

**NOT FOR PUBLICATION  
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HOUSE COMMITTEE ON APPROPRIATIONS**

**STATEMENT OF  
DR. DARRELL GALLOWAY  
DIRECTOR, CHEMICAL AND BIOLOGICAL TECHNOLOGIES  
DIRECTORATE,  
DEFENSE THREAT REDUCTION AGENCY**

**BEFORE THE**

**SUBCOMMITTEE ON DEFENSE  
COMMITTEE ON APPROPRIATIONS  
UNITED STATES HOUSE OF REPRESENTATIVES**

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## **Introduction**

Mr. Chairman and members of the committee, it is an honor to be here today to address the technologies being developed by the Defense Threat Reduction Agency (DTRA) to counter the threat of biological weapons.

DTRA was created in 1998 to consolidate into a single Combat Support Agency those Department of Defense (DoD) elements that had a role in responding to threats posed by weapons of mass destruction (WMD), which encompass chemical, biological, radiological, nuclear, and large-scale high explosive threats capable of mass destruction. DTRA, in partnership with other U.S. Government (USG) organizations, industry, academia, non-governmental organizations, and allies and friendly nations, has expanded the nation's ability to reduce and, where possible, eliminate or minimize WMD threats. DTRA accomplishes its mission through a wide range of activities that span all aspects of the National Strategy to Combat WMD, from non-proliferation, through counterproliferation, to consequence management.

As the Director of DTRA's Chemical and Biological Technologies Directorate, I am responsible for the integration of the Department's Chemical & Biological Defense Program (CBDP) Science and Technology (S&T) portfolio with the broader mission of Combating Weapons of Mass Destruction (CWMD). In that role, my organization explores and develops technologies that can be passed to the Joint Program Executive Office, for further development and fielding to our forces.

## **Biological Countermeasures**

The CBDP explores new capabilities and technologies to counter not only known and existing threats, but novel threats, potentially including genetically engineered biological weapons. This portfolio includes the complete range of means to protect our military forces from the effects of chemical, biological and radiological weapons.

The CBDP S&T strategy is derived from a balanced mix of requirements and innovative insights. In the near term, the CBDP focuses on meeting requirements by

transitioning technologies to programs of record as quickly and efficiently as possible. In the far term, the CBDP focus is increasingly driven by scientific advances and technical innovations with the goal of having countermeasures available when advanced threats emerge.

The development of medical and physical countermeasures against biological weapons requires long-term investment in the pursuit of fundamental scientific knowledge, as well as the development of complex technologies for transition to deployed capabilities. Such developmental work is inherently of a high risk nature, for ideas and approaches that seem promising at the theoretical level, or as implemented in model systems, do not always lead to workable solutions. Transitioning technology from the laboratory to the military operating environment not only takes time, but also requires thoughtful strategies and continuous, rigorous, and disciplined analyses of how, when, and where to expend resources.

Protecting military forces from the effects of biological warfare requires the fielding of detection, protection, and response capabilities. As previously noted, these capabilities may be medical or physical in nature.

Our Detection S&T programs are intended to provide a real-time capability to detect, identify, characterize, quantify, locate, and warn against all known or validated CBRN warfare agent hazards, including Toxic Industrial Materials and nontraditional agents. Related S&T efforts are intended to provide the rapid assimilation of intelligence information, sensor information, and medical surveillance systems and are critical to providing situational awareness and early warning of threats, as well as enabling battlefield commanders to better protect and employ their forces. Related S&T activities address high-performance based modeling and simulation, source term and toxicology, advanced hazard-assessment methodologies, understanding medical effects, interoperability, and battlespace management. Our efforts leverage the full range of DoD and USG high-performance modeling and simulation capabilities.

If WMD agents are used against our forces, we must also have the means for decontaminating personnel and equipment so that operations can proceed with reduced

hazard to forces. Decontamination S&T efforts include advanced understanding of process fundamentals, solution chemistry, solid phase decontamination, and alternative processes by which the risks from residual contamination can be reduced.

In the area of Protection S&T, the goal is the fielding of equipment that provides life sustainment and continued operational capability in a contaminated environment by preventing or reducing individual and collective exposures, and by protecting critical equipment.

Individual protection programs develop new ensembles to be worn by the individual warfighter to provide protection against CB agents. Protective masks with reduced respiratory stress, improved protection, compatibility with weapon sighting systems, and reduced weight and cost are being developed. Respiratory protection projects focus primarily on air purification technologies, as well as materials technologies for mask lenses and face pieces. Protective gloves are being developed that will have greater durability, tactility, and dexterity and that are flame resistant. Protective footwear will provide equal or increased durability while greatly reducing weight and volume. Percutaneous protection technology mainly focuses on the development of materials such as engineered permeable materials that include semipermeable membranes, sorbentloaded semipermeable membranes, nanobarrier materials, and reactive materials.

Collective protection programs develop systems that provide shelters, buildings, and platforms (vehicles, vessels, and aircraft) with a toxic-free environment to support mission continuity without impacting the operations tempo. Air purification technology projects seek temporary and permanent air purification solutions for transportable and fixed-site applications. Advanced vapor separation technologies, advanced aerosol/particulate separation technologies, and filter residual life indicators are being investigated to enhance the performance of both single-pass and regenerable air purification systems. Shelter technology mainly focuses on the development of materials such as engineered permeable materials, impermeable materials, and material treatments. Supporting technologies are being investigated to advance environmental control units,

motor blower units, structural components, and test methodology. Technology improvements are being pursued to reduce power requirements and improve filtration capacity against current and future hazards, with the goal to reduce weight, volume, and cost.

## **Biological Medical Protection**

Along with individual and collective protection, medical systems form the third component of protection from WMD. Medical systems include all pharmaceuticals, biologics, and devices that preserve combat effectiveness by timely identification, diagnosis, and provision of medical countermeasures in response to Joint Service Chemical, Biological, Radiological, and Nuclear (CBRN) defense requirements. My remarks will focus upon biological medical protection.

First, we seek to develop countermeasures which provide both specific and broad-spectrum protection to warfighters prior to their exposure to biological agents. Robust and broadly effective pretreatments are essential components in the layered, system-of-systems approach to force health protection, conserving warfighter operational flexibility, and reducing the logistical burdens of sustaining forces in biological environments. Research in this area explores technologies and validates the effectiveness of candidate vaccine platforms which include the use of engineered viruses, recombinant or fusion proteins, genetic vaccines, and new adjuvants that will be applicable to development of next-generation multiagent biodefense vaccines. The development of “molecular vaccines” as a vaccine platform would permit insertion of new immunogenic cassettes, facilitating rapid development of vaccines effective against new threat agents, such as genetically engineered threats or emerging infectious diseases. Efforts in molecular immunology seek to understand at the molecular level the events that induce and maintain rapid and effective protective immunity, and to exploit that understanding in the rational design of the next-generation biodefense vaccines. Additionally, results from this research may permit augmentation or enhancement of innate immunity, which could provide nonspecific and broad-spectrum protection against biothreat agents.

The next category of countermeasures, therapeutics, are intended to be administered after exposure to a biological agent, to mitigate or curtail the effects of that exposure and sustain forces operating in the hazard area. To meet this requirement, medical research and development is directly tied to warfighter capability requirements. Categories of threat agents addressed in this capability area include viruses, bacteria, toxins, and genetically modified biological agents. Increased emphasis is being placed on technologies and approaches leading to next-generation biodefense therapeutics, including treatments and pharmaceuticals effective against specific agents and broad spectrum therapeutics effective against entire classes of biological or chemical agents. All subareas within the therapeutics capability area depend on the development of validated animal models and surrogate indicators of human efficacy, which would provide a basis for approval by the Food and Drug Administration (FDA).

Finally, early, sensitive, and specific diagnostic testing is an essential means to determine the appropriate treatment for warfighters exposed to biological agents. Diagnostics research is focused on developing assays and evaluating technologies that meet FDA standards for clinical testing. Specifically, the goal is to employ FDA-approved systems to identify and confirm individual exposure to BW agents as soon as possible after exposure, and ideally before symptoms develop, to allow early initiation of the appropriate countermeasure and rapid return to duty. New and existing technologies are being investigated in order to discover, identify, and monitor biomarkers of infection and/or exposure. An increasing emphasis is being placed on the development of presymptomatic diagnosis. Diagnostics research is tied directly to warfighter requirements and is developed with the end-user in mind. Fielded systems should be easy to operate, inexpensive to use and sustain, and highly specific and sensitive. Research in this capability area supports diagnostic systems used in the military reference laboratories, deployable medical facilities, and on the battlefield.

The medical countermeasure program is primarily oriented toward biological threat agents that are already relatively well understood and believed to be suitable for potential use by states or terrorists as biological weapons. However, we know that we

need to prepare for more advanced bio threats in the future, and we have a critical program underway to meet these threats.

### **Transformational Medical Technologies Initiative (TMTI)**

During the 2006 Quadrennial Defense Review, the Department recognized the serious threat posed by rapidly advancing biotechnology that will enable the production of novel or genetically engineered pathogens. In response, the Department initiated a potentially “game-changing” approach to how the Department would develop medical countermeasures against an unknown or emerging agent, known as the Transformational Medical Technologies Initiative (TMTI).

The purpose of this effort is first to develop broad-spectrum therapeutic countermeasures to protect the warfighter from conventional or genetically engineered biological threats, known or emergent. The technologies to be validated have been initially applied to two categories of disease that are particularly hard to treat, viral hemorrhagic fevers, such as Ebola, and intracellular bacterial pathogens, such as tularemia. Rather than just a few more drugs for our doctors’ kitbags, the ultimate goal of this initiative is to develop, demonstrate, integrate and implement an enduring capability to rapidly identify and characterize any emerging, genetically engineered or unknown threat agent and develop a medical countermeasure against it. The use of novel technology platforms and an innovative management approach to achieve seamless integration between drug discovery and development are integral to the acceleration of countermeasure development.

More specifically, TMTI will accelerate the development of new medicines by establishing alliances with academia, the pharmaceutical and biotechnology industries, and government laboratories through which promising enabling platform technologies, as well as potential drug candidates, will be identified and incorporated into the program. Our current portfolio of projects spans the platform technology areas of genomics and bioinformatics, target discovery, drug discovery, test and evaluation, development of animal models and manufacturing. Taken together, these platform technologies,

integrated by a systems biology approach, form the basis of an end-to-end capability to rapidly identify, develop and manufacture novel medical countermeasures. Although the initial TMTI therapeutic development program addresses warfighter requirements to counter hemorrhagic viruses and intracellular bacteria, technology platforms will have the capability to identify any novel or genetically modified biological agent, and to facilitate the rapid preparation and manufacture of therapeutic products. This system of systems approach will also provide the capability to rapidly respond to a given bio-incident by providing key genetic identification and characterization of an unknown agent which would be essential in any course of action, including potential retribution.

Directed development through targeted solicitations has been initiated to broaden the scope of therapies for consideration. Additionally, the development of new indications for drugs currently approved by FDA, and the selection of drug candidates that are already in an advanced stage of development, may significantly reduce the time needed for FDA approval.

Together with Major General Reeves we have established a joint program office to oversee and integrate the ongoing execution of the projects under the TMTI. One of the transformational aspects of this program is the integration between the basic discovery research and advanced development efforts from the beginning of any given project. This assures the early anticipation and resolution of the multiple challenges involved not only in drug discovery, but in manufacturing and regulatory issues, which are also significant challenges.

We have also established stronger relationships with potential performers and are seeing a much larger response on their part. To date, more than 35 projects/contracts have been initiated, with a dozen candidate drug compounds identified so far. These are all contracted to progress to Investigational New Drug (IND) submission to FDA and, absent FDA notification otherwise, would subsequently be able to enter clinical trials by the end of 2011. Significantly, some of these IND candidates represent novel, broad spectrum drugs which will be revolutionary in medical countermeasure development and constitute a significant advance in medical science. A significant percentage of these

candidates are expected to prove successful. However, not all of the current projects will result in a final FDA-approved drug. Importantly, the integrated capability which allows the selective application of different platform technologies against desired threat agent targets will assure the continuous identification and development of new drug candidates. Thus, the program, assuming stable funding, will guarantee a continuous supply of new drug candidates in a timely, regular fashion and have broad application to all aspects of medical countermeasure development, including therapeutics, vaccines and diagnostics. In combination, this effort will provide the best overall approach to countering any emergent bio-agent threats.

With regard to a complete and integrated capability for the development of medical countermeasures, the manufacturing element is the essential culminating component. We are closely monitoring the technologies being developed and demonstrated by DARPA under their Accelerated Manufacture of Pharmaceuticals Program, and approaches to medical countermeasures research and development at the Department of Health and Human Services National Institute of Allergies and Infectious Diseases and the Biomedical Advanced Research and Development Authority. We are making plans to take the most successful of those candidates into further, scale-up demonstration of their potential to comprise an enduring, responsive capability to produce the novel countermeasures that may be necessary in the face of a never-before-seen biological threat.

## **Conclusion**

Mr. Chairman and Members of the subcommittee, we witness daily the significant advances in the biotechnology arena that offer tremendous potential for significant new medical capabilities. The Department believes that these technologies present unprecedented opportunity for potential state or terrorist adversaries to develop biological threats not found in nature, and for which our conventionally developed countermeasures may be useless. If our military force, or our nation, is presented with an attack using such genetically engineered pathogens, it is essential that we have a capability to respond.

Such a capability will require us to work closely with our interagency partners, and to assemble the integrated end-to-end means to move from recognition of an event to production of drugs on a timescale much shorter than has traditionally been possible

I believe that we have assembled a sound, balanced portfolio of medical countermeasure science and technology, one that continues to close down remaining known gaps, and that sets a path towards countering unknowns that are probably inevitably in our future. I urge your support for this effort and our budget request.

I look forward to working with the subcommittee to reduce the threat that biological warfare and terrorism pose to our nation, and I would be pleased to take your questions.