



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

Review of CDC Anthrax Lab Incident

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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 save 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 are taking to address the recommendations.

As a matter of compliance with the select agent regulations, we reported the incident 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 action 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 labs. 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.