



Written Testimony
House Committee on Energy and Commerce,
Subcommittee on Oversight and
Investigations

**Laboratory Safety at the Centers for Disease Control and
Prevention**

Statement of

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Introduction

Good morning Chairman Murphy, Ranking Member DeGette, and members of the Subcommittee. Thank you for the opportunity to testify before you today on the Centers for Disease Control and Prevention's (CDC) ongoing efforts to strengthen the quality and safety of the critically important work at the agency's laboratories. I am Dr. Steve Monroe, the Associate Director for Laboratory Science and Safety, a new position at CDC. My role and office were created last year to serve as the single point of accountability for laboratory science and safety at CDC, and I report directly to the Director, Tom Frieden. I come to this role with 29 years of experience as a microbiologist at the CDC, including serving as the Deputy Director for the National Center for Emerging and Zoonotic Infectious Diseases and Director for the Division of High-Consequence Pathogens and Pathology.

With laboratories across the United States from Atlanta, Georgia, and Ft. Collins, Colorado, to San Juan, Puerto Rico, and Anchorage, Alaska, CDC laboratories play a crucial part in identifying and responding to threats to the public's health. For example, CDC laboratories maintain a vast library of identified pathogens that laboratories from around the world depend on to identify dangerous microbes; these laboratories keep first responders and mine workers safe by evaluating the effectiveness of protective equipment; they screen newborns for rare illnesses and disabilities; they invent new assays for diagnosis of emerging infectious diseases such as Zika and Dengue virus; and they monitor the spread of antimicrobial resistant microbes. Ensuring that this vital work is performed with a commitment to safety and excellence is and will remain a top priority for CDC.

In July 2014, Dr. Frieden testified before this Subcommittee in the wake of a number of safety incidents at CDC laboratories. He testified that those incidents were completely unacceptable, and discussed the agency's response to the incidents and the need for changes both to address the circumstances that contributed to those incidents and to reform and restructure the agency's oversight and management of its laboratories. I am pleased to testify before you today on the progress we have made since then and to discuss the ongoing work at CDC to further strengthen and improve the safety and scientific quality of our laboratories.

Comprehensive Reviews of CDC Laboratory Safety

Following the 2014 incidents, CDC initiated intensive efforts to strengthen safety and quality in the agency's laboratories. That process began with comprehensive reviews of laboratory practices and structure, and identification of needed reforms. Separate comprehensive reviews by an internal CDC workgroup and a workgroup of experts external to the agency were conducted.

A key part of the reform process was the formation of the external Laboratory Safety Workgroup, a workgroup of the Advisory Committee to the Director of CDC. The eleven members of this workgroup were experts and leaders in the fields of biosafety, laboratory science, and research from outside of CDC. In 2014, this workgroup spearheaded an in-depth engagement with CDC, reviewing extensive documentation on our laboratories and safety protocols, surveying laboratory staff, visiting our high-containment laboratories, and meeting in-person with CDC laboratory staff and their leadership. Using the workgroup's findings, the Advisory Committee to the Director issued 19 recommendations to CDC to improve laboratory safety. These recommendations remain a roadmap for our ongoing efforts to strengthen laboratory quality and safety at the agency. CDC tracks progress on the recommendations on a monthly basis and reports this progress to HHS leadership. To date, CDC has completed or initiated action on all 19 of these recommendations, with 11 recommendations having been fully implemented.

Also essential to reforming laboratory safety at CDC was a deep and critical examination from within the agency of our laboratory safety practices. In August 2014, Dr. Frieden established the internal Laboratory Safety Improvement Workgroup and charged it with expediting improvements in laboratory safety and quality and developing its own detailed recommendations for strengthening laboratory safety at the agency. This workgroup developed 148 discrete recommendations, and CDC has initiated action on 138 of these, including fully implementing 44 recommendations. We continue efforts to implement and closely monitor progress on all of the remaining recommendations. We are in the process of developing timeframes for implementation of the remaining recommendations, where applicable.

In addition to the recommendations from internal and external groups, CDC also learned from and made changes based on specific recommendations in after-action reviews it conducted following the 2014 *Bacillus anthracis*, influenza A (H5N1), and Ebola virus laboratory incidents. The United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service, or APHIS, also provided inspection reports and a list of corrective actions regarding each of the three incidents. For the CDC after-action reports, 8 of 8 Ebola recommendations, 23 of 26 the H5N1 recommendations, and 7 of 8 of the *Bacillus anthracis* recommendations have been fully implemented, with work underway on the remaining recommendations. Of the APHIS corrective actions, 22 of 25 have been completed, with actions on the remaining three items in progress. We also launched a box by box and vial-by-vial inventory of more than seven million samples in long-term storage for the infectious disease laboratories and rolled out a new electronic specimen inventory system.

The rigorous internal and external reviews of CDC's laboratory safety practices have been extensive in their scope, depth, and comprehensiveness. The recommendations spanned a broad range of structures and practices that impact laboratory safety including establishment of organizational changes to improve oversight and strengthen regulatory compliance; improvement of communication with laboratory staff; adoption of incident management protocols; and expansion of the use of risk assessments. We continue to implement and track progress on each of the more than 200 recommendations we have received in this process. While more work remains to be done, the progress made to date has been significant, particularly in CDC's laboratory oversight structure and approach.

A Single Point of Accountability for Laboratory Science and Safety

The creation of the position in which I serve—the Associate Director for Laboratory Science and Safety—is the most fundamental change implemented in the wake of the 2014 incidents. When Dr. Frieden testified before this Subcommittee in July 2014, he promised to establish a permanent, CDC-wide single point of accountability for laboratory science and safety. The internal and external workgroups also called for the creation of this role as a critical step to centralize and standardize laboratory safety practices and oversight across the agency. Creating this position and defining its role and function became a top priority for the agency. This new structure is essential to

our ability to assess potential implications of an incident or situation in one lab on other labs, and prevent problems before they occur by learning from experiences in laboratories in other parts of the agency.

The position of Associate Director for Laboratory Science and Safety, or ADLSS, was officially created in 2015 and I assumed this position permanently in September of last year, after having served in the role since May 2015 in an acting capacity. The ADLSS reports directly to the CDC Director and provides high-level oversight and coordination of critical laboratory policies and operations, particularly those associated with laboratory safety and quality management at all CDC campuses.

My office directs two key functions: oversight and direction of CDC laboratory science, quality, and training; and oversight of CDC's laboratory safety and compliance programs. This latter function is especially important to improving laboratory safety and aligns with the recommendations of the internal and external workgroups. My office now provides direct oversight of chemical, radiological, and biological safety, including compliance with select agent regulations, in laboratories across all CDC campuses. This is a key organizational improvement, as these compliance functions were formerly divided across multiple offices. I want to note that my office's role in select agent compliance is distinct from the role of CDC's regulatory arm in the Division of Select Agents and Toxins (DSAT). DSAT is part of the Federal Select Agent Program which, along with USDA's APHIS, regulates the possession, use, and transfer of biological select agents and toxins and enforces those regulations. CDC laboratories that handle select agents and toxins are subject to the requirements of the Federal Select Agent Program, and my office is responsible for ensuring that CDC complies with those regulations in our own select agent laboratories. However, my office does not have authority over and is not involved in overseeing or enforcing requirements of the Federal Select Agent Program in select agent labs in other Federal agencies and departments.

A Culture of Safety

A core recommendation of both the internal and external workgroups was to establish and strengthen a culture of safety in CDC's laboratories. This remains an overarching goal and vision for CDC and my office, and I want to highlight some specific initiatives that have advanced this culture of safety.

An integral part of a culture of safety is transparency about potential safety issues in our laboratories. One of my first acts as the ADLSS was to issue an agency-wide memorandum to reiterate CDC's requirement for staff to report any and all safety issues, and provide clear direction on what channels workers should use to report incidents. Included with the memorandum was a flow chart to clarify incident reporting channels and a Laboratory Infectious Agent Exposure Risk Assessment Tool to ensure that any event involving infectious materials was accurately characterized and reported. We are now in the process of updating this reporting requirement in CDC's internal agency-wide policies.

Another key achievement was the creation of the Laboratory Safety Review Board (LSRB) in March 2015. The LSRB is charged with reviewing and approving protocols for the transfer of biological materials out of Biosafety Level 3 (BSL-3) and BSL-4 laboratories to lower levels of containment, a key issue in the 2014 incidents. The LSRB reviews all new and amended protocols for these transfers and conducts annual reviews of existing protocols. The LSRB has authority to suspend any protocol that it finds is not being conducted appropriately and communicates directly to CDC leadership and laboratories about any incidents, protocol lapses, and suspensions. Finally, the LSRB is charged with reviewing and maintaining quarterly summaries of all material transfer certificates.

CDC also established the Laboratory Leadership Service, or LLS, a fellowship program that prepares early career laboratory scientists to become future laboratory leaders. LLS is modeled after the Epidemic Intelligence Service, and it combines competency-based public health laboratory training with practical, applied investigations and service. LLS fellows are deployed to investigate laboratory incidents and near-misses to understand what happened and what steps are needed to prevent safety issues in the future. The inaugural LLS class began in July

2015, and the program will provide CDC and public health laboratories across the country with a cadre of expertly trained laboratory scientists poised to meet the evolving challenges of laboratory science and safety.

Finally, CDC is also committed to advancing what I describe as the science of safety—applying the same rigorous scientific methods to the safety of our laboratories that we use to confront threats to the public’s health. To spur the science of safety in CDC laboratories, last month my office launched the Laboratory Safety Science and Innovation Intramural Research Fund. This fund provides one-time awards to laboratories across the agency that propose innovative research or solutions to laboratory safety challenges. This year, we will be funding 13 projects that enhance the science of laboratory safety in diverse ways, from developing a 3D lab risk-assessment training tool to improving virus inactivation techniques and evaluating the efficacy of disinfectants.

Last month, we saw a test of CDC’s new laboratory oversight structure when a CDC laboratory worker was diagnosed with a *Salmonella* infection that was likely acquired from their work in a CDC BSL-2 laboratory. *Salmonella* is not a select agent, and the worker has fully recovered and no other people appear to have been exposed. Once DNA fingerprinting conducted at the Georgia Department of Public Health laboratory indicated that the strain of *Salmonella* that caused the infection was the same that the worker had been handling in the laboratory prior to the infection, my office launched an investigation to understand the circumstances that led to the exposure and identify any processes that needed to change to prevent future exposures. While the exposure should not have happened and we are working to reduce the risks involved in working with pathogens in every way possible, CDC responded to this incident with urgency and transparency. Once we received the results of the DNA fingerprinting, we immediately notified Congress, including staff of this Subcommittee, and issued a press statement to notify the public of the likely exposure. We will continue to strive to prevent these incidents from ever happening, but if they do, we will do everything we can to identify and address factors that contributed to the incident and do so swiftly, comprehensively, and openly.

A foundational principle of laboratory safety is having multiple, overlapping layers of protection and containment. GAO’s examination of CDC policies in its report on high-containment laboratories, like the internal

and external reviews, provides additional and valuable feedback on areas where CDC is succeeding and where continued improvements are required. GAO's emphasis on the comprehensiveness of laboratory safety policies is especially valuable and reflects CDC's own 360-degree approach of shoring up and strengthening our laboratory safety policies and practices. We are already hard at work to address the issues GAO highlighted. We are finalizing timelines for the completion of all the 148 recommendations included in the Laboratory Safety Improvement Workgroup report and are developing comprehensive policies to address reporting of laboratory incidents, conducting risk assessments, and transporting of specimens at CDC campuses. In addition CDC is working with HHS and our sister agencies on the HHS Biosafety and Biosecurity Coordinating Council, which on behalf of the Secretary provides a high-level and formal mechanism to coordinate and collaborate on biosafety and biosecurity issues across the Department. The Council's work includes establishing a process to notify HHS leadership about laboratory inspection results and safety incidents.

Supporting U.S. Government Efforts to Strengthen Biosafety and Biosecurity

In addition to the improvements in laboratory safety at CDC, CDC is also participating in U.S. Government efforts to strengthen biosafety and biosecurity. On October 29, 2015, the government released these two sets of recommendations as well as the implementation plans, one from the Federal Experts Security Advisory Panel (FESAP), which conducted an internal U.S. Government review of biosafety and biosecurity practices, and another from the Fast Track Action Committee on Select Agent Regulations (FTAC-SAR), which conducted an external review that focused on the effects of the select agent regulations on researchers and laboratories. Recommendations made by both the FESAP and FTAC-SAR address the culture of responsibility, oversight, outreach, and education; applied biosafety research; incident reporting; material accountability; inspection processes; and regulatory changes and guidance to improve biosafety and biosecurity. In addition, an approach was identified to determine the appropriate number of high-containment U.S. laboratories required to possess, use, or transfer biological select agents and toxins.

The U.S. Government has developed a plan to implement the FESAP's and FTAC-SAR's recommended actions and expects that implementing these recommendations will strengthen biosafety and biosecurity practices and oversight.

Conclusion

CDC's laboratories remain an indispensable link in our public health system, from preventing healthcare associated infections at our Clinical and Environmental Microbiology Laboratory in Atlanta; to understanding the spread of the Zika virus in our vector-borne disease laboratories in Ft. Collins, Colorado; to improving the safety of America's workforce at the National Institute for Occupational Safety and Health laboratories in Morgantown, West Virginia. Ensuring that this critical laboratory work is performed with the utmost commitment to the safety of our workers and the public is, and will remain, a vital priority for the agency.

For CDC, laboratory safety is not a singular objective that can be accomplished and checked off. It is an ongoing commitment to a functioning culture of safety that demands constant and vigilant dedication. A healthy and functioning culture of safety is one where monitoring and reporting are valued, where issues are rapidly and openly addressed as they are identified, and efficient systems are in place to prevent a safety issue from becoming a safety incident. Since Dr. Frieden testified before this Subcommittee, CDC has made great progress in advancing this culture of safety at our laboratories across the country. But more work remains to be done. While the risks of working with pathogens and other hazards can never be completely eliminated, we will continue to reduce and mitigate these risks in every possible way. This includes diligently working to address and build upon the recommendations presented by GAO in its report.

Without question, we are in a better and safer place than we were two years ago. We have established a single point of accountability for all laboratory safety and science across the agency; recruited a corps of laboratory safety leaders to champion safety improvements; and created the Laboratory Safety Review Board to review protocols for the transfer of biological materials out of high-containment laboratories. These and other reforms we

have initiated since 2014 have strengthened laboratory safety and science across the agency and ensure that CDC's laboratories are prepared to meet the complex public health challenges of our day.

Thank you for the opportunity to testify on this important matter. I would be glad to answer any questions you may have.