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STATEMENT OF

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BIOLOGICAL TERRORISM: DEPARTMENT OF DEFENSE RESEARCH AND DEVELOPMENT

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"SCIENCE OF BIOTERRORISM: IS THE FEDERAL GOVERNMENT PREPARED?"

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INTRODUCTION

Mr. Chairman and distinguished committee members, I am Dr. Anna Johnson-Winegar, Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. My office is the single focal point within the Office of the Secretary of Defense responsible for oversight, coordination, and integration of the joint Chemical and Biological Defense Program.

The tragic events of September 11th and the anthrax cases have heightened the public's awareness of the threat posed by biological terrorism. The Department of Defense has seriously considered the threat of biological weapons as a possible means by which states or non-state actors might counter America's overwhelming conventional warfighting strength. In response to the threat and consequences of bioterrorism. Today I wish to focus on the following topics:

<u>First</u>, research and development work of the Department of Defense that may improve the nation's ability to detect, prevent, respond to, and remediate bioterrorist attacks;

<u>Second</u>, planning, coordination, and execution of activities to counter bioterrorism with a focus on science and technology development activities — between the Department of Defense and other federal agencies.

DOD RESEARCH AND DEVELOPMENT TO ADDRESS BIOTERRORISM

Overview and Program Drivers for DoD Biological Defense Science and Technology

Following Operation Desert Storm, the Department of Defense studies identified shortfalls in biological defense capabilities. One result was Congressional direction to the Department of Defense to consolidate chemical and biological defense efforts. In response to Congressional direction in the FY94 National Defense Authorization (P.L. 103-160), DoD established a joint Chemical and Biological Defense Program. The vision of the DoD Chemical and Biological Defense Program (CBDP) is to ensure U.S. military personnel are the best

equipped and best prepared force in the world for operating in future battlespaces that may feature chemically and biologically contaminated environments. The capabilities developed and fielded by the CBDP focus on addressing the needs of the warfighter. As the events of the past few months have shown, the future battlespaces for our warfighters are evolving. Likewise, civilian organizations may increasingly turn to the Department of Defense to leverage technology development efforts to support the needs of homeland security.

The objective of the CBDP is to ensure our forces can maintain freedom of action during deployment, maneuver and engagement, while providing multi-layered defenses for our forces and facilities at all levels. This is accomplished by protecting the force, and minimizing the impact of biological weapons on joint force operations. The CBDP does not provide one capability, but rather a system-of-systems to support joint force operations, intelligence and logistics capabilities. Specific programs and plans are developed to support national military strategy and objectives. The Joint Warfighting Science and Technology Plan is the key planning document, which outlines DoD needs and plans for biological defense to support the warfighter. Key science and technology programs are reviewed annually by an independent expert panel to ensure relevant technologies are being considered and technology risks are appropriately addressed. Specific programs for biological defense programs are defined within Operational Requirements Documents, which provide the basis for advanced development and acquisition. In order to ensure science and technology efforts support future warfighter needs, the Services develop a report documenting Joint Future Operational Capabilities to provide guidance to the science and technology community. Key science and technology projects are defined by Defense Technology Objectives, which highlight high priority science and technology efforts. Finally, the

Department funds and leverages a broad array of basic research efforts in biological sciences and related fields.

Programs for biological defense are categorized broadly under three operational principles: contamination avoidance, protection, and restoration. Contamination avoidance provides automated capabilities to detect, locate, identify, quantify, sample, and plot the extent of all suspected threat agent hazards, and medical surveillance capabilities. Protection includes all medical and non-medical means taken to protect the warfighter from all battlespace biological agent hazards while maintaining normal operational mission tempo. The focus of protection is to prevent exposure or the effects of exposure, and includes medical capabilities, such as vaccines, and non-medical capabilities such as masks for respiratory protection. *Restoration* capabilities include medical and non-medical measures required to restore the joint force, units, facilities, and equipment to near-normal operating conditions after being challenged by a biological agent hazard. These measures include non-hazardous decontamination operations, effective supply and sustainment of all defense assets, and effective medical diagnostics and post-exposure countermeasures required to allow rapid determination of agent exposures and subsequent treatment. *Battlespace management* supports all three principals. *Battle management* includes capabilities to securely access, assimilate, and disseminate medical and non-medical information throughout the joint battlespace, to analyze this information, to predict current and future operational impacts of agent hazards' and to model and simulate the totality of mission operations within the context of the contaminated environment.

DoD Biological Defense Science and Technology Efforts

The fiscal year 2002 President's Budget Request for the DoD Chemical and Biological Defense Program, the Department of Defense included \$508 million for research, development,

test, and evaluation and \$349 million for procurement for a total of \$857 million. The specific funding allocations are detailed in the Annual Report to Congress on the Chemical and Biological Defense Program as well as in the detailed budget requests submitted to Congress. This funding provides support for a variety of state of the art research and development activities to address future warfighting needs. I will provide an overview of some of the technologies used in currently fielded systems, and provide some detail of the science and technology base efforts to provide advanced capabilities to meet current and future needs. Following the descriptions of the science and technology programs, I will provide an overview of the process by which we coordinate these research efforts with other federal agencies.

DoD Biological Defense Science and Technology Efforts – Contamination Avoidance

Three of the key biological detection systems fielded today are the Biological Integrated Detection System, Portal Shield, and the Biological Weapons Agent Sampling Kit

<u>Biological Integrated Detection System (BIDS)</u> uses a multiple technology approach to detect biological agents with maximum accuracy. BIDS is a vehicle-mounted, fully integrated biological detection system. The system is modular to allow component replacement and exploitation of "leap ahead" technologies. The initial version is capable of detecting and presumptively identifying four biological agents simultaneously in less than 45 minutes. The planned upgrade will be capable of detecting and providing presumptive identification of 8 biological agents simultaneously in 30 minutes. The suite is semi-automated and contains next generation technologies such as the Ultraviolet Particle Sizer, Chemical Biological Mass Spectrometer, and the Biological Detector. The Ultraviolet Particle Sizer provides near real-time generic detection and indicates whether particles are biological and whether they are respirable (that is 1 to 10 microns in

size.) The Biological Detector is an antibody-based device capable of identifying specific biological agents. It consists of electronics processing equipment, fluid processing modules, reservoirs for antibody reagents, and a light addressable potentiometric sensor to provide biological agent identification. It provides identification of the biological agent detected and the relative concentration of biological particles in the atmosphere . The Chemical Biological Mass Spectrometer (CBMS) detects and characterizes chemical and biological threat agents. The CBMS does not provide specific identification of biological agents, but provides generic detection (biological or non-biological) and categorizes them based on the predominant phospho- or other polar lipid detected in the mass spectra (for example, indicates whether the particle are encapsulated viruses, or gram-positive or gram-negative bacteria.)

- <u>Portal Shield</u> is a network sensor system that provides automated biological point detection capability to protect high value fixed sites against BW attacks. The sensor is modular in design and can detect and presumptively identify up to eight biological agents simultaneously in less than 25 minutes. It uses an aerosol collector and ultraviolet particle sizer and detects agents by means of immunochromatographic assay tickets.
- <u>Biological Weapons Agent Sampling Kit</u> uses low cost, disposable assay ticket which can provide rapid detection from environmental samples. This uses a similar detection technology as Portal Shield but is intended to support manual sampling.

One of the key developmental capabilities that could further enhance detection capabilities is the Joint Point Biological Detection System, which will provide automated point and mobile biodetection, with reduced size, weight, and power requirements compared to existing systems.

Within the science and technology base, the following Defense Technology Objectives detail key biological detection efforts.

- <u>Standoff Biological Aerosol Detection</u> The objective of this effort is to develop and demonstrate technology for an advanced, wide-area, standoff biological detection capability to both detect and discriminate biological aerosol clouds at operationally significant concentrations. Some technologies under consideration include imaging (ultraviolet (UV), near infrared (IR), long wave IR), millimeter wave, and polarization (UV, IR) spectroscopy.
- <u>CB Agent Water Monitor</u> The objective of this effort is to develop system concepts and technologies for the detection and identification of hazardous chemical and biological agents in potable water. The system will most likely consist of two or more integrated technologies that have been optimized to meet a specific challenge. Current biological detection technologies rely on analytical techniques, which range in processing times from hours to days. Hundreds of commercially available water test kits have been evaluated for potential to meet user needs. In addition, key technology development effort include Fourier Transform InfraRed Attenuated Total Reflection (FTIR-ATR) spectroscopy, molecular imprinted polymers, Biodetection immuno-tickets, Pyrolysis-Gas Chromatograph-Ion Mobility Spectroscopy (GC-IMS), Surface-Enhanced Raman Spectroscopy, and automated colorimetric test kit.
- <u>Activity-Based Detection and Diagnostics</u> The objective of this effort is to demonstrate engineering of cells and tissues that is directed toward the development of activity detection systems for biological and chemical threats. The program approach is based on robust extraction of cell and tissue signatures of agent response and could

provide detection of hazardous materials based on physiological response rather than the specific construction of the biological pathogen or toxic compound.

- <u>CW/BW Agent Screening and Analysis</u> The objective of this effort is to provide enabling technologies to support monitoring of non-proliferation efforts such as the Biological Weapons Convention, and which may be used for security screening for homeland security. A variety of technologies are being explored to support specific objectives, including (1) Agent and Byproduct Extraction Technologies—for effective and rapid isolation of target compounds from complex samples; (2) Agent and Byproduct Screening Technology—develop hand-held real-time, simple-to-operate screening methods devices for field operations; (3) Agent and Byproduct Determinative Analysis to increase instrument analytical speed and sample throughput, improve instrument portability and ruggedness, and develop target compound-specific analytical libraries; and (4) Remote and Nondestructive Evaluation Techniques—develop highly portable, noninvasive interrogation equipment for agents and their precursors or byproducts within containers of all compositions shapes and configurations.
- <u>Biological Warfare Defense Sensor Program</u>— The objective of this effort is to develop a fully integrated, well-characterized sensor system for the effective real-time detection of biological agents to enable pre-exposure detection and discrimination. To accomplish this task, the fabrication of the first-generation automated time-of-flight mass spectrometer was developed and characterized.

In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the detection and identification of biological agents. Key technologies to *detect aerosols at a*

distance include differential scattering/differential absorption of light (DISC/DIAL), Frequency Agile Laser (FAL), Light Detection and Ranging (LIDAR), and infrared sensors. Key technologies for *point detection and identification* of biological agents by species and strain include flash GC/MS, Bio MS, microfluidics, force diffusion assay, polymer technologies (e.g., electroactive, nonspecific doped), aerogel characterization/development, Up-converting phosphors, gene probe sensors for Polymerase Chain Reaction (PCR) diagnostic systems, biodiffractive grating sensors, multiarray and single-particle detection technologies, and molecular recognition technologies (e.g., DNA sequencing). Key technologies for surface contamination detection of biological agents include Time-of-Flight Mass Spectrometer, and biocontaminant detection and identification strategies, such as culture quantitation and quantitative PCR analysis. Key technologies for *medical surveillance* are being developed to support disease identification as rapidly as possible. Technologies for mobile laboratory specimen analysis include rapid and automated dissemination, recording and archiving of medical surveillance reports and analyses, rapid hand-held screening assays and immunoassays, and specimen processing/gene amplification. Technologies for rapid biological sample preparation and screening include microfluidics, biomarker ionization, PCR, optical fiber simultaneous orthogonal detection, bacterial endospore detector, force amplified biosensor, and gene probe detection.

In addition, basic research and supporting sciences are being leveraged. One example is *aerosol sciences* for advance aerosol collection systems with significantly reduced size and power requirements and improved collection efficiency. One of the most important research areas being exploited is genomics and related basic sciences. Advances in genomics have provided genome maps of many of the pathogens of concern, including *Yersinia pestis* (plague)

and *Bacillus anthracis* (anthrax) among others. Genome maps provide fundamental scientific understanding that will be used to develop understanding of disease pathogenesis, advanced vaccines, diagnostics, detection systems, and other methods to counter the effects of pathogens.

DoD Biological Defense Science and Technology Efforts – Protection

Protection capabilities include non-medical and medical technologies. <u>Non-medical</u> <u>protection</u> includes efforts to prevent exposure to or the effects of biological agents. The primary route of exposure for biological agents is by inhalation. A variety of protective masks have been developed and fielded to protect individual from exposure. To protect against exposure as a result of contact, various protective clothing items, including suits, boots, and gloves, have been fielded and advanced systems are under development. Within the science and technology base, the following Defense Technology Objectives detail key protection efforts.

- <u>Advanced Adsorbents for Protection Applications</u> The objective of this effort is to develop advanced adsorbent bed materials and compositions to enhance the chemical agent and toxic industrial materials air filtration protection capabilities of current single-pass filters and regenerative filtration systems under development; and reduce the size, weight, encumbrance, and cost of existing filtration systems. Technologies being developed include temperature and pressure swing adsorption (TSA/PSA) techniques to support regenerable filtration, and a variety of novel adsorbent technologies, such as carbon nanotubes; novel carbon, silica, alumina-based reactive sorbents; metal oxide nanoparticles, surface modified carbon, reactive impregnated carbon, novel structured carbons, and layered adsorbents.
- <u>Self-Detoxifying Materials for CB Protective Clothing</u> The objective of this effort is to incorporate agent reactive catalysts and biocides directly into protective clothing and

demonstrate their capability to self-detoxify. Technologies may include electrospun selfdetoxifying membranes, N-halamine treated textiles, and materials containing reactive nanoparticles.

Medical protection includes efforts to prevent the effects of biological agents.

Technologies include vaccines to protect against viral, bacterial, and toxin agents, and advanced delivery mechanisms. While advances in biotechnology and genetic engineering poses the threat resulting from the development of biological agents designed to defeat detection or protection capabilities, advances in these sciences provide powerful tools to protect against a broad spectrum of pathogens. Within the science and technology base, the following Defense Technology Objectives outline key medical protection efforts.

- <u>Medical Countermeasures for Encephalitis Viruses</u> The objective of this effort is to develop medical countermeasures against threat of the Venezuelan equine encephalitis (VEE) viruses (members of the alphaviruses family). Recombinant vaccine technology will be exploited to provide effective vaccine candidates.
- <u>Multiagent Vaccines for Biological Threat Agents</u> The objective of this effort is to produce a vaccine or vaccine delivery approach that could be used to concurrently immunize an individual against a several biological threats. Bioengineered and recombinant vaccine technologies (naked DNA vaccines or replicon vaccines) will be exploited to achieve multivalent vaccines that are directed against multiple agents, yet use the same basic construct for all of the agents.
- <u>Medical Countermeasures for Brucellae</u> The objective of this effort is to develop a genetically characterized live, attenuated vaccine that elicits cellular and humoral

immunity against the four pathogenic species of Brucella and that is capable of protecting 90% of vaccinated warfighters against disease after aerosol challenge.

- <u>Recombinant Protective Antigen Anthrax Vaccine Candidate</u> The objective of this effort is to characterize (biochemically and immunologically) a recombinant protective antigen (rPA) anthrax vaccine, including preliminary development of an appropriate *in vitro* correlate of PA- induced protective immunity against *Bacillus anthracis* aerosol exposure. This supports the development of the next generation anthrax vaccine that will provide equal or greater protection over the current vaccine, reduce the number of shots required to induce immunity, and have fewer adverse effects.
- <u>Recombinant Plague Vaccine Candidate</u> The objective of this effort is to complete the pre-clinical development of the recombinant F1-V fusion protein plague vaccine candidate. Successful completion of this recombinant vaccine will provide protection against aerosol exposure.
- <u>Needle-less Delivery Methods for Recombinant Protein Vaccines</u> The objective of this effort is to develop alternatives to the injection of recombinant protein-based vaccines that result in mucosal and systemic immunity to these agents. This effort will seek to determine whether the route of administration of a vaccine can induce improved mucosal, systemic, humoral, or cellular immunity, especially for protection against aerosolized pathogens, including staphylococcal enterotoxins (SE), *Bacillus anthracis* (anthrax), and *Yersinia pestis* (plague). Intranasal, transdermal, inhalation, or oral immunization strategies may be safer and more efficacious methods for stimulating mucosal and systemic immunity. These strategies will be useful for the administration of a significant number of vaccines currently planned to obtain total force protection.

In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the development of medical prophylaxes against bacterial, viral, and toxin agent hazards, including all identified validated threat agents. Key technologies include recombinant vaccine development efforts (e.g., gene insert, gene shuffling techniques), immunomodulators to provide enhanced immunity against any pathogen, active and passive immunoprophylaxes, novel genomic, molecular genetics, molecular phylogeny, active site-directed inhibitors, receptor antagonists, and small molecule antibiotics and protein inhibitors.

Vaccines provide a critical capability for protection against biological warfare agents. In order to transition vaccine technologies from the laboratory to production, the Department of Defense established the Joint Vaccine Acquisition Program (JVAP) in 1997 to facilitate compliance with clinical trials and to procure sufficient quantities of biological defense vaccines to protect U.S. forces. However, production efforts under the JVAP are not sufficient to meet all requirements. Currently, the Department of Defense is working with numerous other organizations— including Health and Human Services, the Office of Homeland Security, and others—to evaluate the feasibility of a national vaccine production facility that would provide sufficient vaccines to protect not only U.S. forces, but the civilian population of the United States, and possibly other countries as well. The overall plan and requirements for this facility have been outlined in a report entitled, "Report on Biological Warfare Defense Vaccine Research & Development Programs," which was submitted to Congress in July 2001.

DoD Biological Defense Science and Technology Efforts – Restoration

Restoration capabilities include technologies for *medical therapeutics*, *medical diagnostics*, and *decontamination*. The medical treatment of biological agents requires a

response tailored to each specific threat. Advanced technology approaches are also focusing on generic approaches that will provide broad spectrum protection against a variety of biological agents. A critical capability for effective treatment includes training to recognize and treat biological agents through such courses as "Medical Management of Biological Casualties" and related courses, which are available on the internet at www.biomedtraining.org. Therapies that improve survival and lessen time for return to duty have been developed. These include commercially available antibiotics, including ciprofloxacin, doxycycline, and tetracycline. Antiviral therapeutics are being developed for orthopoxyiruses. In the near term, DoD plans to deliver a technical data package supporting investigational new drug for labeled use of cidofovir for post-exposure treatment of smallpox. Rapid portable diagnostics enabling quick medical response for exposed warfighters are being pursued. Currently fielded diagnostics capabilities rely on immunological response assays. The Joint Biological Agent Identification and Diagnosis System is being developed and would be based on genetic primers using polymerase chain reaction (PCR) technology to provide more rapid and accurate diagnosis. The key Defense Technology Objectives that support therapeutics and diagnostics are:

 <u>Common Diagnostic Systems for Biological Threats and Endemic Infectious Diseases</u> — The objective of this effort is to develop state-of-the-art technologies (platforms/devices) capable of diagnosing infectious disease and biological agents in clinical specimens. The devices will be used by preventive medicine personnel for disease surveillance and monitoring, and by medical laboratory personnel for the diagnosis of disease due to natural and BW threat agents. Efforts will focus on an immunologically based membrane device to rapidly detect host immune responses to etiologic agents or the antigens or products of the agents themselves, and on miniaturized polymerase chain reaction

technology for detection and identification of nucleic acids of natural infectious disease and biological agents

 <u>Therapeutics Based on Common Mechanisms of Pathogenesis</u> — The objective of this effort is to develop a suite of medical countermeasures against broad classes of biological pathogens (bacterial, viral, bioengineered, *etc.*) that share common mechanisms of pathogenesis.

In addition to these technologies, a variety of other technologies are being developed under the science and technology program to address specific technology limitations related to the development of medical therapeutics and diagnostics. Some technologies for <u>therapeutics</u> include gene therapy, immunotherapy, antibacterial therapeutics (*e.g.*, bacterial lytic enzymes, complex biosignatures, novel broad spectrum antibiotics, genetic metabolic path, broad spectrum antibodies, thioaptamers, nanoparticles, target pathogen DNA, antigenomic countermeasures, transcriptional/translation inhibitors), antiviral therapeutics (e.g., novel viral blocking, stock drug subunits, universal path protection, second-generation vaccines, genome based agents, pokeweed antiviral protein, combinatorial technology, antigenomic countermeasures, prodrug development, countermeasures for viral induced effects), and antitoxin therapeutics (e.g., toxin neutralization, target replacement, respiratory/mucosal countermeasures, neutralization of toxin- induced effects, superantigen toxin inhibitors).

Some technologies for <u>diagnostics</u> include mini-PCR, fluorescent probe chemistry, rapid portable nucleic acid analysis, rapid portable immunoassay techniques, GC/MS, colorimetric assays, microsonication technology, cellular or tissue activity detectors (e.g., detectors utilizing cellomics), specimen processing/reagent preparation for field use.

Decontamination supports post-attack restoration of forces and operations to a nearnormal capability. Decontamination is organized into three categories that reflect operational urgency: immediate, operational, and thorough decontamination. Decontamination also entails special considerations for patients, sensitive equipment, aircraft, fixed sites, and the retrograde of equipment. DoD doctrine addresses consequence management decontamination operations, which uses civilian standard operating procedures, including hypochlorite solutions, and soap and water solutions. Some of the existing systems include the M291 Skin Decontaminating Kit, the M295 Individual Equipment Decontaminating Kit, and the sorbent decontaminating system, which is replacing the existing decontaminant with a non-aqueous and less caustic decontaminant. There are three key development efforts. One is the *Joint Service Sensitive Equipment Decontamination* which is focused on the development a non-aqueous decontaminant to provide a first ever capability to decontaminate chemical and biological warfare agents and toxins from sensitive electronic, avionics, electro-optic equipment, and vehicle interiors. A second effort is the Joint Service Fixed Site Decontamination System, which will provide a family of decontaminants and applicators to provide the capability to decontaminate ports, airfield, and rear-area supply depots. A third effort is the Superior Decontaminant System, which seeks to develop effective decontaminants that react effective with all valid chemical and biological threats and are less corrosive and expensive than current decontaminants. Within the science and technology base, the following Defense Technology Objectives detail key restoration efforts.

• <u>Enzymatic Decontamination</u> — The objective of this effort is to develop and demonstrate a new generation of enzyme-based decontaminants that are nontoxic, noncorrosive, environmentally safe, and lightweight (freeze-dried concentrate).

- <u>Oxidative Decontamination Formulation</u> The objective of this effort is to develop a non-corrosive, material compatible, non-toxic and environmentally oxidative CB decontaminant to replace Decontamination Solution 2 (DS2) and supertropical bleach/ high test hypochlorite (STB/HTH).
- <u>Environmental Fate of Agents</u> The objective of this effort is to develop a validated threat agent fate model that is capable of accurately predicting the persistence of a chemical agent dispersed on surface materials relevant to fixed site operational scenarios. These models will support decontamination efforts by allowing clean up efforts to focus on areas that pose greatest hazards and where decontamination might be achieve through non-material processes (e.g., hot air/hot water wash, weathering).

Decontamination efforts also draw on an extensive array of basic research and supporting technologies. Current decontaminants cause adverse effects to physical, optical, electronic, or mechanical properties of the items being decontaminated and are not environmentally friendly. Some of the technologies being explored to address these limitations include material survivability technology, supercritical fluidics, decontaminant coating technologies, thermal desorption methodologies, gas phase decontamination, chemical matrix strategies, and novel approaches using non-ozone depleting solvents, plasma, oxidation catalysts, peroxycarboxylic acid (peracids), novel surfactants and microemulsions, dioxiranes, and nanoparticles. To reduce dependence on water, non-aqueous technologies are being explored, including gas phase decontaminants, destructive adsorption, and organic chemical matrix strategies. A critical challenge is personnel and patient decontamination. Enzymatic decontamination, antimicrobial nanoemulsions, skin and wound decontaminants, and other methods for personal decontamination that does not harm the individual are being explored.

DOD INTERAGENCY COORDINATION ON BIOTERRORISM RELATED RESEARCH AND DEVELOPMENT

The key organizations responsible for the management and transition of science and technology efforts for chemical and biological defense are (1) the Joint Science and Technology Panel for Chemical and Biological Defense, and (2) the Joint Medical Chemical and Biological Defense Research Program. These organizations help to ensure effective coordination of efforts among the Service Laboratories and Defense Agencies, including the Biological Warfare Defense program of the Defense Advanced Research Projects Agency (DARPA). In addition to management responsibilities, DoD provides many unique resources that can be used in the development of countermeasures to biological terrorism. Some of these unique resources include high containment (biosafety level 4) laboratories, aerosol exposure test chambers, live agent test facility, simulant test grids, and personnel with exceptional scientific expertise.

The Department of Defense has established a set of requirements for the successful completion of military operations in chemical and biological environments. We submit an Annual Report to Congress documenting our progress in meeting these requirements. My office regularly coordinates its efforts with the Department of Energy, Department of Health and Human Services, and the intelligence community through the Counterproliferation Review Committee, which reports annually to Congress on its progress (provided as a classified document to Congress).

In order to coordinate efforts between the Departments of Defense and Energy, we have submitted a report to Congress in March 2001 on the integrated chemical and biological defense research, development, and acquisition plan. This plan focused on biological detection

technologies and seeks to leverage similar technologies to support different mission, that is Department of Defense is focused on support for the warfighter, while Department of Energy is focused on support for domestic preparedness and homeland security.

In order to meet the challenge of biological warfare across the spectrum, our program must address the need for both materiel improvement and operational concepts to use the new and improved equipment. In order to address the issue of bioterrorism, we have documented gaps and deficiencies in exercises, such as TOPOFF, and these will be the focus of reprioritized efforts within the Department of Defense. One of the lessons of the TOPOFF exercise was that to work effectively during an actual crisis, various governmental agencies must actually exercise beforehand or their "cultural differences" will overcome any plan. We will continue to work with other agencies, including the new office of homeland security, to ensure good working relationships. One specific area we will focus on is to help define what support the Department of Defense can provide and work with other agencies to define what support they request and need.

While the DoD can provide unique expertise and materiel support, it is not charged with lead federal agent responsibilities as described in the Federal Response Plan. In the area of domestic terrorism medical response, the Department of Health and Human Services takes charge and requests support as needed. However, the Department of Defense provides materiel support to other organizations.

Congress has provided a number of statutory methods for the Department of Defense to support other federal, state, and local agencies in preparing for and responding to weapons of mass destruction (WMD) terrorism. Requests may come to the department for operational support or for the purchase of equipment. These requests are approved on a case-by-case basis.

My office has dealt with a number of requests from other-federal agencies for individual and collective protective equipment and access to vaccines, while the operational support provided by the Department is coordinated through the Secretary of the Army. The Department will continue to provide this support within statutory and regulatory limits and balance requests against the readiness of military forces to accomplish their warfighting mission.

DoD can offer many of its systems, either those in the field or in development, and expertise that may prove useful to civilians. DoD's chemical and biological detection equipment could be applied in civilian situations, as can many of our medical countermeasures. However, the provision of materiel alone does not enhance capability, it needs to be accompanied by valid operational concepts, training, and maintenance.

Our armed forces are trained primarily to fight foreign adversaries. However, our forces also maintain significant capabilities to support homeland security, through such operational units as the Chemical and Biological Rapid Response Team, the Technical Escort Unit, the WMD-Civil Support Teams, and the Marines' Chemical and Biological Incident Response Force (CBIRF).

In order to enhance our Nation's overall capabilities the Department of Defense participates in programs to support the transition of military equipment and concepts to otherthan-DoD agencies. Specifically,

- The Technical Support Working Group (TSWG), rapidly prototypes emerging technologies for high priority federal interagency requirements (www.tswg.gov);
- The InterAgency Board for Equipment Standardization and Interoperability (known as the IAB), is a partnership with federal, state, and local agencies focused on the

capabilities necessary for fire, medical, and law enforcement responses to WMD terrorism (www.iab.gov);

- The Domestic Preparedness Program, mandated under the 1997 Nunn-Lugar-Domenici legislation, trained and equipped municipalities to address WMD terrorism (the program transferred to the Department of justice in 2000, reports remain available at www2.sbccom.army.mil/hld/); and
- Interagency Agreements with departments of Justice's Office Domestic Preparedness to purchase equipment in support of Justice's grant program;
- Medical training programs from the U.S. Army Medical Research Institutes for Infectious Disease and Chemical Defense; and
- The White House Office of Science and Technology Policy chaired Weapons of Mass Destruction Program, Research and Development Subgroup.

These efforts represent a snap shot of the Department's procurement and research support to address bioterrorism. As the Lead Federal Agencies assess their needs, DoD anticipates additional requests of or participation in these groups.

Some of the Department's requirements to protect the military force correlate with civilian requirements to protect the population against biological terrorism. For instance, one of the concepts being investigated for the development and production of biological defense vaccines is a vaccine production facility. In order to coordinate the needs of the interested agencies, the DoD, relatively early in the process of considering alternatives for vaccine acquisition, established a Federal Interagency Advisory Group. Participants, in addition to those from DoD agencies, have included representatives from:

- The White House [Office of Homeland Security, Office of Science and Technology Policy, National Security Council, Office of Management and Budget],
- Federal Emergency Management Agency,
- Department of Health and Human Services (DHHS) [National Institutes of Health, Public Health Service, Food and Drug Administration, Centers for Disease Control and Prevention, and the Office of the Assistant Secretary for Health and The Surgeon General]
- Department of Agriculture
- US Agency for International Development.

This group, which I chair, has served as a highly effective and productive forum for discussions concerning U.S. vaccine acquisition—particularly vaccines for defense against biological warfare agents—for force health protection and public health needs for the civilian sector.

CONCLUSION

For operational responses to biological terrorism, the Department of Defense is working closely with the lead federal agencies as defined in the Federal Response Plan to ensure a well coordinated response. As I discussed, the Department of Defense is exploring an extensive array of leading edge scientific approaches to counter biological warfare and biological terrorism threats. We are working closely with several other federal agencies to provide unique science and technology resources to support national security and homeland security needs. We will continue to work closely with other agencies to ensure that the warfighter is protected with the best available technologies and that U.S. citizens are provided as great a degree of protection as

possible. Thank you for the opportunity to speak here today, I would be happy to respond to any questions.