



THE COMMITTEE ON ENERGY AND COMMERCE

Memorandum

July 14, 2014

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on “Review of CDC Anthrax Lab Incident”

On Wednesday, July 16, 2014, at 10:00 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled “Review of CDC Anthrax Lab Incident.”

The Subcommittee will focus on the recent incident at the Centers for Disease Control (CDC) laboratory that is suspected of potentially exposing 84 CDC staff to live anthrax because established safety practices were not followed. The incident also led CDC Director Thomas R. Frieden to shut down the Bioterror Rapid Response and Advanced Technology (BRRAT) laboratory until certain issues are resolved and issue a moratorium on transfers of biological material leaving any CDC high-containment lab until adequate measures are in place. This matter will be discussed in the context of recent events of the last week involving the discovery of smallpox vials in a Food and Drug Administration (FDA) lab on the National Institutes of Health (NIH) campus and a report to the CDC leadership about a transfer from a CDC lab to a United States Department of Agriculture (USDA) lab of an avian influenza cross-contaminated with a highly dangerous influenza strain, H5N1. The purpose of the hearing is to analyze what went wrong; why the anthrax incident occurred, whether the recent incidents over the last week raise systemic concerns, and what can be done about it, including possible legislative action.

I. WITNESSES

Two panels of witnesses will testify at the hearing:

Panel One

- Thomas R. Frieden, M.D., M.P.H., Director, Centers for Disease Control and Prevention;
 - Accompanied by Joseph Henderson, Deputy Director, Office of Security and Emergency Preparedness, Centers for Disease Control and Prevention;
- Jere Dick, D.V.M., Associate Deputy Administrator, Animal and Plant Health Inspection Services, U.S. Department of Agriculture; and,

- Nancy Kingsbury, Ph.D., Managing Director, Applied Research & Methods, Government Accountability Office.

Panel Two

- Sean G. Kaufman, M.P.H., President and Founding Partner, Behavioral-Based Improvement Solutions, LLC, Woodstock, Georgia; and,
- Richard Ebright, Ph.D., Rutgers University, Board of Governors Professor of Chemistry and Chemical Biology.

II. BACKGROUND

Last month, a safety breach at the CDC in Atlanta was suspected of possibly exposing 84 CDC lab workers to live anthrax. The CDC is viewing the breach as a “wake up call” that has alerted the agency to a major problem. The CDC Director, Dr. Thomas Frieden, tasked a group led by Dr. Harold Jaffe, CDC’s Associate Director for Science, to conduct a full assessment and report preliminary results by early July.

A. The CDC Report

On Friday, July 11, 2014, the CDC Director held a press conference disclosing the results of CDC’s report of the incident,¹ and CDC made the report publicly available. The following facts are derived from the CDC report.

On June 5, 2014, a lab scientist at CDC’s BRRAT laboratory prepared extracts of several select agents² including *Bacillus anthracis* (anthrax) for the purpose of evaluating a process known as matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry, a method of rapid identification of bacteria for infectious disease diagnosis. Initial sample preparation was performed at the BRRAT BSL-3 (biosafety level 3) laboratory for processing on MALDI-TOF equipment at a BSL-2 (biosafety level 2) laboratory.

The lab scientist followed a protocol that was developed by the MALDI-TOF equipment manufacturer, but had been modified by CDC’s Bacterial Special Pathogens Branch (BSPB) laboratory. According to this modified protocol, the lab scientist incorporated a check after 10 minutes of incubation to determine whether the material was non-viable or inactive, which was required for safe transportation. The scientists filtered half of the extract so that in the next steps there were 8 plates of filtered extract and 8 plates of unfiltered extract. After the 10-minute incubation in formic acid and other substances, the extracts were plated with agar, a growth agent, and incubated again, after which they were tested again for inactivation. While the BSPB method recommended a 48 hour incubation period, a decision was made to test after only 24

¹ Report on the Potential Exposure to Anthrax, Centers for Disease Control and Prevention (July 11, 2014).

² There were seven select agents, but anthrax was the only spore-forming bacteria agent that would not have been assured of inactivation.

hours. No growth on any of the 16 plates was observed by the test. This test involved removing material onto separate plates which the scientist intended to dispose of immediately. This disposal was delayed due to a mechanical problem. The extracts were then conveyed to an adjoining BRRAT BSL-2 laboratory. They were subsequently moved to a BSPB and Biotechnology Core Facility Branch on separate days: June 6, June 11, and/or June 12, 2014.

On June 13, 2014, a BRRAT laboratory scientist removed the undisposed testing plates, which had sat for eight days in the BSL-3 incubator. The scientist discovered growth on the plate that had used unfiltered anthrax.

The incident immediately was reported to a Select Agent Program Responsible Official in the Environmental, Safety and Health Compliance Office and the Division of Select Agents and Toxins (DSAT). CDC conducted two studies (at CDC and an independent laboratory, respectively) to determine whether the formic acid and acetonitrile treatment was effective in inactivating the anthrax. They concluded that the treatments were effective at inactivating vegetative cells of anthrax and a high percentage, but not all of anthrax spores. CDC further concluded that it was possible, though unlikely, that certain CDC staff had been exposed to viable anthrax.

The CDC report found the primary contributing factor to this incident was the lack of an approved, written study plan reviewed by CDC senior staff to ensure that the research design was appropriate and met all laboratory safety requirements. The report also noted the following other contributing factors: use of unapproved sterilization techniques; transfer of material not confirmed to be inactive; use of live anthrax inappropriate for this experiment; inadequate knowledge of peer-reviewed literature related to inactivation of anthrax; and lack of a standard operating procedure or process to document inactivation in writing in the BRRAT lab.

The CDC report made the following conclusions:

- The scientists' failure to follow an approved, written study plan that met all laboratory safety requirements led to dozens of employees potentially being exposed.
- There was a lack of standard operating procedures to document when biological agents are inactivated properly in laboratories, as well as a lack of adequate laboratory oversight of scientists performing work in these labs.
- The critical nature of CDC investigations to detect and respond to naturally occurring and man-made events with select agents while ensuring the safety of staff are paramount and should be guided by the highest standards.

B. CDC Response and Actions

CDC did not notify the Committee and the public until June 19 about the incident. In an internal CDC e-mail on June 20, Dr. Frieden apologized to the CDC workforce for the delay in notification.

In response to the incident, CDC provided preventive antibiotic treatment to CDC staff identified as potentially being exposed. On June 30, 2014, the CDC advised some employees to stop taking antibiotics after preliminary tests suggested it was “highly unlikely” they were inadvertently exposed to live anthrax.³ No instances of illness have been reported. The normal incubation period of anthrax can take up to five to seven days, although there are cases occurring 60 days after exposures. Infection can occur through the skin, breathing in anthrax spores, or eating tainted food.

CDC conducted environmental testing in all potentially impacted areas. CDC closed the BRRAT Laboratory until appropriate training and safety measures are ensured. In addition, the head of the BRRAT lab was reassigned. The BRRAT laboratory is the primary bioterrorism laboratory located at the CDC. It is a state-of-the-art facility that develops and validates new Laboratory Response Network (LRN) assays, processes suspicious samples, and provides 24-hour diagnostic support to bioterrorism response teams. For FY 2013, CDC spent \$982,000 on the BRRAT lab.⁴

As a result of the anthrax and cross-contaminated avian influenza incidents, on July 11, 2014, CDC issued, effective immediately, a moratorium on the movement (i.e., transfer inside or outside the agency) of biological materials (i.e., infectious agents, active or inactivated specimens) from BSL-3 or BSL-4 facilities. The moratorium will remain in place pending review by an advisory committee.

In addition to the moratorium, CDC initiated the following steps:

- Established a high-level working group, reporting to the CDC Director, to, among other duties, accelerate improvements in laboratory safety, review and approve, on a laboratory-by-laboratory basis, resumed transfer of biological materials outside of BSL3 and BSL4 laboratories, and serve as the transition group for the single point of accountability on laboratory safety called for in the review of the potential exposure to anthrax incident.
- Began the process of establishing an external advisory group for laboratory safety. Invitations to participate in this group will be issued by July 18, 2014.
- Initiated an investigation to determine root causes that led to contamination of another avian influenza virus by the H5N1 virus.
- Reported the incident through the proper channels to the select agent oversight body, Animal and Plant Health Inspection Services (APHIS).
- Established a review group, under the direction of CDC’s Associate Director for Science, to look at the systems, procedures, and personnel issues leading to this event and means of

³ Julie Steenhuysen, “CDC says anthrax exposure ‘highly unlikely,’” Reuters (July 1, 2014).

⁴ E-mail from CDC staff to Committee staff, July 11, 2014.

preventing similar events in the future. This review will be done in conjunction with the internal investigation and in coordination with the working group.

- Undertook appropriate personnel action.

CDC also has implemented or is in the process of implementing the following key recommendations highlighted in the report to address the root causes of the anthrax incident:

- CDC established a CDC-wide single point of accountability for laboratory safety. Dr. Frieden announced Dr. Michael Bell as the CDC Director of Laboratory Safety, who would report directly to him.
- The BRRAT Laboratory will not be conducting work with any select agent until a series of reviews and approvals are completed. BRRAT laboratory scientists do not have access to select agents, which have been placed in storage-only mode. These restrictions will remain in place until changes have been put in place to prevent similar future incidents.
- Appropriate personnel action will be taken with respect to individuals who contributed to or were in a position to prevent this incident.
- All inactivation procedures for laboratories working with select agents and other dangerous pathogens throughout CDC are being reviewed carefully and will be updated as needed.
- CDC will improve its response to future internal incidents by the rapid establishment of an incident command structure, such as CDC uses for external events.
- The implications for the use of select agents, including for CDC's regulatory functions through CDC's Division of Select Agents and Toxins will be reviewed carefully to incorporate any lessons learned.

C. USDA/ APHIS Inspection

The USDA's APHIS conducted an independent investigation from June 23 to July 3, 2014, to determine whether CDC was in compliance with Federal select agent regulations.⁵

In a July 10, 2014 letter to the CDC, APHIS submitted its report of the CDC anthrax lab incident. APHIS found that CDC deficiencies related to seven regulatory requirements.

1. Biosafety

⁵ Pursuant to an October 19, 2012 Memorandum of Understanding, APHIS provides the lead inspector for all inspections of registered entities owned by CDC. APHIS has led 10 inspections of CDC select agent laboratories since becoming the lead agency on these inspections, seven of them at CDC's Roybal Campus. E-mail from CDC staff to Committee staff, July 11, 2014.

The CDC inactivation protocol was faulty as it 1) was suitable for only biological material that lacked spore formation and 2) had been modified without validation. Furthermore, there was no oversight on the use of the protocol by principal investigators. The requirements for personal protective equipment use were inconsistent. For example, posted signs called for, but did not identify, proper equipment.

2. Incident Response, Decontamination Procedures and Training

Disinfectant used for decontamination of vials and bags was expired, and researchers could not remember if they used expired bleach to decontaminate areas after the potential release was identified. Lab workers had not been trained to decontaminate all relevant areas or properly use decontaminants. They were trained inadequately regarding the characteristics, properties, and risks of the anthrax. Furthermore, the BRRAT personnel were not trained properly in use of special agent inactivation protocol. The CDC lab, which had provided them with the protocol, failed to give adequate instructions and advise them of its limits.

3. Occupational Health Program

The CDC Occupational Health Clinic was not prepared adequately to respond to the exposure of a large number of individuals. Staff left the clinic without knowing the extent of their risk of exposure. At least some of the lab workers who potentially were exposed in the most recent incident were not examined for five days following notification. Clinic management was not informed in a timely manner of the scope of the potential exposure; however, even after employees were informed and the clinic was overwhelmed, it did not request a staff increase from CDC management. Some supervisors were advised that their staff should self-monitor rather than visit the clinic. Communication problems hampered providing correct information. For example, CDC employees were told they were not in danger, yet the labs and hallways were decontaminated, which seemed inconsistent with the information provided by the clinic.

4. Incident Response; Responsible Official

Management failed to provide clear leadership, identification of chains of command, clear and consistent communication of decontamination processes to subordinates, or prompt decontamination and lockdown of affected areas. Confusion extended to identifying the appropriate decontamination chemical, incorporating proper personnel, and coordination of effort. Interviews with CDC personnel indicated there was no clear focus on who was leading the decontamination effort. One of the CDC labs with the anthrax was not secured appropriately on the day the release was identified, allowing individuals without approval to continue access to space containing or exposed to anthrax. In addition to inadequate lockdown and failure to arrest exposures, posting of signs indicating possible exposures was delayed for days.

5. Notifications of theft, Loss and Release

Post-incident reports were inaccurate, inconsistent, and incomplete. For example, the storage location of some of the vials was omitted and the number of specimens potentially

contaminated was initially misidentified. The inspection indicated that materials were transferred within two plastic Ziploc bags between labs, which did not meet the “durable” requirement for secondary containment.

6. Restricting access to select agents and toxins, security risk assessments

Anthrax was stored in unlocked refrigerators in an unrestricted hallway, and workers freely passed through the area at the time of inspection. Signs were not even placed on the refrigerators to prevent their being opened. Where a sign did note use of inactive anthrax, it did not prohibit entry. The key to one of the refrigerator doors sat in its lock. At the time of inspection, containers of anthrax were missing and had to be tracked and located by the inspection team. Anthrax still was sitting in an unregistered and unlocked lab and other areas that had not been registered for special agent use or storage.

7. Records

Upon identification of the potential release, no documentation was created for intra-entity transfer of materials back to properly registered space, thus lacking verification of material and quantities to be transferred.

D. Reaction to the Anthrax Incident

Even before the smallpox and cross-contaminated bird flu incidents were reported last week, the anthrax exposure incident was viewed as “unprecedented in the history of American research on bioweapons and other deadly pathogens prompting alarm among researchers who have already warned about the consequences of lax laboratory oversight globally.”⁶ A June 26, 2014 editorial in the New York Times stated that “[i]t is distressing that the Centers for Disease Control and Prevention, which is supposedly expert at handling extremely dangerous pathogens, was so sloppy this month that it potentially exposed more than 80 people at its laboratories in Atlanta to deadly anthrax spores.” The editorial added that the incident carries a “stark warning that even the best laboratories can slip up, with potentially catastrophic consequences”

CDC leadership has found the incident disturbing because CDC is held to the highest standard of safety given its responsibility for administering the Federal select agent program over other Federal agencies and other regulated entities. As Dr. Frieden noted in his press conference last Friday, “CDC is the reference laboratory to the world.”

E. History of the Select Agent Program

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. § 262a) requires the Department of Health and Human Services (HHS) to regulate select

⁶ S. Begley and J. Steenhuisen, “Multiple protocol breaches behind anthrax exposure at U.S. federal labs,” Reuters (June 21, 2014).

agents, which are biological materials that have the potential to pose a severe threat to public health and safety. Examples of some select agents are anthrax, tularemia, smallpox, and plague.

Within HHS, this responsibility has been assigned to the CDC, Division of Select Agents and Toxins (DSAT).⁷ CDC regulates select agents that could pose a severe threat to public health and safety. USDA's APHIS regulates select agents and toxins that could pose a severe threat to animal or plant health. CDC and APHIS establish select agent regulations and monitor and enforce compliance with Federal select agent regulations.

DSAT regulates more than 300 facilities for the possession, use, or transfer of biological select agents and toxins (BSAT), in accordance with HHS select agent regulations (42 Part 73). CDC laboratories that possess BSAT fall under this regulatory responsibility.⁸ As of July 10, 2014, there are 324 entities registered with the Federal Select Agent Program (FSAP) for possession, use, or transfer of select agents.⁹ There are 11,034 individuals with active approvals to access select agents at FSAP-registered entities.¹⁰ There are 472 CDC staff with active security risk assessment approvals to access select agents.¹¹ About 15 percent of entities registered to work with select agents were subject to inspection overlap (multiple Federal agencies inspecting within a 2-year period).¹²

All inspections include review of biosafety practices, security, incident response, training, and records management. Since 2005, DSAT has conducted nine inspections at the CDC Roybal campus that included the BSL-3 laboratories in Building 18. Four of these inspections were done jointly with APHIS. In September 2012, CDC reported that USDA's APHIS agreed to assume lead responsibility for inspections of CDC laboratories that are regulated under the FSAP.¹³

Section 19 of the select agent regulations requires that incidents of theft, loss, or release of select agents and toxins be reported to either CDC/DSAT or USDA/APHIS select agent regulators. DSAT refers cases of significant regulatory non-compliance to HHS-OIG for investigation and to assess whether the imposition of civil money penalties would be appropriate.

F. Biosafety and Laboratory Best Practices

⁷ For FY 2013, CDC DSAT spent \$13,682,997.

⁸ Attachment to September 4, 2012 letter from Thomas R. Frieden, M.D., M.P.H., Director of CDC, to The Honorable Fred Upton, Chairman of the House Energy and Commerce Committee.

⁹ E-mail from CDC staff to Committee staff, July 11, 2014.

¹⁰ *Id.*

¹¹ *Id.*

¹² GAO, "Overlap and Duplication: Federal Inspections of Entities Registered with the Select Agent Program," GAO-13-154, January 2013. <http://www.gao.gov/products/GAO-13-154>

¹³ *Id.*

The CDC and the NIH have established four main levels of biosafety (BSL-1 to BSL-4) to guide laboratory researchers in the safe handling of biological agents.¹⁴ Each biosafety level is associated with specific physical and procedural protections. In general, the more dangerous the pathogen is to public health, the higher its recommended biosafety level. Procedures deemed unlikely to produce disease in healthy humans should be conducted at BSL-1. Those that may cause disease in healthy humans, but for which immunization or antibiotic treatment is available, should be conducted at BSL-2. Procedures that may cause serious or potentially lethal diseases as a result of pathogen inhalation should be conducted at BSL-3. Procedures that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease should be conducted at BSL-4. Generally, the term “high-containment laboratory” refers to BSL-3 and BSL-4 laboratories.

G. CDC Lab Research

CDC works to protect Americans from rare but deadly pathogens like Hantavirus pulmonary syndrome, Ebola and Marburg viral hemorrhagic fevers, rabies, monkeypox, smallpox, and anthrax.¹⁵ Because the pathogens that cause these diseases are so deadly, with many of them considered bioterrorism threats that are regulated as Tier 1 select agents, CDC maintains biosafety level (BSL)-3 and BSL-4 laboratories. These labs support epidemiologic investigations, research, and prevention efforts to reduce the public health threat of these hazardous and infectious high-consequence pathogens. According to an April 2014 U.S. government report to the United Nations, CDC reported spending a total of more than \$30 million in 2013 on select agent research.¹⁶

High containment laboratories, which conduct research on bioweapon agents, have proliferated since the 2001 anthrax attacks in which spores mailed to news media offices and two U.S. senators killed five people and infected seventeen others.¹⁷ In February 2013, the GAO reported to the bipartisan leadership of the Committee that there was an increased risk of laboratory accidents, given weaknesses in lab oversight and the lack of national safety standards.¹⁸ The GAO had recommended in 2009¹⁹ that the National Security Advisor make a single Federal agency responsible for assessing lab standards, but in the 2013 report, GAO noted

¹⁴ Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Biomedical and Microbiological Laboratories (BMBL)*, 5th edition, 2009.
<http://www.cdc.gov/biosafety/publications/bmb15/>

¹⁵ CDC FY 2015 Congressional Justification 101.

¹⁶ See United States of America, Confidence Building Measure Return covering 2013, Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, Submitted to the United Nations on April 15, 2014, at 79-90.

[http://www.unog.ch/80256EDD006B8954/\(httpAssets\)/7B8EB5C27800D7A9C1257CC3005010BE/\\$file/BWC_CB_M_2014_UnitedStates_PUBLIC.pdf](http://www.unog.ch/80256EDD006B8954/(httpAssets)/7B8EB5C27800D7A9C1257CC3005010BE/$file/BWC_CB_M_2014_UnitedStates_PUBLIC.pdf)

¹⁷ In 2009, there were over 240 entities with at least 1,362 BSL-3 laboratories in the United States registered under the Federal select agent program. This expansion has continued. As already noted in the memorandum, CDC reported to the Committee that there are 324 entities registered.

¹⁸ GAO, “High-Containment Laboratories: Assessment of the Nation’s Need Is Missing,” GAO-13-466R (February 25, 2013).

¹⁹ GAO, “High-Containment Laboratories: National Strategy for Oversight Is Needed,” GAO-09-74 (September 21, 2009).

that the National Security Staff and the Office of Science and Technology Policy rejected the recommendation as “unnecessarily broad and cumbersome.”²⁰

H. Past CDC Lab Incidents and Reports

Last Friday, the CDC disclosed several previous incidents in the past decade of CDC improperly sending select agents to other laboratories.

On July 9, 2014, the CDC Director learned that on March 13, 2014, the CDC influenza lab had shipped an influenza virus that was cross-contaminated with the “highly pathogenic” H5N1 influenza virus to a lab at the USDA. CDC learned of the contamination on May 23, 2014, and CDC confirmed the contamination a few days later. Confirmation of the contamination was conducted without notification of the CDC supervisory chain of command, and the CDC leadership was not notified until six weeks later.

In 2006, the CDC BRRAT lab had a similar incident with transferring anthrax that was not properly inactivated. CDC scientists had taken anthrax, thought it was inactivated, and sent it to an outside lab in March 2006 and to another lab, which was an unregistered entity, in April 2006. These transfers were determined by CDC in May 2006 to be an apparent violation of Federal select agent regulations (42 C.F.R. § 73.16). Although the incident also occurred at the BRRAT lab, it did not involve the same scientists. CDC reported that the scientists were not involved in the recent incident, were not at BRRAT at that time, and did not know about the prior incident. As a result of this incident, the CDC implemented a policy for transferring select agents, but this policy was not applied during the recent incident.

In 2006, another CDC lab sent three separate shipments to the same outside lab that was not a registered entity. The shipments were found to contain live *Clostridium botulinum* due to inadequate inactivation procedures. This botulinum bacterium produces neurotoxin botulin, which is the most potent toxin known, producing a potentially fatal paralysis known as botulism. A 2010 HHS OIG audit found that the scientists did not perform tests that would have detected activation, and that CDC’s biosafety plan did not require scientists to perform tests to confirm that select agent organisms were successfully inactivated before transferring them.

In 2009, newly available test methods showed that a strain of *Brucella*, which can cause a highly contagious bacterial infection called brucellosis, was shipped to outside labs as early as 2001. CDC scientists thought that the strain that was shipped was an attenuated vaccine strain, but the strain that was shipped was a select agent.

In March 2014, APHIS conducted an inspection of CDC labs, including the BRRAT lab. Among the concerns noted were: inventory records for select agents, such as botulinum and anthrax, were not accurate or complete; the biosafety plan did not contain procedures for

²⁰ GAO, note 13, at 3.

decontamination for the entire laboratory in the event of gross contamination; the pass-through autoclave was not operational at the time of inspection.²¹

The Inspector General of HHS issued three reports in 2008, 2009, and 2010, documenting several concerns at CDC laboratories.²² For example, CDC labs working with the most dangerous agents did not always ensure the physical security of the pathogens or restrict access to them, did not ensure security during transfers to other labs, and did not always ensure that personnel received required training. CDC has cited a favorable 2012 review of CDC's labs led by Canada's public health agency since those reports to deny that there is a safety problem.

Past Committee oversight work has examined a series of safety incidents at CDC such as the CDC's Emerging Infectious Diseases Laboratory in Atlanta having repeated problems with airflow systems designed to prevent the release of infectious agents.²³ In response to a GAO report on CDC laboratory practices, CDC seemed to downplay the safety problem of human error and suggest that modern technology could address concerns.²⁴

Media reports have raised questions over why the CDC did not follow its recommended approach arising from the CDC investigation of an outside lab sending live anthrax.²⁵ In 2004, a Maryland lab accidentally sent a batch of live anthrax that was thought to have been heat-killed to a children's hospital in California.²⁶ The CDC investigated the incident, and as a result of the investigation, the private lab broadly adopted a process called biorisk management. CDC

²¹ Autoclave operability problems perversely may have led to the discovery of the safety breaches in the anthrax incident. The CDC report noted that the CDC lab scientist had planned to autoclave the plates containing the anthrax, but had difficulty opening the autoclave door and returned the plates to the incubator. "If the plates had been autoclaved after 24 hours, as planned, the event would not have been discovered." CDC Report, note 1, at 6.

²² J. Steenhuisen and S. Begley, "Insight: CDC didn't heed own lessons from 2004 anthrax scare," Reuters (June 30, 2014). This review would have been based on redacted versions of the reports, but the Committee has obtained unredacted versions.

²³ Letter from The Honorable Fred Upton, Chairman, and The Honorable Henry A. Waxman, Ranking Member, *et al.*, House Energy and Commerce Committee to Dr. Thomas Frieden, Director, CDC (June 25, 2012). On August 10, 2012, in part of its response to the Committee's request, CDC submitted a narrative, "Building 18 High Containment Laboratory, Key Issues/Incidents," January 1, 2005 – June 22, 2012. This narrative did not include the 2006 incidents involving the live anthrax and botulinum transfers, or the brucellosis transfers, that CDC revealed on July 11, 2014. With regard to the Building 18 incidents, *see also* Alison Young, "Airflow problems plague CDC bioterror lab," USA TODAY, (June 13, 2012), and Alison Young, "Security lapses found at CDC bioterror lab in Atlanta," USA TODAY (June 28, 2012).

²⁴ GAO, "High-Containment Labs: National Strategy for Oversight is Needed," note 17. See GAO statement on highlight page ("Four highly publicized incidents in high-containment laboratories, as well as evidence in scientific literature, demonstrate that [] while laboratory accidents are rare, they do occur, primarily due to human error or systems [] failure, including the failure of safety equipment and procedures . . .") and CDC comments at 85 ("We also urge GAO to note that even if the laboratories had been operational, there still would not have been any threat of exposure to any laboratory workers, CDC employees, or the public. The draft report currently does not discuss a very important facility design approach that ensures biocontainment . . .").

²⁵ J. Steenhuisen and S. Begley, "Insight: CDC didn't heed own lessons from 2004 anthrax scare," Reuters (June 30, 2014).

²⁶ *See, e.g.*, M. Enserink and J. Kaiser, "Biodefense Research: Accidental Anthrax Shipment Spurs Debate Over Safety," *Science*, June 18, 2014; R. Vesely and I. Hoffman, "Anthrax incident spurs concern: Some believe scare at Children's Hospital Oakland exposes loopholes in biodefense," *Oakland Tribune*, (June 12, 2004).

officials state that the agency has its own risk management system, and that the biorisk guidelines were not necessarily appropriate for CDC.²⁷

Finally, the disclosure of the CDC's improper handling of select agents was made just days after vials of smallpox were discovered in an FDA lab building on the NIH campus. The vials dated back to 1954, were packed in a cardboard box in a cold storage room, and apparently were undisturbed for decades. The vials were flown to CDC, and testing of samples from two of the six vials has already shown the smallpox was viable.

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

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

III. ISSUES

The following issues will be examined at the hearing:

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

²⁷ *Id.*

- Is Congressional action necessary? If so, what actions?
- What are the most effective ways to improve biosafety at the CDC?
- Should the CDC labs be inspected by USDA APHIS? Is there sufficient independence given that APHIS is CDC's partner in overseeing select agents? Does APHIS have the expertise to oversee CDC's handling of select agents?

IV. CONTACTS

If you have any questions about this hearing, please contact Alan Slobodin at (202) 225-2927.