STATEMENT FOR THE RECORD

OF

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CHEMICAL AND BIOLOGICAL DEFENSE

BEFORE THE

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COMMITTEE ON ARMED SERVICES

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INTRODUCTION

Mr. Chairman, Congressman Langevin, and distinguished members of the subcommittee, I am honored to testify on behalf of the Department of Defense (DoD) Chemical and Biological Defense Program, the U.S. Army as the Program's Executive Agent, and as the Joint Program Executive Officer for Chemical and Biological Defense. I am pleased to appear alongside my civilian leaders and partners who have articulated the global security environment, strategic priorities, and the mission of countering weapons of mass destruction. I am going to provide an update regarding the Chemical and Biological Defense Program contribution to the latter mission. My update will focus on biosurveillance, diagnostics, the new Medical Countermeasures Initiative, and non-traditional agent defense. I will conclude by briefly highlighting several activities in response to the call by the Secretary of Defense for greater efficiency in DoD program management.

MISSION AND BACKGROUND

Enacted by Congress in 1993, Public Law 103-160 created the Chemical and Biological Defense Program. The law required the Secretary of Defense to assign responsibility for overall coordination and integration of chemical and biological defense programs to a single office within the Office of the Secretary of Defense. The Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs has that responsibility and is the focal point for oversight of the Program. Public Law 103-160 also established the U.S. Army as the Chemical and Biological Defense Program Executive Agent to coordinate and integrate research, development, test and evaluation, and acquisition for the Military Services.

Primary components of the Chemical and Biological Defense Program are the Joint Staff's Joint Requirements Office for Chemical, Biological, Radiological and Nuclear Defense to establish priorities and requirements, the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense to execute science and technology programs that provide the technical basis for future capabilities, and the Joint Program Executive Office for Chemical and Biological Defense for the advanced development, procurement,

fielding, and life-cycle management of systems. The Chemical and Biological Defense Program Test and Evaluation Executive establishes test policy and standards while the Program Analysis and Integration Office oversees budget execution. Outside the DoD, the Chemical and Biological Defense Program works closely with other federal stakeholders, such as the Department of Health and Human Services and the Department of Homeland Security. We also maintain a strong international program that includes America's closest allies.

FISCAL YEAR 2012 DEPARTMENT OF DEFENSE BUDGET REQUEST

The Fiscal Year 2012 Budget Request for the Chemical and Biological Defense Program includes $254 million for procurement, $771 million for advanced development, and $502 million for science and technology efforts for a total of $1.52 billion. The President's budget request represents an executable and integrated medical and non-medical joint program that balances the immediate need to field capabilities and solutions against the long-term research efforts necessary to guard against technological surprise. In addition to a healthy science and technology base program, a promising advanced development component, and continued procurement of essential defense systems, the budget request represents a strategic shift toward a comprehensive response to the threat of bioterrorism and emerging chemical threats. Our focus on biosurveillance, diagnostics, the new Medical Countermeasures Initiative, and non-traditional agent defense supports this shift.

BIOSURVEILLANCE

Our ability to obtain early warning about the deliberate use or natural emergence of dangerous pathogens hinges upon the development of a global biosurveillance network. The Chemical and Biological Defense Program's role is to develop and integrate technologies to enable early warning, identification, and continued situational awareness of existing or potential global threats. We provide the diagnostics, detectors, collectors, reference materials, medical prophylaxis and therapeutics, and data fusion technologies to enable the DoD to execute its part of the biosurveillance mission, while providing information and products to other federal agencies, as appropriate.

Over the past year, the Chemical and Biological Defense Program established the Joint Product Management Office – Biosurveillance and tasked it with the mission of developing and integrating biological defense technologies to enable early warning, identification, and continued situational awareness of potential global health threats. This office serves as the biosurveillance focal point to facilitate portfolio integration across the Joint Program Executive Office for Chemical and Biological Defense as well as integrate with other DoD, interagency, and international efforts. The office also manages key DoD programs enabling biosurveillance such as the Joint Biological Agent Identification and Diagnostics Program, the Next Generation Diagnostic System, and the Critical Reagents Program.

Open lines of communication are critical to meet the challenges of an evolving biological threat. Only when medical, public health, and environmental data and reporting technologies are integrated will our leaders be able to make the quick and accurate decisions that save lives. Internal to the DoD, we continue to build strong working relationships with the policy and healthcare elements within the Office of the Secretary of Defense to include a key partnership on disease surveillance and influenza diagnostics with the Armed Forces Health Surveillance Center and its Global Emerging Infections Surveillance and Response System. We are prototyping an information management tool in the Republic of Korea to enable the U.S. Forces Korea Surgeon to see medical and environmental data in real-time as one common operating picture.

External to the DoD, the Chemical and Biological Defense Program has agreements with the Department of Homeland Security BioWatch Program to share data and concepts of operations and provide biosurveillance assays. The Joint Program Executive Office for Chemical and Biological Defense is building upon interagency relationships with the Department of Homeland Security, the Department of Agriculture, and the Department of Health and Human Services. Internationally, we maintain partnerships with our closest allies. All of this internal, external, and international collaboration is aimed at defining roles and responsibilities for specific areas of collaboration as a mechanism to leverage funds, reduce duplicative efforts, and accelerate the development of technologies to achieve the objectives outlined in the *National Strategy for Countering Biological Threats*.

As we look to the future, our equipment and systems will need to be adaptable and flexible to detect biological threats, both naturally occurring and intentionally created, early enough to initiate a rapid and effective response. To inform our development efforts, we are conducting a comprehensive market survey of the hardware technologies enabling biosurveillance. The results of this survey will be shared with our DoD and interagency partners when completed this spring. Additionally, we have directed a study to explore technology needs towards achieving environmental biological surveillance and hazard detection within the context of the *National Strategy for Countering Biological Threats*.

DIAGNOSTICS

Diagnostics is fundamental to biosurveillance and it is a key area of our expertise in the Chemical and Biological Defense Program. The Joint Product Management Office – Biosurveillance develops and integrates state-of-the-art chemical and biological diagnostic and identification systems to enable both force protection and force health protection. As noted earlier, it leads an integrated portfolio of two diagnostic system acquisition programs, the Joint Biological Agent Identification and Diagnostic System and the Next Generation Diagnostic System, as well as the Critical Reagents Program.

The Joint Biological Agent Identification and Diagnostic System is a reusable, portable, modifiable biological agent identification and diagnostic system capable of rapid, reliable and simultaneous identification of multiple biological agents and other pathogens of operational concern. The system is fielded to over 300 locations worldwide with the National Guard Bureau, Navy, Marine Corps, Army, and Air Force. The system has Food and Drug Administration cleared diagnostics tests for Anthrax, Plague, Tularemia, and Avian Influenza as well as over seventy pre-emergency use authorization data packages ready for deployment upon declaration of a national emergency.

Funded in the fiscal year 2012 budget request, the Next Generation Diagnostic System program will develop a family-of-systems, providing modular orthogonal diagnostics capabilities

across all operational echelons (tactical, field confirmatory, and fixed facilities). It will be fielded over several acquisition increments. The system will also include enabling technologies to enhance the screening, collection and transport of clinical samples for diagnostic analysis and back-end data analysis and fusion.

The Critical Reagents Program houses the most extensive collection of quality-controlled biological defense reagents and test materials used throughout the Federal Government. A national resource for the biological defense community, the Critical Reagents Program serves as the principal resource of high quality, validated, and standardized biological detection assays and reagents that meet the requirements of the warfighter and joint biological defense systems. These assays and reagents also facilitate the transition of new technologies and coordinate their advanced development, efficient production, and timely distribution.

With these three programs in our portfolio, the Chemical and Biological Defense Program is leading the DoD diagnostics effort and remains well positioned to further contribute to emerging DoD biosurveillance requirements.

MEDICAL COUNTERMEASURES INITIATIVE

As this subcommittee is aware, the national security threat posed by bioterrorism and infectious disease is real. Our national security is challenged by the complexities associated with rapidly responding to a biological attack with countermeasures that limit impacts and subsequent loss of life. In his 2010 State of the Union Address, President Obama stated, "The United States must have the capacity to respond faster and more effectively to bioterrorism or an infectious disease." National leadership has renewed and elevated the importance of a national solution with the DoD playing a critical role given our successful development of medical countermeasures approved by the Food and Drug Administration for specific chemical and biological agent threats. In fiscal year 2012, the DoD begins to establish a dedicated medical countermeasure advanced development and flexible manufacturing capability for the purpose of national defense. This new effort is aligned with the DoD mission of protecting our people. Threats to the warfighter are also likely threats to the nation. Further, forces are currently

deployed where exposure to unknown or indigenous pathogens is likely. Vital to any response is the agile development and manufacturing of medical countermeasures in quantities to treat affected populations rapidly. To this end, we are collaborating with the Department of Health and Human Services to create a national biodefense rapid manufacturing capability.

The DoD Medical Countermeasures Initiative encompasses three major elements: a science and technology component, a test and evaluation component, and an advanced development and manufacturing component. Both the science and technology and the advanced development and manufacturing components will be managed by the Chemical and Biological Defense Program while the test and evaluation component will be executed by the U.S. Army Medical Research and Materiel Command. Science and technology efforts will be concentrated in three areas: 1) novel platform/expression systems for medical countermeasures, 2) advancement of regulatory science, and 3) advancements in flexible manufacturing technologies. The test and evaluation component will provide a national test and evaluation facility for animal studies to support development of medical countermeasures. The advanced development efforts will be concentrated in two areas: 1) further maturation of novel platform/expression systems and integration into a production process, and 2) establishment of a Technical Center of Excellence comprised of an advanced development and flexible manufacturing capability. Ultimately, the DoD Medical Countermeasures Initiative's three major elements will coalesce to provide a 'one-stop shop' for all future DoD biological medical countermeasure development.

During early fiscal year 2012, the DoD plans to award a multi-year contract to establish, commission, and validate this advanced development and manufacturing capability. The Chemical and Biological Defense Program's two medical advanced development offices, the Joint Project Manager – Chemical and Biological Medical Systems, and the Joint Project Manager – Transformational Medical Technologies will use this capability for advanced development and manufacturing of their products.

The DoD Medical Countermeasures Initiative was developed not only in response to the President's call to redesign our medical countermeasure enterprise during the 2010 State of the Union but also pursuant to *Executive Order - Medical Countermeasures Following a Biological*

Attack (December 30, 2009), *Homeland Security Presidential Directive 18, Medical Countermeasures Against Weapons of Mass Destruction* (January 31, 2007), and *Homeland Security Presidential Directive 10, Biodefense for the 21st Century* (April 28, 2004).

NON-TRADITIONAL AGENT DEFENSE

A fundamental component of countering advanced threats is addressing non-traditional agents. Non-traditional agents are chemicals and biochemicals reportedly researched or developed with potential application or intent as chemical warfare agents, but which do not fall in the category of traditional chemical warfare agents, toxic industrial chemicals, or toxic industrial materials. The Chemical and Biological Defense Program develops capabilities to counter non-traditional agents through an integrated portfolio process focusing on the enabling science and technology, test and evaluation, and the advanced development of detection, medical countermeasures, decontamination, and individual protection products.

A national level non-traditional agent defense research, development, test, and evaluation strategy has been published to develop a research and development capability through a comprehensive interagency effort. The Chemical and Biological Defense Program's three phase integration into the national strategy is funded across the DoD Future Years Defense Program. In the near-term (fiscal years 2010 – 2011), we are accelerating scientific understanding, rapidly fielding interim defense capabilities, and continuing ongoing non-traditional agent defense efforts. For the mid-term (fiscal years 2012 – 2016), we will complete scientific understanding, continue to field integrated defense capabilities, and expand efforts to emerging non-traditional agent threats. In the far-term (fiscal year 2017 and beyond), we plan to expand non-traditional agent scientific understanding and complete fielding of defensive capabilities for emerging non-traditional agent threats.

DOD EFFICIENCIES INITIATIVE

Pursuant to Under Secretary of Defense for Acquisition, Technology & Logistics Dr. Ashton B. Carter's September 14, 2010, *Implementation Directive for Better Buying Power*, we are integrating measures to ensure all of our programs are affordable and provide a positive return on investment for the taxpayer. These measures include eliminating low impact but high-cost requirements, increasing competition, and improving cost estimation and management through every program's life cycle. Within my command, we are realigning our organizations to be more cost-effective. For example, we recently consolidated three of our subordinate organizations into one, thereby reducing staff by thirty-one full time positions and accruing a cost avoidance estimated at $5 million. Further, we have reduced our contractor support and other overhead saving several millions this year. Finally, I have mandated a workload study to help us further reduce overhead within the Joint Program Executive Office for Chemical and Biological Defense by $100 million over the Future Years Defense Plan. As a whole, the Chemical and Biological Defense Program understands the importance of maximizing efficiency while providing the capabilities necessary to protect both our military and civilian populations.

CONCLUSION

Today we face a broad array of threats, both natural and manmade. This challenge will only increase with the exponential growth in the field of biotechnology, global industrialization, and the wealth of scientific information available through mass communications. There are multiple needs in the medical and non-medical chemical and biological defense arena that are addressed in the President's budget. The Chemical and Biological Defense Program respects the fiscal limitations our country faces and is rising to this challenge by creating efficiencies. I urge the Congress to fund the development of improved chemical and biological defense capabilities to protect our citizens in this changing and uncertain environment. Mr. Chairman, Congressman Langevin, and members of the subcommittee, on behalf of the men and women of the Chemical and Biological Defense Program, thank you for the opportunity to appear before you. We are grateful for the support and leadership we receive from Congress.