsistent with physical inventories (exposing a failure to properly account for all samples of select agents that were in storage on site) and cases where important safety or security procedures were not included in written plans. During one inspection, APHIS inspectors reported that the inspected facility did not submit required forms for an incident related to possible exposure or release of a select agent or toxin.

- **Problems with employee training were observed four times by APHIS inspectors in the six inspections between January 2013 and March 2014.** Problems identified by APHIS included absence of records or observed conditions indicating that staff had not received full or appropriate training regarding inventory control, threat awareness, security, incident response, and biosafety.

III. PROBLEMS IDENTIFIED BY APHIS IN THE JUNE ANTHRAX TRANSER

In June 2014, after the anthrax transfer, APHIS inspectors conducted an investigation of the incident and the CDC facility.

In the report describing the June 2014 investigation, APHIS identified problems with facilities and equipment (finding that decontaminant solutions and materials were expired); problems with the failure to use appropriate procedures (noting that CDC staff failed to use appropriate procedures and protocols to inactivate the transferred anthrax and that "the clinic was inadequately prepared to respond to the exposure of a large number of individuals"); problems with staff training (finding that staff "in registered laboratories were not appropriately trained in use of the inactivation protocol" and were "not appropriately trained in the characteristics, properties, and risks of the agent"); problems with paperwork and documentation (noting that "no formal approval process was in place for a new inactivation procedure" and that no documentation was created for potentially contaminated samples transferred between CDC labs); and problems with safety and security (finding that laboratories containing potentially live anthrax samples were not appropriately secured and that samples were stored in unlocked refrigerators).

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH 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

August 4, 2014

Dr. Thomas R. Frieden
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30333

Dear Dr. Frieden:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, July 16, 2014, to testify at the hearing entitled "Review of CDC Anthrax Lab Incident."

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 Monday, August 18, 2014. Your responses should be mailed to Brittany Havens, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to brittany.havens@mail.house.gov.

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

Sincerely,

Tim Murphy
Chairman
Subcommittee on Oversight and Investigations

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

Attachments

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

Review of CDC Anthrax Lab Incident

July 16, 2014

Centers for Disease Control and Prevention (CDC) Responses to Questions for the Record

The Honorable Billy Long

Are there any research programs at the CDC that require mandatory vaccination? If so, which are they and why are those vaccinations mandatory while the anthrax vaccination is voluntary?

Although CDC has a longstanding practice of strongly recommending vaccinations for employees at all CDC laboratories that work with agents for which there are Food and Drug Administration (FDA)-licensed vaccines, vaccination has not been mandatory. However, as part of the broad review of lab safety at CDC, CDC is reviewing issues related to vaccination of employees that work in laboratories with agents that cause vaccine-preventable diseases.

The Honorable Phil Gingrey

What is the impact and cost estimate with regard to the BRRAT laboratories being shut down throughout this moratorium period?

Closure of CDC's Bioterrorism Rapid Response and Advanced Technology (BRRAT) laboratory impacts numerous U.S. and state government activities, because the BRRAT laboratory is critical to the operation of the Laboratory Response Network (LRN). The LRN is a nationwide network of approximately 150 laboratories that uses highly sophisticated tests to examine clinical and environmental samples for the presence of biological threat agents. The BRRAT laboratory develops tests and assures the performance of testing materials that are routinely used in the LRN. The BRRAT laboratory also provides technical and public health support to the U.S. jurisdictions participating in the Department of Homeland Security's BioWatch Program, which utilizes LRN assays for verification of positive tests, and provides 24/7 technical support to the LRN laboratories and Federal Agencies that are engaged in analyzing potential threat materials.

As long as the closure of the BRRAT laboratory is short-term, it will not degrade the Nation's ability to respond to a bioterrorism event. Although the physical laboratory space is closed, the BRRAT laboratory scientific staff continues to monitor and respond to technical questions related to potential bioterrorism activities around the clock, and the LRN is still able to detect and respond to potential threats. In the next three to six months, the laboratory will be needed for the production, development, quality assurance, and distribution of assays and reagents for the LRN to use for testing and analysis. Actions are underway to enable reopening of the BRRAT laboratory.

We expect that the moratorium's impact on the BRRAT laboratory will be budget neutral. A majority of the laboratory's costs are fixed (*e.g.*, personnel, equipment, equipment maintenance agreements, facilities). While activities conducted in the sections of the BRRAT laboratory that were impacted by the moratorium are on hold, a majority of these activities will be completed in the future on a more accelerated timeline.

The Honorable Gregg Harper

In the September 2012 letter that you sent to the committee responding to concerns about CDC lab safety, you stated that a senior official was designated to report directly to you about safety issues. Who was that senior official?

CDC designated Mr. Joe Henderson to provide reports directly to the CDC director regarding concerns and complaints related to safety at CDC's laboratories. Assigning Mr. Henderson this role was one of the key steps that CDC implemented in 2012 to address biosafety and biosecurity concerns raised by an incident in our Emerging Infectious Diseases Laboratory at Roybal Campus earlier that year. Mr. Henderson was also responsible for coordinating CDC's internal investigation of incidents at certain high-containment laboratories in Building 18 that were of particular concern at the time.

It should be noted that Mr. Henderson is the Director of CDC's Office of Safety, Security, and Asset Management (OSSAM) and reports to CDC's Chief Operating Officer. OSSAM consolidates multiple business services offices that are involved with CDC's laboratory safety improvement efforts. OSSAM's services include several thematic areas that are directly relevant to these efforts: protection and safety of the CDC population, physical and personal security of CDC staff and contractors, operations and maintenance of CDC owned and leased property, health and wellness within the CDC community, transportation, and commitment to continuous quality improvement and sustainability.

Mr. Henderson also serves as Vice Chair of CDC's internal Laboratory Safety Improvement Workgroup (LSIW), newly formed as part of the more robust changes being made now to heighten lab safety and security. He and Dr. Michael Bell, Chair of LSIW and Interim Director of Laboratory Safety, both have leadership roles in LSIW to ensure that their distinct work areas (business operations and science) in addressing laboratory safety are well-coordinated. In addition, their reporting structure, in which Dr. Bell reports to the CDC Director and Mr. Henderson reports to the Chief Operating Officer on all matters (including lab safety), allows for checks and balances in CDC's laboratory safety improvement oversight.

What were the results of that action?

In this role, Mr. Henderson completed a comprehensive review of the incidents and adequacy of corrective measures taken to address them. He and laboratory program leadership also took additional steps to improve laboratory safety overall, including consolidating sources of safety and other information for laboratory staff.

The Honorable Bill Johnson

Do you use the National Science Advisory Board for Biosecurity for any sort of consultation?

The National Science Advisory Board for Biosecurity (NSABB) provides advice, guidance, and leadership regarding biosecurity oversight of dual use research of concern to all Federal Departments and Agencies with an interest in life sciences research. CDC, along with other Government Agencies, has an ex officio, non-voting member on the NSABB. To effectively respond to biosecurity concerns within the Agency, CDC formed an internal Institutional Biosecurity Board, which—as one of its primary functions—interfaces with NSABB and also ensures our Agency implements NSABB guidance.

The Honorable Billy Long

How many CDC laboratory workers received the FDA licensed anthrax vaccine prior to the anthrax incident last month as recommended by the CDC, its Advisory Committee on Immunization Practices for lab workers since 2002?

It is important to note that the FDA-licensed anthrax vaccine requires an annual booster to maintain immunity; therefore, going back 12 months prior to the date of discovery of the recent anthrax event gives a snapshot of the current anthrax vaccination status of CDC staff. Going back further than 12 months would not yield accurate numbers about the present, because staff who previously received the vaccine, but skipped the annual booster, would not be considered current.

For the 12-month period prior to the date of the recent anthrax event, 22 CDC staff were immunized against anthrax and are considered current, 4 staff had received at least three doses (after the third dose, immunity is considered adequate but not durable), and two staff are in the process of receiving anthrax immunizations.