DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Lab Safety and Inactivation of Microbiological Agents at NIH

Testimony before the

House Committee on Energy and Commerce

Subcommittee on Oversight and Investigations

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September 23, 2016

Good morning Mr. Chairman, Ranking Member DeGette, and distinguished Members of the Subcommittee, it is an honor to appear before you today to discuss the National Institutes of Health's (NIH) efforts to improve oversight of biosafety and biosecurity measures in high-containment laboratories, including those that work with biological select agents and toxins. My testimony today will focus on the General Accountability Office's (GAO) report, "High Containment Laboratories: Improved Oversight of Dangerous Pathogens Needed to Mitigate Risk" and its recommendations related to the inactivation of microbiological agents – a process that renders these organisms safe for downstream research outside a high containment laboratory.

I am Jeffrey Potts, NIH Biorisk Manager for the Biorisk Management Branch within the NIH Division of Occupational Health and Safety (DOHS). The DOHS at 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 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 Biorisk Management (BRM) Branch is responsible for providing regulatory compliance oversight and expert guidance to the NIH community for matters involving research with high-consequence pathogens. Among other activities, the BRM is responsible for implementing the NIH Biosurety Program and the NIH Select Agent Program.

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 pathogens including those that are select agents. While appreciating the value of studying these select agents, 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.

Consistency is essential to biosafety practice. At NIH, all high containment laboratories are held to the same high operational standards whether or not select agents are being worked with or stored in these laboratories. My role at NIH is the oversight of these operational requirements such as; semi-annual inspections, annual training of research and support personnel, annual engineering validations, participation in Personnel Reliability Programs, and annual review of laboratory specific standard operating procedures, including the inactivation of infectious agents. NIH has been and remains a proponent of rigorous inactivation protocols tailored to the research being conducted. Pathogen inactivation procedures are undertaken to enable important biomedical research such as the development of vaccines, development or use of diagnostic assays, or removal from a high containment laboratory to facilitate research using procedures not requiring a viable organism. Rigorous testing for verification of inactivation protocol efficacy is required. At NIH, inactivation and testing protocols are developed through collaboration of investigators and Biorisk Management staff, review by the biosafety officer, and ultimately review and approval by the NIH Institutional Biosafety Committee. Investigations of any inactivation method failures and recommended corrective actions are also the responsibility of the BRM. These policies and procedures extend beyond select agents to all infectious agents that may be removed from a high containment laboratory for downstream use.

Enhanced coordination among Federal partners is advancing biosafety and biosecurity at NIH laboratories and others across the country. The research community at-large looks to two essential publications when conducting biological research: the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), which are a term and condition of NIH funding; and the Centers for Disease Control and Prevention (CDC)/NIH publication *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). As the BMBL is a joint publication of the CDC and NIH, we are committed to continuing our work with the CDC's Office of the Associate Director of Laboratory Science and Safety to achieve consistency and standardization of the definition used for inactivation in these guidance documents used by the research community.

In addition to these guidance documents, work with select agents is regulated by either CDC and/or USDA. As the regulatory authorities, NIH will look to these two offices to establish minimum criteria and definitions. It is critically important that every effort is made to harmonize language to ensure a clear and consistent message. NIH is committed to working with CDC and USDA to ensure comprehensive and consistent guidance for development, validation, and implementation of inactivation protocols.

Among other recommendations, the GAO report called for greater consistency in the collection of data related to biosafety incidents involving incomplete inactivation or failures. Under the *NIH Guidelines,* incidents involving recombinant and synthetic nucleic acid molecules must be reported to NIH. In order to provide greater accuracy in data collection and retrieval concerning inactivation failures, NIH revised its Template for Reporting Incidents subject to the *NIH Guidelines.* Now, the reporting template includes "incomplete inactivation" as a category of reportable incident. NIH has also begun keeping records regarding all infectious materials

subjected to inactivation procedures in our own high containment laboratories, including the destination to which these materials are distributed or shipped. To provide for broader application of this practice, in the upcoming revision of the BMBL, guidance will be included on documenting the shipment of such inactivated material.

The GAO report being released today provides a valuable analysis and recommendations that will inform policies and procedures on inactivation moving forward. To fully implement the GAO recommendations and the guidance that will be in the BMBL, outreach to the research community to reinforce the importance of effective inactivation and associated record-keeping is critical. In May 2017, NIH will be holding its third Safety by Design Symposium and Workshop, the topic of which will be "Microbial Inactivation – Lessons Learned and a Way Forward." This Symposium will provide scientific personnel an opportunity to share experiences regarding the use of various inactivation modalities (physical, chemical, and irradiation); successes and failures; and scientific information gaps. The Symposium format will allow an opportunity for participants to discuss and recommend ways to improve current practices.

NIH is committed to biosafety outreach to the broader research community. An example is NIH's National Biosafety Month, which will occur in October. National Biosafety Month is a period during which NIH-funded research institutions are encouraged to refocus their attention on their biosafety policies, practices, and procedures. This year, the outreach effort will encourage institutions to evaluate their biosafety programs, collaborate with their peers on biosafety, and commit resources to ensure they have robust biosafety governance structure in place.

I want to assure the Subcommittee that NIH remains committed both to 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 continuing strong leadership.

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