RECORD VERSION

STATEMENT BY

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ON

THE FISCAL YEAR 2015 BUDGET REQUEST FOR THE DEPARTMENT OF DEFENSE AND COMBATING WEAPONS OF MASS DESTRUCTION IN A CHANGING GLOBAL ENVIRONMENT

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INTRODUCTION

Mr. Chairman, Congressman Langevin, and distinguished members of the subcommittee, thank you for the opportunity 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 be joined by my leaders and partners who set the strategic priorities for the mission of countering weapons of mass destruction. I am going to provide an update regarding the Chemical and Biological Defense Program contribution to this mission, specifically focusing on the Program's four areas of emphasis which are medical countermeasures, diagnostics, biosurveillance, and non-traditional agent defense. I will also note the role of the countering weapons of mass destruction research and development community in the mission to destroy Syrian chemical weapons.

MISSION AND STRUCTURE

The DoD Chemical and Biological Defense Program was created by Public Law 103-160, enacted by Congress in 1993. 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 task and is responsible for oversight. Public Law 103-160 also established the U.S. Army as the Executive Agent for the Chemical and Biological Defense Program with the mission of coordination and integration of 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 foundation for future capabilities, and the Joint Program Executive Office for Chemical and Biological Defense to manage 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. External to the DoD, the Chemical and Biological Defense Program works closely with our federal agency partners such as the Department of Health and Human Services and the Department of Homeland Security. We also maintain an active international engagement and collaboration program that includes several of our Nation's closest allies.

FISCAL YEAR 2015 DEPARTMENT OF DEFENSE BUDGET REQUEST

The Fiscal Year 2015 Budget Request for the Chemical and Biological Defense Program includes $320.5 million for procurement, $553.6 million for advanced development, and $407.2 million for science and technology efforts within a total of $1.387 billion. The budget request supports the Program's four enduring strategic goals:

1. Equip the force to successfully conduct military operations to prevent, protect against, and respond to chemical, biological, radiological, and nuclear threats and effects.
2. Prevent surprise by anticipating chemical, biological, radiological, and nuclear threats and developing new capabilities for the Warfighter to counter emerging threats.
3. Maintain infrastructure to meet and adapt current and future needs for personnel, equipment, and facilities within funding constraints.
4. Lead the enterprise to integrate and align activities to fulfill the Chemical and Biological Defense Program mission.

Continued realization of these strategic goals is significantly impacted by progress in the Program's emphasis areas of medical countermeasures, diagnostics, biosurveillance, and non-traditional agent defense.

MEDICAL COUNTERMEASURES

Medical countermeasures include capabilities to protect the Warfighter against chemical, biological, and radiological threats. The Chemical and Biological Defense Program develops both prophylaxes, such as vaccines to immunize personnel, and therapeutics to treat personnel in the event of exposure. *Homeland Security Presidential Directive – 18: Medical Countermeasures Against Weapons of Mass Destruction (2007)* directed U.S. government agencies to collaborate on the development of medical countermeasures. A primary mechanism for that collaboration is the Public Health Emergency Medical Countermeasures Enterprise. This body coordinates Federal efforts to increase national preparedness with respect to medical countermeasures. It is led by the Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and includes the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, the DoD, the Department of Veterans Affairs, the Department of Homeland Security, and the Department of Agriculture. Mr. Andrew Weber, the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs, represents the DoD at the most senior level of this interagency body. Typifying coordination within the Enterprise is the Portfolio Advisory Committee which works to align DoD and Department of Health and Human Services resources for medical countermeasures development and infrastructure. Other Enterprise mechanisms for collaboration include the integrated product teams established to synchronize the continued efforts of several agencies against specific threats such as Anthrax and Botulism.

While there is a great deal of collaboration and coordination, it is important to understand that different agencies have different requirements based on their distinct missions. For instance, critical to the DoD is protecting deployed military forces prior to

exposure or attack while the Department of Health and Human Services emphasizes responding to attacks and threats to the U.S. population after exposure. *Homeland Security Presidential Directive - 18* affirmed the unique nature of DoD requirements, stating, “The Secretary of Defense shall retain exclusive responsibility for research, development, acquisition, and deployment of medical countermeasures to prevent or mitigate the health effects of WMD threats and naturally occurring threats to the Armed Forces and shall continue to direct strategic planning for and oversight of programs to support medical countermeasures development and acquisition for our Armed Forces personnel.” The composition of the DoD Chemical and Biological Defense Program medical countermeasures portfolio is determined by the Warfighter’s funded requirements and based on Warfighter threats and priorities. The Joint Staff’s Joint Requirements Office for Chemical, Biological, Radiological, and Nuclear Defense identifies future operational capability needs including medical countermeasures with input from the Military Services, the Joint Staff-led Capabilities Based Assessments, and the Combatant Commands. The output of this process is the Joint Priority List, which identifies and prioritizes required capabilities.

To accelerate the fulfillment of our unique requirements, the Chemical and Biological Defense Program is establishing the DoD Medical Countermeasures Advanced Development and Manufacturing Capability, a dedicated state-of-the-art center of excellence focused on flexible, modular, and disposable single-use manufacturing techniques. The intent is flexible and modular manufacturing to support DoD quantities, which have historically been significantly less than the quantities required by the Department of Health and Human Services, while working with our unique industrial base which in this specialized area is normally small businesses. The facility will cover a full array of development and production services and be capable of Biosafety Level 3 manufacturing. As we establish a product pipeline feeding Chemical and Biological Defense Program medical countermeasure programs of record to the center of excellence, we intend to implement lessons learned on each additional DoD product with advances in new regulatory sciences and manufacturing processes to shorten development cycles and eliminate redundancies. The goal of the effort is to

enable faster delivery of medical countermeasures designed to protect and treat military personnel. This past October, the prime contractor for the DoD Medical Countermeasures Advanced Development and Manufacturing Capability began construction of a thirty-acre complex in Alachua, Florida, using privately secured financing to fulfill the contract awarded by the DoD. We anticipate that the facility will be completed by the end of fiscal year 2015.

DIAGNOSTICS

Diagnostic capabilities provide health care providers with timely and accurate information to inform individual patient treatment. Additionally, the threat identification information obtained during diagnostic testing will provide commanders with situational awareness of biological hazards to support Force Protection and Force Health Protection decision making. Our diagnostic end state is to provide seamless biological warfare diagnostic capabilities throughout all echelons of the DoD Combat Health Support System and to facilitate the use of next generation diagnostic capabilities by the DoD in the areas of field analytics, infectious disease biosurveillance, cooperative engagement, and pathogen discovery.

The Chemical and Biological Defense Program has sharpened the DoD diagnostics portfolio by increasing the capability of our fielded system, some 340 of which have been provided to the Military Services. The Joint Biological Agent Identification and Diagnostic System is a portable system capable of rapid, reliable, and simultaneous identification of specific biological agents and pathogens. By partnering with the U.S. Army Medical Research and Materiel Command and the Food and Drug Administration, we have made accessible additional diagnostic assays for high consequence, low probability biological threat agents for use during declared public health emergencies. This collaboration has facilitated the availability of viral hemorrhagic fever diagnostic assays for use during a declared emergency and adds previously unavailable preparedness capabilities to this fielded system.

Looking to the future, our Next Generation Diagnostics System is under development. It will be part of a family of systems supporting medical diagnostics and surveillance across echelons of care, with the additional objective to provide common biological identification materiel solutions across our portfolio of equipment. The Next Generation Diagnostics System Increment 1 – Deployable Component recently completed competitive prototyping and the winning contractor is in the process of developing Food and Drug Administration cleared medical diagnostics devices as well as diagnostic assays. Increment 1 of the system offers increased ease of use over the currently fielded system as well as immediate military utility through available commercial-off-the-shelf assays cleared by the Food and Drug Administration. The plan is for the Next Generation Diagnostics System Increment 1 to replace the Joint Biological Agent Identification and Diagnostic System beginning in 2017.

BIOSURVEILLANCE

Consistent with *Homeland Security Presidential Directive – 21: Public Health and Medical Preparedness* (2007), the *National Strategy for Countering Biological Threats* (2009), the *National Strategy for Biosurveillance* (2012), and the Global Health Security Agenda (2014), the Chemical and Biological Defense Program is moving forward assertively to apply its expertise and equipment to improve situational awareness for the Warfighter and the Nation. The *National Strategy for Biosurveillance* 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 Chemical and Biological Defense Program’s competencies lend themselves well to this complex challenge. We are determined to advance biosurveillance technology by integrating chemical and biological defense systems so that field detectors, diagnostic devices, and information systems can better inform battlefield commanders.

A prime example is the ongoing Joint United States Forces Korea Portal and Integrated Threat Recognition advanced technology demonstration, also known by the acronym, JUPITR. Led by the Joint Program Executive Office for Chemical and Biological Defense and supported by U.S. Army Edgewood Chemical Biological Center, this advanced technology demonstration is providing specific detection and analysis resources to address the need for biosurveillance on the Korean Peninsula. The objective is to significantly increase defense capabilities to mitigate impending biological threats to U.S. Forces Korea and the Republic of Korea. Currently underway, JUPITR is providing, 1. a web-based portal that facilitates unclassified collaboration by automatically collecting and sharing biological threat information as well as generating hazard analysis and situation reports to better inform command decision-making; 2. new, cutting edge laboratory equipment to identify biological toxins and pathogens of concern much more rapidly than current systems in use at U.S. Forces Korea facilities; 3. an assessment of a variety of environmental field sensors to determine the best product for biological detection and identification by U.S. Forces Korea; and, 4. integration of a suite of non-chemical and non-biological force protection sensors, such as cameras and radar, with chemical and biological standoff and point sensors to demonstrate a chemical and biological early warning capability. The JUPITR advanced technology demonstration is expected to be completed during fiscal year 2015.

NON-TRADITIONAL AGENT DEFENSE

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 2010 Quadrennial Defense Review directed the DoD to increase resources for research and development of countermeasures and defenses to non-traditional agents. The Fiscal Year 2015 Budget Request continues to evaluate non-traditional agent threats and test developmental technologies to enhance the capability of Chemical and Biological Defense Program systems to counter these threats. To address the need for a near term capability to combat emerging threat

materials, we have already provided Domestic Response Capability kits to the National Guard weapons of mass destruction civil support teams resident in all 50 states. These kits provide emerging threat mitigation capability that includes detection, personnel protection, and decontamination.

ELIMINATION OF SYRIA'S CHEMICAL WEAPONS

In anticipation of the need to address Syria's chemical weapons stockpile in the context of the Syrian Civil War, the DoD created the Field Deployable Hydrolysis System, a transportable, high throughput neutralization system designed to convert chemical warfare materiel into compounds unusable as weapons. The DoD response in this case is an excellent example of collaboration and agility in capability development. An acquisition effort was launched in February of 2013 and the first system was delivered less than six months later. A government team comprised of the Joint Program Executive Office for Chemical and Biological Defense, the Defense Threat Reduction Agency, U.S. Army Edgewood Chemical Biological Center, U.S. Army Chemical Materials Activity, and U.S. Army Contracting Command produced this capability which is now deployed aboard the motor vessel *Cape Ray*. When this roll-on/roll-off type ship receives Syrian chemical warfare materials, it will head out to international waters to carry out the neutralization process using the Field Deployable Hydrolysis System, a capability that the U.S. would not have but for this innovative joint effort within the DoD.

CONCLUSION

As this subcommittee is well aware, a confluence of technological, political, and economic factors are making the current security environment as challenging as any Congress and the President have faced in the Nation's history. Continued collaboration is critical to advancing chemical, biological, and radiological defense science and engineering to maintain the technological advantage currently held by our forces. I look forward to continued cooperation with the subcommittee to meet the DoD's unique

requirements for specific systems for the Warfighter. 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 again for the opportunity to appear before you today and thank you for your continued support.