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TESTIMONY OF

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Strengthening Security and Oversight at Biological Research Laboratories

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Chairman Cardin, Senator Kyl, and distinguished Members of the Committee:

Thank you for the opportunity to discuss with you the safety and security at our nation's biological research laboratories. Our nation's laboratories are a keystone to the life science research, and are essential to developing public health infrastructure and medical countermeasures crucial to protecting U.S. citizens from biological threats, whether as a result of natural or intentional actions.

The purpose of this testimony is to discuss DoD regulations, practices, and procedures put in place since the 2001 Anthrax incidents that can be applied to improved laboratory biosecurity. It's imperative that the implementation of best practices on a national scale optimize the security of biological agents while providing minimal impact to life science research necessary to develop public health and medical countermeasures against these agents.

I will provide an overview of how the DoD regulations came into existence, how they have been implemented, their proposed integration into current national efforts, and a possible way forward to develop best practices and procedures for Biosafety Level (BSL)-4 laboratory safety and security.

The DoD BSL-3 and BSL-4 laboratories operate as a critical element of our biodefense efforts to understand pathogens of concern and to develop medical

countermeasures to defeat these pathogens, whether they are biological warfare agents or infectious diseases to which our Armed Forces may be exposed.

Following the 2001 Anthrax incidents, Congress passed a series of legislative initiatives to control human, plant, and animal pathogens of concern, this legislation led to the expansion of Select Agent Regulations (42CFR Part 73, 7CFR Part 331, and 9 CFR Part 121). These regulations required each Federal agency to conduct safety and risk assessments, but did not preclude agencies from implementing efforts above and beyond those required by the regulations for safeguarding biological select agents and toxins.

The term "select agent" used in the legislation was used to refer to a specific group of chemical or biological agents that historically have been evaluated and developed for use in weapons. Although the United States does not have a biological weapons program, the use of this term and its historical connotation within the DoD as being associated with weapons programs heavily influenced the direction the Department would take to safeguard its biological agents. Accordingly, the DoD drew from its current chemical and nuclear programs safeguarding measures in developing its regulation for so called biological select agents and toxins, which the Department uses only for basic and applied research in the development of vaccines, therapeutics, and protective countermeasures.

The current DoD risk management framework for safeguarding select agents and toxins consist of a four-fold approach: biosafety, biosecurity, personnel reliability, and agent accountability. Biosafety consists of the application of knowledge, techniques, and

equipment to prevent personal, laboratory, and environmental exposure to potentially infectious agents or biohazards. Biosecurity refers to the protection, control, and accountability of high consequence biological agents and toxins: critical relevant biological materials; and information within laboratories to prevent unauthorized possession, loss, theft, misuse, diversion, or intentional release. The Biological Personnel Reliability Program (BPRP) consists of security background investigations as well as medical, mental health, and drug screening. Agent Accountability consists of the registration of agents, personnel, entities and locations, agent inventory control, and limiting access to registered personnel.

All of the above measures implemented by DoD far exceed the prescribed requirements of the Select Agent Rules. This does not mean that the additional measures constitute a series of best practices and procedures, but only represents the extrapolation of the DoD current weapons material safeguarding policies as applied against biological agents. In fact, they highlight the challenges that arise from the direct application of DoD current policies for safeguarding weapons material to the unique situation of defensive research on biological organism. Biological agents differ from nuclear and chemical threats by their nature and by virtue of their context. Nuclear and chemical are entirely manmade. Biological agents are found throughout nature and exist in the context of infectious disease and public health threats, notwithstanding that they can be potentially used for hostile purposes. This is not to say that there are elements of these regulations that could not be incorporated into best practices. However, a series of studies both

within the DoD and externally suggest that some elements of this program may be too extreme and could not be implemented by other agencies or the civilian sector without severe impact. For example, the use of Single-Scope Background Investigations precludes foreign nationals or personnel having limiting factors, such as financial difficulties or prior non-criminal legal actions, from working with select agents. These background investigations are time intensive and expensive, making it unlikely that academia and industry could support the costs of numerous background investigations. Additionally it would preclude a large segment of exceptionally qualified and talented researchers, particularly foreign national researchers who currently make daily contributions to the advancement of medical and other life science research, from participating in this activity that is so important to the nation. Several recent studies highlight the lack of data to demonstrate such detailed background investigations provide substantial value over the current Department of Justice Security Risk Assessment.

Studies conducted over the past two years by the National Science Advisory Board for Biosecurity, the Defense Science Board, National Academy of Sciences, and the Executive Order 13486, which established the Working Group on Strengthening the Laboratory Biosecurity of the United States, have explored the efficacy and efficiency of current and proposed regulations and policies to strengthen laboratory biosecurity. Reports from the National Science Advisory Board for Biosecurity and the Defense Science Board were submitted to the Executive Branch with a series of recommendations and policy options that can be applied to establishing best practices and procedures for

the nation. The Executive Order 13486 Working Group and the National Academy of Sciences reports are in their final stage of staffing and will be submitted to the Executive Branch in the very near future. Additionally, the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight is soon submitting its report to the Executive Branch.

A potential way forward is to allow the National Security Council to use its Inter-Agency Policy Committee process, in conjunction with input from industry and academia, to review the recommendations and policy options from the collective reports and develop an approach for the nation that optimizes the balance of science and security. Once such an approach is identified, legislative action could be well targeted to ensure the full range of helpful measures needed to enable its implementation.

In summary, the current DoD safety and security measures for safeguarding biological select agents and toxins are derived from its protocols that originally were developed to safeguard its nuclear and chemical weapons materials and not the biological organisms that are critical to developing defenses against our adversaries' biological weapons and naturally-occurring infectious diseases. Although these practices derive from a robust history of security, they most likely would not constitute the basis for best practices and procedures for the nation as they would discourage participation by critical organizations and could be limiting to medical and other life sciences research programs. A more prudent approach would be to exploit the information gathered by the various studies conducted over the past two years and develop a series of appropriately tailored

policies and practices that maintain a balance between safety and security and the pursuit of a robust biological research and development program to ensure the ability to respond to naturally-occurring pathogens, defense of the U.S. homeland, and protection of our Servicemembers.

Thank you for this opportunity to address you on this matter of national importance as well as your continued support to the Department of Defense. I would be happy to answer any questions you and the Members of the Committee may have.