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STATEMENT OF

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Introduction

Chairman Wilson, Ranking Member Langevin, and members of the Subcommittee, thank you for giving me the opportunity to testify on Departmental efforts to Counter Weapons of Mass Destruction (CWMD).

I have the privilege of serving as the Deputy Assistant Secretary of Defense for Chemical and Biological Defense (CBD) as a principal advisor on Chemical and Biological defense matters to the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs (ASD(NCB)). In this capacity, I oversee, integrate, and coordinate the Department's Chemical and Biological Defense Program (CBDP). This program develops capabilities to enable the Warfighter to deter, prevent, protect against, mitigate, respond to, and recover from chemical and biological (CB) threats and their effects. I execute this responsibility in coordination with the Secretary of the Army as Executive Agent to ensure we maintain focus on the operational users and their requirements.

The primary components of the CBDP are the Joint Staff J-8 Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense, which collects, integrates, and validates requirements for the Services and Combatant Commanders; the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense, which executes programs that provide the technical basis for future capabilities; the Joint Program Executive Office for Chemical and Biological Defense for the advanced development, procurement, fielding, and life-cycle management of CBD systems; and the Chemical and Biological Defense Test and Evaluation Executive, which establishes test policy and standards.

The Department of Defense (DoD) CBDP also works closely with the interagency and international partners to coordinate and leverage efforts and accomplishments, ensuring that the DoD, the Nation, and the global community are unified and successful in providing affordable and effective CWMD capabilities.

My testimony focuses on initiatives that address capabilities to prepare, protect, and respond to current and emerging CB threats across the operational spectrum. The wide spectrum of threats requires application of an integrated, layered approach for the development of countermeasures. It is critical that we develop capabilities that reduce operational risk and mission impact to the Joint Force and its partners from CB threats.

CBD Strategic Overview

The strategy of the CBDP aligns with the June 2014 DoD Strategy for Countering Weapons of Mass Destruction (CWMD), which outlines the elements and enablers of the Department's approach for countering CWMD. CBDP efforts support the continuous cycle of preparing, principally through investments that: "ensure staff expertise; and sustain the Department's science and technology, research and development, and acquisition competencies." CBDP executes its responsibility in support of the Department's strategic approach and provides capabilities supporting the three CWMD strategic lines of effort. These lines of effort are:

- 1) **Prevent Acquisition** focuses on ensuring that those not possessing WMD do not obtain them. One of the primary methods of increasing barriers to acquisition and proliferation of WMD will be through pathway defeat—activities focusing on the specific nodes and linkages in an adversary's WMD pathway.
- 2) Contain and Reduce Threats focuses on reducing risks posed by extant WMD. DoD will remain prepared to lead or support operations to locate, characterize, secure, exploit, and destroy WMD in a range of contingency environments and under varying security and political conditions.
- 3) **Respond to Crises** focuses on activities and operations to manage and resolve complex WMD crises. DoD will assume that hostile non-state actors who acquire WMD or material of concern will plan to use them, and the Department will react accordingly. DoD will be prepared to avoid or defeat WMD attacks and mitigate their immediate effects so as to allow effective operations to continue.

The CBDP supports these lines of effort through materiel and non-materiel capabilities that are interoperable within the Joint Forces and other DoD and United States Government partners countering WMD. The President's Fiscal Year (FY) 2016 budget reflects efforts to balance the dynamic tensions of budget, threat, and scientific development to provide a program that is agile and flexible so as to rapidly adapt to the evolving strategic landscape.

Global and Emerging Threats

CB threats are dynamic. The rapid advancement and global proliferation of biological and chemical technologies and knowledge greatly extends the spectrum of plausible actors, agents, concepts of use, and targets. These advances enable states to develop unique CB threats with the intent of circumventing our current defenses, while simultaneously permitting non-state actors to pursue less sophisticated CB threats.

The proliferation of WMD is among the greatest challenges facing the United States, and countering WMD is a top priority in the U.S. National Security Strategy. Accordingly, the CBDP continues to focus on developing enhanced levels of flexibility and adaptability to anticipate, identify, and quickly respond to the challenge. Supporting the rebalance toward the Asia-Pacific region while maintaining a regional focus on countering WMD in the Middle East demands a robust set of CB defense capabilities for countering state and non-state aggressors.

While reasonable threat assessments may be made regarding state-sponsored threat developments, the ideologies of transnational organizations and violent extremists, and their lower observability, have created a more volatile threat environment. Rapid advances in biotechnology are making it easier to develop biological attack capabilities. Chemical technologies are likewise evolving at a progressive rate, and when used alone or with other technologies can create traditional or emerging non-traditional agents (NTAs).

Some threats are naturally occurring, and as such infectious diseases must be a focus of the CBDP. The DoD often deploys forces into areas where unusual diseases are endemic, hence a requirement for countermeasures to protect the force. Second, many naturally occurring pathogens are suited for use by adversaries. An unexplained outbreak of anthrax may be

traceable to natural or manmade causes; however, both require the same suite of medical countermeasures. Finally, the Department must be ready to play an important role in responding to pandemics.

Understanding that the history of warfare is marked by the element of surprise, the CBDP must operate across three timeframes: near, mid, and far. In the near term, any terrorist attack will most likely use a classic biological agent, such as anthrax, or a readily available industrial chemical, such as chlorine. While an attack using a modified agent is more likely to emerge over the mid to far term, we must evolve our defensive capabilities over time to meet this potential evolution. Incorporating solution sets that allow the entire Joint Force to operate effectively in a CB contaminated environment is paramount.

Key CBDP Accomplishments

Ebola Response and Preparedness: Medical Countermeasures, Diagnostics, Transport Isolation System, and Biosurveillance

CBDP efforts have been instrumental in providing capacity and capabilities supporting the Department's response to the Ebola outbreak in West Africa. Through the Public Health Emergency Medical Countermeasures Enterprise, the CBDP expedited several advanced products, including an Ebola vaccine and several Ebola therapeutics, into clinical trials in the U.S. and West Africa in less than six months. DoD also developed and fielded a Food and Drug Administration (FDA)-approved capability for Ebola diagnosis. This diagnostic kit was the first to be granted Emergency Use Authorization during the recent Ebola outbreak, and it remains the primary diagnostic used across the U.S. Government. In tandem with these diagnostics efforts, the CBDP, in coordination with interagency and international partners, developed a rapid biosurveillance portal capability to gather and synchronize information. This portal improved situational awareness for Ebola in West Africa. Further protective measures were supported through the development and fielding of a Transport Isolation System, which increases caregiver and aircrew safety while transporting Ebola-exposed patients on military aircraft. By taking action to address this exponentially growing epidemic, we have saved lives and enhanced stability and security in the region, while reducing the threat that this fatal disease could arrive on U.S. shores and spread among our population.

Research, Development and Acquisition (RDA)

CBDP RDA efforts continuously support the strategic approach to preparing for CWMD events and providing critical capabilities enabling response to WMD crises. It is imperative that the Department continue to reduce risks by advancing the technical readiness of countermeasures and ensuring rapid response capabilities to deliver mature technologies. The Ebola emergency response reminds us that a technological warm-base enables rapid capability development and deployment.

The CBDP continues to conduct research and develop technologies for a range of chemical defense capabilities, including detection, medical countermeasures, decontamination, and protection, and advances fundamental scientific knowledge in the physical sciences and threat agents to support defense capabilities. Recent accomplishments include: advancing characterization and toxicity estimates, advancing fundamental information supporting improved detection, transition of decontamination efforts to advanced development, and transition of

enhanced medical countermeasures. Additionally, the DoD continues to support interagency efforts to develop NTA defense capabilities and has created mechanisms, networks, and processes where data and information is shared across the DoD and the Interagency. The DoD recently created an NTA Defense Research, Development, Test, and Evaluation Strategy to synchronize objectives for NTA defense solutions, acquisition planning, and programming actions.

To counter biological threats, vaccinations are available to prevent disease caused by two of the leading biological warfare threats (anthrax and smallpox). DoD continues to make progress on additional vaccine candidates for plague, botulinum toxins, Ebola and Marburg viruses, ricin, and equine encephalitis viruses; and nerve agent pretreatments. Our efforts have furthered the development of novel therapeutics for bacterial and viral threats, including Ebola.

The National Strategy for Biosurveillance, published in July of 2012, defines biosurveillance as, "the process of gathering, integrating, interpreting, and communicating essential information related to all-hazards threats or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and to enable better decision-making at all levels." The CBDP is developing enhanced and integrated biosurveillance systems; these systems are comprised of RDA efforts supporting improved environmental detection systems, rapid medical diagnosis, and integrated information systems. Through FY 2015, the Joint United States Forces Korea Portal and Integrated Threat Recognition advanced technology demonstration, also known by the acronym JUPITR, continues to provide specific detection and analysis capabilities to address the need for biosurveillance on the Korean Peninsula. It will enhance the ability of U.S. Forces Korea and the Republic of Korea to respond to biological threats.

Improved Risk Assessment Process

We are now using a more rigorous, risk-informed approach to develop and assess our portfolio. Current and emerging threats are compared to capabilities within the context of planned and future operations. We continually evaluate our portfolio to assess ways to mitigate risks through a layering of capabilities, such as integrated protection for threats that present a challenge to our detection systems. We consider Force Management Risk through the lens of modernization, and Institutional Risk through our ability to develop capabilities now and in the future. Through this process, we identify areas within CBD that present the most risk to the Warfighter, both now and in the future, and then shape our portfolio to best reduce that risk, from science and technology (S&T) through advanced development, testing, and fielding.

Through this risk-based process, we have determined that the threat of undetected attacks upon the force remains one of CBDP's most intractable problems. Detection, identification, and attribution of attacks remain significant technological challenges. Detection capability to proactively prevent contamination remains elusive, particularly for biological threats. While an improved "detect-to-treat" capability is showing promise, the window for early detection and warning to prevent casualties requires continued dedicated efforts. As a result, we are pursuing vaccines and therapeutics for the most dangerous threats that we currently cannot detect in adequate time to warn the Warfighter to take other protective measures.

While the risk of a newly emerging threat may be difficult to foresee, we mitigate the potential risks from surprise in three ways. First, we look at the evolving threat and emerging technologies that could be used as enablers of our defenses. Second, we maintain a robust capability within DoD laboratories to anticipate and counter surprise. Finally, we exercise our response to unanticipated threats.

Looking Forward: FY2016 Efforts

The President's FY 2016 CBDP Budget request of \$1.285 billion includes a total of \$395 million for S&T, \$510 million for advanced development, and \$279 million for procurement and fielding of capabilities. Addressing the various CB risks requires S&T to understand the threat and the development of an end-to-end portfolio of capabilities across the spectrum of protection (e.g. physical and medical prophylaxis capabilities), detection (e.g. detection and diagnostic equipment), and response (e.g. decontamination and medical therapeutic capabilities). Tying these capabilities together requires the communication of early warning, indications, and situational awareness (e.g. biosurveillance tools).

Fielded technologies must meet the needs of the end-users. As such, incorporating input from Warfighters and other end-users is an integral component of the CBDP activities. Starting with S&T input, concepts development, and requirements generation, end-users participate and shape the technology that is transitioned to advanced development, tested, and fielded. Direct, end-user feedback informs our mission and allows us to fulfill our commitment to serve the Warfighter.

Chemical Research, Development and Acquisition (RDA) Capabilities

The DoD has active programs that provide the capabilities required to respond to chemical threats in a layered approach. We invest in detection equipment to identify chemical agents and provide situational awareness for response. We also provide protective equipment to shield against exposure, and we develop responsive medical countermeasures.

The DoD's development of chemical defense capabilities is a key part of an integrated national effort to address traditional and non-traditional threats. In this budget request, we continue to conduct research and develop technology for a range of chemical defense capabilities, including detection, medical countermeasures, decontamination, and protection and advance fundamental scientific knowledge in the physical sciences and threat agents needed to support these defense capabilities. The proliferation of NTA information, implications of operational use, and asymmetric impacts of employment on the force have compelled the DoD to accelerate efforts to counter NTAs.

Biological RDA Capabilities

The DoD also continues to prepare for the intentional use of biological agents against the Joint Force, our allies, and partners. Rapid advancements in biotechnology are making it easier for an adversary, whether state or non-state, to develop biological weapons. Biological threats from an attack, accidental release, or natural occurrence have the potential to cause enormous damage in terms of lives lost, economic impact, and ability to recover. As stated in the National Strategy for Countering Biological Threats, "fanatics have expressed interest in developing and using

biological weapons against us and our allies." We are working proactively to prepare for both existing and emerging biological threats and to respond rapidly when necessary.

Biological agents have the capacity to spread without regard to borders, conflicts, or intentions. As such, countering biological threats lies at the nexus of security and health, and must be addressed by all stakeholders involved, to include health, defense, law enforcement, private, international, and non-governmental counterparts. One of our primary initiatives in FY 2016 to address this challenge is the Global Health Security Agenda (GHSA), which is an international effort to enhance the World's ability to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental, or intentionally caused. The recent Ebola outbreak in Western Africa highlighted the need for this work. In his State of the Union address, the President recognized the efforts of U.S. military personnel, scientists, and health care professionals in rolling back the Ebola virus disease in West Africa, saving countless lives. He also stated that "the job is not yet done, and the world needs to use this lesson to build a more effective global effort to prevent the spread of future pandemics." The DoD is committed to serve this mission.

CBDP ongoing activities to develop biosurveillance and diagnostic tools, as well as prophylactic and therapeutic medical countermeasures support the GHSA. Diagnostic systems used by military clinics and field laboratories are critical to the early identification and confirmation of a broad range of chemical, biological, and radiological hazards, including emerging infectious diseases. In addition to the DoD-developed and fielded FDA-cleared capability for diagnosis of Ebola, we are now moving forward with a next generation diagnostic capability for biological warfare agents and infectious diseases outside of established medical centers. The FY 2016 budget request includes expanding that capability to include the ability to diagnose multiple biological warfare agents within a single test. Additionally, CBDP is developing comprehensive, easy-to-use diagnostic platforms; advancing new diagnostic devices though the FDA approval process; and addressing the looming concerns associated with antimicrobial and multi-drug resistance pathogens.

The FY 2016 budget requests continuation of CBDP prevention and treatment efforts. We continue efforts on vaccine candidates for plague, botulinum toxins, Ebola and Marburg viruses, ricin, and equine encephalitis viruses; and nerve agent pretreatments. Efforts continue supporting research and development of novel therapeutics for bacterial and viral threats, and we continue to advance a fundamental understanding of the physiological response to biological threats to enable continual progress on countermeasures.

Institutional Capabilities

We must continue to invest in the intellectual and physical capabilities critical to addressing CB defense. Part of our Institutional Risk Assessment involved reviewing the DoD assets critical to our continued development of CBD capabilities and intellectual capacity to be able to respond to surprise. The main assets are the U.S. Army Medical Research Institute for Infectious Disease (Fort Detrick, Maryland), U.S. Army Medical Research Institute for Chemical Defense (Aberdeen Proving Ground, Maryland), Edgewood Chemical and Biological Center (Aberdeen Proving Ground, Maryland), and West Desert Test Facility (Dugway Proving Ground, Utah).

The FY 2016 budget request funds research and sustainment to ensure the continued operation of these critical institutional capabilities.

DoD must be flexible and agile to meet a broad range of medical countermeasure needs for agents encountered by the Joint Force. To meet this need, the Department has continued its investment in a manufacturing capability through the Advanced Development and Manufacturing (ADM) facility being developed in Alachua, Florida. The DoD ADM and the Health and Human Services (HHS) Centers for Innovation and Advanced Development and Manufacturing (CIADM) capabilities are complementary. Supported by a joint governance board, DoD and HHS have managed the design of their respective capabilities to ensure maximal use of the national capability and to ensure that the DoD is technically matched to the scale required for the Joint Force. In partnership with HHS, we are revolutionizing national capabilities to respond to emergencies and address threats to DoD personnel and U.S. citizens across the globe.

Conclusion

Chemical and biological threats to our troops, homeland, allies, and civilians around the world are very real and constantly evolving. Consequently, DoD must develop agile programs to respond. The Chemical and Biological Defense Program is working to strengthen our capabilities to effectively prepare, protect, and respond to these threats. I ask you to support the President's FY 2016 budget request so we can continue to advance and deliver these capabilities.

I appreciate the opportunity to testify today and will be pleased to answer your questions.