

STATEMENT FOR THE RECORD  
OF  
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CHEMICAL AND BIOLOGICAL DEFENSE  
BEFORE THE  
SUBCOMMITTEE ON TERRORISM, UNCONVENTIONAL THREATS AND  
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## **INTRODUCTION**

Madam Chair, Congressman Miller, and distinguished Members of the Subcommittee, I am honored to testify on behalf of the Department of Defense 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 the Assistant to the Secretary of Defense for Nuclear and Chemical and Biological Defense Programs, Mr. Andrew C. Weber, and the Director of the Defense Threat Reduction Agency and U.S. Strategic Command Center for Combating Weapons of Mass Destruction, Mr. Kenneth A. Myers. Mr. Weber and Mr. Myers have set the context regarding the global security environment, strategic priorities, and the mission of countering weapons of mass destruction. I am going to identify what the Chemical and Biological Defense Program contributes to the mission, specifically in the areas of biosurveillance, medical countermeasures, and non-traditional agents. Before I conclude I will speak briefly about acquisition reform, which, as this Committee knows, is indispensable to developing the capabilities needed to counter weapons of mass destruction.

## **MISSION AND STRUCTURE**

Of the eight military mission areas in countering weapons of mass destruction, the Chemical and Biological Defense Program's mission is largely in passive defense and weapons of mass destruction consequence management, meaning we provide technologies to minimize or negate the effects of chemical and biological agents employed against U.S. forces and the homeland. We provide capabilities to the U.S. Military so it may operate unconstrained in contaminated environments. Additionally, we develop multi-purpose equipment such as biological agent diagnostic capabilities that can be used by civilian first responders and medical professionals.

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 Secretary designated the Assistant to the

Secretary of Defense for Nuclear and Chemical and Biological Defense Programs as 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, acquisition, and the requirements of the Military Services.

Key organizational elements of the Chemical and Biological Defense Program now include 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, the Joint Program Executive Office for Chemical and Biological Defense for the advanced development and fielding of capabilities, the Chemical and Biological Defense Program Test and Evaluation Executive to maintain the readiness of test and evaluation infrastructure and establish test policy, and the Program Analysis and Integration Office to oversee budget execution. External to the Department of Defense, the Chemical and Biological Defense Program works closely with various Federal agencies. By necessity, we collaborate with our counterparts in the Department of Health and Human Services and the Department of Homeland Security.

## **FISCAL YEAR 2011 DEPARTMENT OF DEFENSE BUDGET REQUEST**

The Fiscal Year 2011 Budget Request achieves a structured, executable, and integrated medical and non-medical joint Chemical and Biological Defense Program that balances urgent short-term procurement needs against the long-term science and technology efforts necessary to preserve our technological edge. In addition to supporting a comprehensive science and technology base program, this budget starts or continues procurement of a variety of defense systems which provide our Warfighter with the best available equipment to survive, fight, and win in contaminated environments. The President's budget request for the Chemical and Biological Defense Program includes \$370 million for procurement, \$812 million for advanced development, and \$396 million for science and technology efforts, for a total of \$1.578 billion.

## **BIOSURVEILLANCE**

### *Status*

As described by Mr. Weber, the goal of biosurveillance, global and domestic, is to prevent or mitigate the impact of an expected or unexpected infectious disease outbreak, be it introduced by humans intentionally or naturally occurring. Successful implementation of a comprehensive biosurveillance strategy requires an enterprise-wide government approach. The Chemical and Biological Defense Program is uniquely positioned to leverage its enterprise capabilities. Our efforts contribute to many functions across the biosurveillance continuum. We produce Food and Drug Administration-approved medical diagnostics, develop and field systems that monitor the environment for biological threats, and provide critical confirmatory analysis for these environmental sensor systems. Ensuring our ability to do the latter analysis, our Critical Reagents Program houses the most extensive collection of quality-controlled biological defense reagents and test materials used throughout the Federal Government and by Allied nations.

The Chemical and Biological Defense Program provides the Warfighter with an integrated early warning information system for responding to a threat. We envision a similar biosurveillance tool to share early warning threat indicators and associated pathogen or disease information across Federal agencies and to hold data repositories and analytical tools for intelligence gathering and epidemiological studies.

The protection of our forces against the biological threat expands beyond the traditional military focus – we must integrate with international and domestic capabilities to protect our forces from emerging infectious diseases. Accordingly, we provide analytical, survey, communications, protection, and response capabilities in support of homeland defense. We are heavily engaged with interagency stakeholders in the continuous development of concepts of operations, exercises, and missions that pertain to sampling, collection, and early warning

surveillance measures. For example, the Installation Protection Program is one of the first efforts to field a full spectrum of chemical, biological, radiological, and nuclear installation protection capabilities designed for military installations around the world. Under this effort, the Department of Defense works closely with state and local governments as well as with the Department of Homeland Security BioWatch program to assess and field environmental monitoring tools, sensor and detection technologies, and a joint concept of operations.

We have also succeeded in tying medical diagnostic and surveillance capabilities together with biological detectors to provide a common operating picture within the United States Forces Korea theater of operations. This is an example of the Chemical and Biological Defense Program applying its sensor and medical diagnostic capabilities to make biosurveillance a reality. Such efforts represent the strong precedence and partnerships in place that can be leveraged in support of a national biosurveillance strategy.

### *Looking Ahead*

Additional integration and technology gaps must be addressed in order to achieve an integrated surveillance, warning, and response system for emerging and future threats. The Chemical and Biological Defense Program Science and Technology community, led by the Defense Threat Reduction Agency's Joint Science and Technology Office for Chemical and Biological Defense is working to address shortfalls in the synchronization and integration of information from all chemical, biological, radiological, and nuclear defense assets throughout the battlespace. A significant challenge is to integrate relevant information into the Military Services' information systems and architectures. The Joint Science and Technology Office for Chemical and Biological Defense is also working to address shortfalls in detection. Standoff (at a distance) identification of biological agents remains a fundamentally difficult problem. At least in the near to mid-term, standoff technologies are unlikely to provide the same fidelity of information provided by point (immediate) sensors.

Pursuant to Homeland Security Presidential Directive 10, *Biodefense for the 21st Century*, the Chemical and Biological Defense Program is working within the Department of

Defense and with interagency partners such as the Department of Health and Human Services and the Department of Homeland Security to both integrate existing capabilities and transition developmental capabilities as they mature. To accelerate this process, the Chemical and Biological Defense Program is employing innovative acquisition management through the Joint Program Executive Office for Chemical and Biological Defense “Trail Boss” concept. This effort seeks to increase the speed with which emerging threats are addressed by combining or using technologies already underway. The biosurveillance “Trail Boss” is working to improve how we currently integrate our products and systems into the existing national biosurveillance structure. We are positioned to aggressively pursue a global and domestic biosurveillance capability as an extension of current work in diagnostics, detection, and early warning.

### *Progress*

Medical response and preparedness is an important element of biosurveillance. In 2009, the Secretary of Health and Human Services declared a Public Health Emergency due to pandemic influenza. The next day the Centers for Disease Control and Prevention asked us to add identification of 2009 H1N1 flu (previously known as swine flu) as a capability on a system we developed that provides deployable medical units with a way to identify and diagnose human disease. The Chemical and Biological Defense Program partnered with the Centers for Disease Control and Prevention and the Armed Forces Health Surveillance Center’s Division of Global Emerging Infections Surveillance and Response Systems to prepare the submission for the Food and Drug Administration. A mere 83 days after submitting the request to the Food and Drug Administration, the Department of the Army Office of the Surgeon General received notice that the Food and Drug Administration granted our Emergency Use Authorization request. This is a process that normally takes 18 to 24 months. We are continuing to expand this diagnostic capability to include other infectious diseases.

In order to further ensure Department of Defense capabilities function as part of a complete system, we are working toward integrating the Chemical and Biological Defense Program’s Transformational Medical Technologies Initiative with biosurveillance efforts. The Transformational Medical Technologies Initiative has made significant strides in moving our

response capability beyond disease surveillance and diagnostics toward the provision of effective medical treatments. Recently, the Initiative rapidly characterized and tested a treatment for H1N1 in an animal population. Studies are also planned to evaluate this platform for broad spectrum applicability against other influenza strains, including Tamiflu resistant H1N1, Avian H5N1 and a seasonal influenza virus, H3N2. Previously, this same platform generated therapeutics demonstrating pre-clinical efficacy against other threats, including the viral hemorrhagic fevers, Ebola and Marburg. Understandably, there is a long way to go for us to be able to work this type of capability through the Food and Drug Administration process for use in humans. Nonetheless, this is the kind of relevant and timely innovation produced by the Chemical and Biological Defense Program that advances the Nation's ability to counter emerging biothreats.

## **MEDICAL COUNTERMEASURES**

### *Status*

The Chemical and Biological Defense Program partners with government, industry, academia, and international organizations for the materiel development and manufacturing of Food and Drug Administration-approved medical countermeasures. These efforts leverage Department of Health and Human Services-BioShield and Department of Defense investments and purchase products once they are licensed. The Department of Defense has interagency agreements with the Centers for Disease Control and Prevention to share licensed anthrax and smallpox vaccines from the Strategic National Stockpile. The agreements establish the framework for the acquisition, storage, management, and delivery of these vaccines to meet Department of Defense operational and inventory requirements.

An effort is underway that integrates medical countermeasure development programs within the Federal Government. The Integrated National Biodefense Portfolio Initiative, also known as "One-Portfolio," synergizes efforts of the Department of Defense and the Department of Health and Human Services as well as other agencies whose mission involves addressing the same challenges. The vision is government-wide coordination of research and development of medical countermeasures for biological threats. Accomplishments of the Integrated National

Biodefense Portfolio Initiative to date include harmonization of a common set of standards for technology maturity, an improved understanding of the expected regulatory requirements on biodefense product development, and mapping of pipelines for several biological threat medical countermeasures. Actual cost, knowledge, and program sharing continues. The “One-Portfolio” effort responds to the clear need for an integrated end-to-end national biodefense portfolio to leverage investments and maximize preparedness. We hope to expand the “One Portfolio” effort to include chemical and radiological threats as well as biological threats.

As Congress is aware, surge capacity for emergency response within the biological medical countermeasure industrial base is problematic. Adding capacity in an existing or new facility requires significant time and resources to achieve Food and Drug Administration approval. Modular and flexible manufacturing concepts may save time in establishing manufacturing infrastructure, but Food and Drug Administration approval will still take time and resources. We will continue to work with our interagency and intra-agency partners to establish capabilities and acquisition strategies that provide us the maximum flexibility for surge production. An example of this partnership is the Memorandum of Understanding between the Chemical and Biological Defense Program and the Defense Advanced Research Projects Agency, under which the Agency manages the Advanced Manufacturing of Pharmaceuticals program. The goal of the program is to create a rapid, flexible, and cost-effective production system capable of producing bulk doses of protein for any vaccine within 12 weeks of notification.

### *Looking Ahead*

The Chemical and Biological Defense Program’s Transformational Medical Technologies Initiative continues to gain momentum. Over the next 24 months, program performers will conduct clinical studies in support of licensure of maturing hemorrhagic fever virus therapeutics and submit Investigational New Drug applications for additional medical countermeasures against intracellular bacterial pathogens and hemorrhagic fever viruses. They will develop validated models critical for drug safety and efficacy testing.

In the short-term, the funding profile of the Transformational Medical Technologies Initiative is dynamic, matching the progression of project development from basic research toward advanced development as its portfolio matures. As projects mature, the Initiative's funding profile must be stable and predictable, requiring a continuous infusion of funds for basic and applied research as well as a vigorous advanced development program.

### *Progress*

The Chemical and Biological Defense Program maintains a high rate of success for programs on track toward Food and Drug Administration approval. Since 2000, our Chemical and Biological Medical Systems Office has received Food and Drug Administration approval, licensure, or clearance for seven medical countermeasures, completed 14 Investigational New Drug submissions, conducted 22 human clinical trials, and received one Emergency Use Authorization. We developed two enabling technologies and anticipate an additional 14 Investigational New Drug applications over the next five years. These accomplishments are directly related to the Chemical and Biological Defense Program's expertise in Food and Drug Administration regulatory compliance, drug development, full life-cycle management, and the ability to collaborate with other agencies and Allied governments.

## **NON-TRADITIONAL AGENTS**

### *Status*

The non-traditional agent threat presents complex challenges for the Nation and our Warfighter. In preparation for responding to a potential attack, the Chemical and Biological Defense Program is working to field solutions for detection, medical countermeasures, decontamination, and protection along with associated doctrine, equipment, and training. The Department of Defense, interagency partners, and international partners are working to establish a common response plan and a sensible research and development program that includes defensive measures, non-proliferation, and other mission areas. The Joint Program Executive Office for Chemical and Biological Defense "Trail Boss" for non-traditional agents is surveying

the entire Chemical and Biological Defense Program for upgraded technologies that will detect, protect against, or counteract these agents. Our understanding of the agents' physical properties, health affects, and the effectiveness of medical countermeasures is critical to our success.

### *Looking Ahead*

Our strategy to address non-traditional agents is funded across the Future Years Defense Program. In the near-term (fiscal years 2010 and 2011), we plan to accelerate scientific understanding, field interim defense capabilities, continue to identify shortfalls, and incorporate tactical doctrine for safe execution of military operations in the presence of non-traditional agents. In the mid-term (fiscal years 2012 to 2017), the Chemical and Biological Defense Program will mature the scientific understanding and field integrated defense capabilities while looking ahead to evolving trends.

### *Progress*

Among our efforts relevant to countering non-traditional agents, the Chemical and Biological Defense Program is developing the Bioscavenger medical countermeasure. It is a prophylactic regimen intended to prevent incapacitation and death from exposure to a wide range of nerve agents. Food and Drug Administration approval for the recombinant Bioscavenger product is estimated for 2017. The Department of Defense is also exploring development of a catalytic Bioscavenger to more efficiently eliminate nerve agent intoxication.

## **ACQUISITION REFORM**

### *Status*

Changes to the Defense Acquisition System directed by Congress are refocusing the way we manage acquisition programs. Recent regulatory and statutory changes, such as the Weapons Systems Acquisition Reform Act of 2009, target the early phases of the acquisition development cycle. There are new requirements for robust analysis of alternatives prior to initiating the

acquisition process, increased competition, emphasis on systems engineering, competitive prototyping, and the evaluation of technology maturity so that our acquisition programs are ready for the next phase of development. In order to reduce the risk of failure, the Chemical and Biological Defense Program is applying the tools of this acquisition reform to programs that pose particular technical challenges. Implementing these reforms reduces technical risk, validates design and cost estimates, supports evaluation of manufacturing processes during the later stages of development, and helps to refine requirements. The bottom line for us is a more holistic acquisition strategy and a better chance for success.

### *Looking Ahead*

Our holistic approach for managing acquisition programs requires stakeholder collaboration and early involvement toward determining whether formal entry into the Defense Acquisition System is appropriate. If so, the reforms ensure we get the requirement and technology right before we proceed with a materiel solution (new capability). The decision to proceed is known as the Materiel Development Decision; we issued six within this enhanced process in fiscal year 2009: Transformational Medical Technologies Initiative-Hemorrhagic Fever Virus Therapeutics, Joint Biological Standoff Detection System Increment II, Joint Biological Tactical Detection System Increment I, Human Remains Decontamination System, Filovirus Vaccine, and the Joint Effects Model Increment II. In fiscal year 2010, the Chemical and Biological Defense Program has already conducted four materiel development decisions and plans to conduct six more before the end of fiscal year 2011.

### *Progress*

In fiscal year 2009, the Chemical and Biological Defense Program fielded over 1.3 million individual pieces of equipment to our servicemen and women around the globe. This new equipment represents improvements to capabilities service members depend on for protection. We continue to plan and program for additional innovations.

## CHALLENGES

### *Balanced Investment*

Balancing the level of Research, Development, Test and Evaluation funding with Procurement funding is critical to our success. While our investments in biosurveillance, medical countermeasures, and non-traditional agents are the focus, we must neither underfund nor deemphasize the range of protection, medical, detection, decontamination, and information system requirements that establish the layered “defense-in-depth” strategy we employ to protect our personnel. The layered “defense-in-depth” strategy is necessary and requires significant and consistent investment as reflected in the President’s fiscal year 2011 budget request for the Chemical and Biological Defense Program.

As we ramp up efforts in biosurveillance, medical countermeasures, and non-traditional agent defense, the preponderance of our investment will be Research, Development, Test and Evaluation dollars. It is important to note that medical countermeasure development is much more expensive compared to other systems. This cost is another factor in our shift towards a budget heavy in Research, Development, Test and Evaluation funds. Further, acquisition reform is driving us to do more up-front work and competitive prototyping, which again increases the demand for additional Research, Development, Test and Evaluation funding.

### *Test and Evaluation Infrastructure*

One of the most fundamental challenges facing the Chemical and Biological Defense Program stems from the prohibition on conducting open-air test and evaluation using real biological and chemical agents. Developers and testers must rely upon the use of sophisticated test chambers in controlled environments to prevent release of agents while obtaining the most relevant information needed to confirm the function of our defense systems. Evaluation of defense system performance under operational conditions requires the employment of simulated biological and chemical agents in field tests. The use of test chambers, control methodologies,

and simulated agents is a significant portion of the Chemical and Biological Defense Program investment portfolio.

## **CONCLUSION**

Today we face a broad array of threats, both natural and man-made. 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. We are obligated to fund the development of improved chemical and biological defense capabilities to protect our citizens and ensure our security in this changing and uncertain environment. Madam Chair, Congressman Miller, and members of the subcommittee, on behalf of the men and women of the Chemical and Biological Defense Program—our military personnel, civilians, and contractors, thank you for the opportunity to appear before you and we greatly appreciate the tremendous support and leadership we receive from Congress.