

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Laboratory Safety at NIH

Testimony before the

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Subcommittee on Oversight and Investigations

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Good Morning Mr. Chairman, Ranking Member DeGette, and distinguished Members of the Subcommittee. It is an honor to appear before you today to discuss how the National Institutes of Health (NIH) implements biosafety and biosecurity measures in high containment laboratories.

The NIH has an important mission to conduct research that will lead to the development of treatments, diagnostics, and vaccines to address public health needs, including medical countermeasures to address the ever-evolving threat of newly emerging and re-emerging infectious diseases caused by pathogen exposure. Studying biological select agents and toxins – so-called “select agents” – that have been declared by the Federal Government to have the potential to pose a severe threat to public health and safety is necessary to develop new vaccines and treatments with the potential to save millions of lives. While appreciating the value of studying these select agents, the NIH also recognizes the importance of appropriate precautions and containment measures to ensure the research is conducted in the safest manner possible.

Compliance with and constant vigilance over the implementation of biosafety standards is extremely important to our mission. The Division of Occupational Health and Safety (DOHS) at the NIH provides leadership in the development and implementation of occupational health policies, standards, and procedures applicable to biomedical research that is conducted through our intramural research program, including laboratories on the main campus in Bethesda, Maryland; Research Triangle Park, North Carolina; Baltimore, Maryland; Frederick, Maryland; Hamilton, Montana; and Phoenix, Arizona. The NIH Institutional Biosafety Committee provides recommendations to the NIH Director in matters pertaining to intramural use of microbial agents, their vectors, and recombinant DNA. In addition, each NIH Institute and Center (IC) has an active Safety Committee that assists the IC Scientific Director in assuring that employee

participation is emphasized in laboratory safety management and implementation. DOHS safety professionals serve on each of these committees to provide advice and guidance, and help ensure consistency in operationalizing NIH safety policies. Scientific Directors are routinely engaged in assuring rigorous adherence to procedures and developing solutions when any safety issues are identified. It is important to note that this activity happens at the level of the IC, particularly because safety measures must be tailored to the specific agents involved.

In addition to IC leadership, all scientists are responsible for protecting themselves, their co-workers, the public, and the environment as they conduct their research. Scientists take a personal risk when they choose to work with these agents, and they do so to protect the public, so their vigilance over safety measures is critical for maintaining public confidence in the research enterprise.

In the summer of 2014, six sealed, decades-old, ampules of smallpox were found in a cold storage room in a Food and Drug Administration (FDA)-occupied and leased laboratory building located on the NIH campus. The presence of smallpox on the NIH campus was alarming to the entire NIH research community, and initiated much action on the part of the NIH leadership. Upon making this discovery, all of the proper notifications and security steps were taken according to our safety protocols. The Centers for Disease Control and Prevention (CDC) and the Federal Bureau of Investigation was contacted and joint custody of the ampules was transferred to the CDC. NIH's established protocols and procedures, which included training regarding select agent handling, ensured that at no time was anyone on campus or the public at risk. NIH takes this incident very seriously and we have implemented new policies and procedures in the intervening years to prevent such an event from happening again.

First, NIH identified and inventoried all potentially hazardous biological materials stored in all NIH owned and leased facilities including all infectious agents, non-regulated toxins, poisons, and venoms. During this sweep, which took place from July to September 2014, nearly 35 million samples were inventoried. Subsequent to this first step, a quality assurance check was performed on a sampling of all reported material. Additionally, NIH and other Federal agencies launched a National Biosafety Stewardship Month. Under this initiative, extramurally funded institutions were asked to voluntarily join the Federal laboratories in similarly reviewing their own procedures, training, and inventories of infectious agents and toxins – all with an eye toward optimizing their programs of biosafety oversight.

For the long-term strategy, NIH developed the *Potentially Hazardous Biological Materials Management Plan*, which addresses accountability at all levels of NIH and has been fully implemented. This management plan has established:

- A mandatory centralized inventory of all potentially hazardous biological materials;
- Procedures for annual updates of inventories and more frequent updates if necessary;
- Procedures for transferring ownership/responsibility of biological materials when a researcher leaves the NIH;
- Procedures for random audits of laboratories' potentially hazardous biological holdings against the inventories;
- Appointment of an individual to oversee and be responsible for each common shared use and storage area, as well as implementation of an assurance process so that these appointments continue to be filled during the NIH annual management control review;
- Revised NIH policies for safety and health management and for working safely with potentially hazardous biological materials;

- Implementation of a biological surety policy requiring participation of personnel who work in secure select agent laboratories;
- Requirements for registering all stored biological materials with the DOHS (*previously NIH registered only active work with infectious agents*).

In February 2015, the External Laboratory Safety Workgroup (ELSW) to the CDC Advisory Committee to the Director reviewed our policies and practices as a follow-up to the 2014 incident. The ELSW affirmed that NIH's response to the discovery of the smallpox was prototypical and that NIH has implemented all of the recommendations made. The report states, "The NIH Intramural DOHS Program is a model program for institutions supporting extramural NIH research as well as for other institutions and agencies. The commitment of NIH leadership toward laboratory safety is evident and is demonstrated at all levels examined by the ELSW."

In addition to the affirmation of our safety and health program by ELSW, the GAO review of high containment laboratories that we meet here today to discuss, found NIH's policies for laboratory management of hazardous biological agents to be comprehensive.

In October 2015, the Assistant to the President for Science and Technology, John Holdren, initiated parallel Federal and non-Federal reviews that resulted in specific recommendations to strengthen our government's biosafety practices and oversight system for Federally-funded activities. The Federal Expert Security Advisory Panel (FESAP) was tasked with conducting coordinated federal review to evaluate our intramural research safety practices. For the non-Federal review, the National Science and Technology Council established an interagency Fast Track Action Committee on Select Agent Regulations (FTAC-SAR) to conduct a comprehensive review of the impact that the select agent regulations have had on science, technology, and national security more broadly. These comprehensive reviews provided a set of

recommendations that address many of the factors associated with recent laboratory incidents in the United States and that will inform future policy to advance biosafety and biosecurity at NIH. Further, the NIH also supported 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.

In closing, as Principal Deputy Director of the NIH, I can assure this Subcommittee that the senior leadership at NIH took appropriate action in 2014 and continues to act today to ensure the safety of the public and the scientists whose mission it is to find new ways to enhance health, lengthen life, and reduce illness and disability. We remain committed to preserving the public's trust in NIH research activities through best safety practices and strong leadership.

Thank you, Mr. Chairman.