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HOUSE ARMED SERVICES COMMITTEE

STATEMENT OF

THE HONORABLE
HANS MARK

DIRECTOR, DEFENSE RESEARCH AND ENGINEERING

DOD CHEMICAL AND BIOLOGICAL DEFENSE PROGRAM

October 20, 1999

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UNTIL RELEASED BY THE SUBCOMMITTEE ON PROCUREMENT,
HOUSE ARMED SERVICES COMMITTEE

I. Introduction

Good morning Mr. Chairman and distinguished members of the committee. I am honored to appear before your committee today to discuss the chemical and biological defense program of the Department of Defense. I am Hans Mark, Director of Defense Research and Engineering in the Office of the Secretary of Defense, and I am accompanied today by some of my colleagues who are the senior managers of various elements of the program.

II. DoD Chemical and Biological Defense Program Overview

A. The Chemical and Biological Threat

As outlined by the witnesses who preceded me on earlier panels today, the chemical and biological weapons threat is serious and is potentially increasing in diversity and frequency. Currently, there are over 20 countries with known or suspected chemical and biological weapons programs. In addition, there are a number of non-national groups with access to such weapons. Assessing the threat is complicated by several interrelated changes, including the proliferation of weapons, technological advances, unstable political regimes, shifting regional power balances, and the increasing threat of terrorism. The threat will be exacerbated with continued and more frequent deployment of U.S. forces worldwide. The countries that are of greatest concern to the United States are located in regions in which the United States has well defined national security interests. Therefore, it is of paramount importance that we continue to maintain a credible, robust capability to protect our forces and provide them capabilities to operate effectively in a chemically or biologically contaminated environment.

B. Implications from Advances in Technology

Despite revolutionary developments in biotechnology, great cost and technological barriers still block the ready development of novel biological warfare (BW) agents. The detailed understanding of genetic structures has not yet led to the ability to completely and predictably control these genetic mechanisms. One can be certain, however, that significant advances in biotechnology will continue. Classical BW threat agents pose the greatest concerns for the near- and mid-term. Far-term threats are not so easily predicted. Biotechnology is a two-edged sword. Work on offensive biological weapons is forbidden by law in the United States. However, the same is not

true of many potential adversaries. Thus, it is important to have a vigorous research program to explore genetic mechanisms that can be applied to protecting our people from attacks using biological weapons. I have made a number of public statements indicating the very high priority that I personally put on research and development (R&D) in biotechnology. A sample is attached (see Figure 1).

The future likelihood of infectious agents being created for BW purposes will be influenced by several technological trends; the four most significant are listed below:

1) Increased employment of genetically engineered "vectors", in the form of modified infectious organisms, as therapeutic tools in medicine, and the techniques will become more widely available;
2) Increased understanding of infectious disease mechanisms and microbial genetics that are responsible for disease processes;
3) Further understanding of the human immune system function and other disease mechanisms, which can explain the circumstances that cause individual susceptibility to infectious disease; and
4) Improved vaccines and antidotes, perhaps to the point where "classical" BW agents will offer less utility as a means of causing casualties.

The extreme lethality of biological agents has long been known. However, lethality is only one of many characteristics necessary to consider in the development, production, and employment of a BW agent. Scientific advances may allow improvement of other characteristics to facilitate their use as weapons. Potential characteristics of novel biological agents or microorganisms that could be produced through genetic engineering methodologies are:

1) Benign microorganisms, genetically altered to produce a toxin, venom subfraction, or endogenous bioregulator;
2) Microorganisms resistant to antibiotics, standard vaccines, and therapeutics;
3) Microorganisms with enhanced aerosol and environmental stability;
4) Immunologically altered microorganisms able to defeat standard identification, detection, and diagnostic methods; and
5) Combinations of one through four with improved delivery systems.

All systems for responding to needs for genetically engineered and emerging threats are fundamentally in place. New approaches to medical countermeasures within the Department of Defense (DoD) take advantage of advances in molecular biology and genetic engineering. These are being applied to most of the threat agents. One major approach to counter biological agents involves altering the agent of concern by site-directed mutagenesis of the pathogen's genes to produce attenuated strains that can establish benign infections, which elicit immunity to the virulent parent strains. A second major approach uses expression systems to present critical structural subunits of the pathogen that causes the host to generate a protective immune response against the intact virulent organism. In general, these approaches offer several advantages over the classical methods of vaccine production such as reduced reliance on growth of pathogenic organisms, better characterization of vaccine components, expression of genetically altered immunogens, and potential improvements in production scale up. Potential disadvantages include technical difficulty in designing recombinant proteins that are as immunogenic as the native proteins.

Advances in technology, specifically genetic engineering and recombinant DNA, are being exploited by the Chemical and Biological Defense (CBD) Program and the Defense Advanced Research Projects Agency (DARPA) Biological Warfare Defense (BWD) Program to develop countermeasures to BW threat agents, including potentially modified agents. One example of such an effort is the Defense Technology Objective to produce multi-agent vaccines to counter biological threat agents. This Defense Technology Objective seeks to produce a vaccine, or vaccine delivery approach, that could be used to concurrently immunize an individual against a range of biological warfare threats with a single product. 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.

Examples of other medical programs exploiting recombinant DNA technology include: (1) medical countermeasures for Staphylococcal Enterotoxin B; (2) medical countermeasures for Encephalitis viruses; and (3) common diagnostic systems for biological threats and endemic infectious diseases.

Fortunately, the United States is the world leader in R&D related to biotechnology and pharmacology, the fields most important to the defense applications that I have listed. For example, more than one third (36 percent) of all pharmaceutical research in the world is performed in laboratories located in the United States. Japan is a distant second at 19 percent. Pharmaceutical companies in the United States spent more than $20 billion on R&D in 1998. Forty-five percent of all the pharmaceuticals introduced in the world between 1975 and 1994 originated in the United States. While quantity is important, it is the quality of the work performed in the United States that is really the critical factor. This has been recognized again two weeks ago by the award of the Nobel Prize in Medicine to Professor Guenter Blobel of the Rockefeller University in New York. Professor Blobel received his Ph.D. at the University of Wisconsin in 1967 and has been a member of the faculty of Rockefeller University ever since. His work concerned the understanding of genetic diseases such as cystic fibrosis, and he employed techniques of DNA manipulation closely related to those I have mentioned in previous paragraphs.

C. Requirements, Priorities, and Resources

The chemical and biological defense program is threat-driven not technology-driven. This is because the products created by the program is for defensive purposes. The chemical and biological (CB) threat motivates the user to identify requirements and the capability needed, which in turn forms the basis for requirements for the research and acquisition community. The Defense Intelligence Agency provides us with continually updated reports and assessments. These reports assess the impact of chemical and biological weapons in the possession of potential adversaries on how we fight. The requirements are therefore generated to meet user identified materiel shortcomings. Requirements in the form of Mission Needs Statements and Operational Requirement Documents are created by our joint user community under the leadership of the Joint Service Integration Group (JSIG). The result is that our programs respond to validated threat assessments and user mission requirements, not to technologies.

Joint and service unique research, development, and acquisition (RDA) efforts are structured to support the framework of the three mission areas of CB defense: (1) contamination avoidance (detection, identification, warning and reporting and reconnaissance); (2) force protection (individual, collective and medical support); and (3) decontamination. The

current CB programs support the men and women in all military services and in all environments. The programs impact all joint warfighting capabilities, while providing an integrated system of systems on the battlefield. It is essential to view all chemical and biological defense programs as an integrated whole, with each mission area important to the survival of the forces. Our armed forces need the full spectrum of defensive equipment to survive, fight, and win in a contaminated environment. Protective clothing may be of little value if we do not provide the appropriate detection and warning systems.

The chemical and biological defense program consists of all DoD RDA efforts that develop and procure systems designed to provide U.S. forces with the ability to operate effectively in the presence of CB agents. The department's fiscal year 2000 (FY00) budget request for the CBD Program is approximately $716M: $339M for research, development, test & evaluation (RDT&E) and $377M for procurement. In addition, DARPA manages and executes a complementary and coordinated science and technology program at the level of $146M (see Figure 2). These RDT&E resources allow the DoD to maintain the research programs. This permits important technology base research to continue on high priority areas, which will provide us with the next generation of CB defense capabilities.

III. DoD Chemical and Biological Defense Program Management

Public Law 103-160, (Section 1701) of the National Defense Authorization Act for Fiscal Year 1994, directed the Secretary of Defense to take concrete management and oversight actions:

- Assign responsibility for overall coordination and integration of DoD CB defense (non-medical and medical) RDA programs to a single office within the Office of the Secretary of Defense (OSD);
- Exercise oversight of the programs through the Defense Acquisition Board;
- Improve cooperation and collaboration among the military services and the other agencies involved in the program;
- Designate the Army as executive agent for DoD to coordinate and integrate RDA programs of all services;
- Submit funding requests for CB defense RDA in the DoD budget as a separate account. Funding requests may not be included in the service budgets; and

- Submit an annual report to Congress concerning nuclear, biological, and chemical (NBC) defense readiness and plans to improve the program.

The department has implemented all Public Law 103-160 requirements. The implementation of the public law has provided the catalyst for major improvements in the CBD Program; it has led to increased cost effectiveness, enhanced coordination, improved execution of the program, and resulted in a more robust funding for CB defense. With a consolidated management structure and continuing emphasis on joint requirements and joint developmental programs, the department is fielding significant quantities of new and improved equipment (see Figure 3). I want to take this opportunity to thank this committee and the Congress as a whole for prodding us to create this effective organization and then to provide us with the resources to make things happen. In the past five years, the resources allocated to the department's chemical and biological defense programs have doubled (see Figure 2). All of us are grateful to you for this strong support.

The Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense – DATSD(CBD) – is the focal point within the department for the comprehensive oversight of the CBD Program. I am pleased to report that this position has recently been assumed by Dr. Anna Johnson-Winegar, a distinguished life scientist with broad experience in military R&D. The DATSD(CBD) is responsible for the oversight, coordination, and integration of all CB defense medical and non-medical acquisition efforts and provides the overall guidance for planning, programming, budgeting, and executing CB defense programs. The DATSD(CBD) remains the single office within OSD responsible for oversight of the DoD CBD Program.

The DATSD(CBD) is also the Executive Secretary of the OSD NBC Defense Steering Committee. The OSD NBC Defense Steering Committee provides direct oversight of the DoD CBD Program in accordance with Public Law 103-160 (50 USC 1522). The OSD NBC Defense Steering Committee is composed of the following members:

1) Director, Defense Research and Engineering;
2) Director, Defense Threat Reduction Agency (DTRA);
3) Director, CB Defense Directorate, DTRA, (DTRA(CB)); and
4) Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense – DATSD(CBD).

I am the senior member of the committee, and I act as the chairman.

The OSD NBC Defense Steering Committee is supervised by the Under Secretary of Defense for Acquisition and Technology. The Steering Committee provides the fiscal and programming guidance to the Joint NBC Defense Board (JNBCDB) to develop the Program Objectives Memorandum (POM). Specifically, the Steering Committee also provides the appropriate inputs from the DTRA and DARPA. The JNBCDB issues POM preparation instructions to the subordinate groups, which review the validated requirements and build the POM strategy recommendations. Each military service is represented and has one vote. There are also several non-voting members. The CBD Program is divided into the following commodity areas:

- Contamination avoidance,
- Individual protection,
- Collective protection,
- Decontamination,
- Medical CB defense, and
- Modeling & simulation.

These commodity areas correspond to the projects under the budget program elements. There is also a program budget element to support program management and oversight, user testing, and doctrine development. The JSIG is the principal steering group that oversees the coordination and integration of service and CINC requirements and priorities for RDT&E and initial procurement. The Joint Service Materiel Group (JSMG) is the principal steering group that manages the execution of RDT&E materiel development efforts to ensure that program risk is mitigated across commodity areas and the ongoing efforts are complementary but not duplicative.

A Medical Program Sub-Panel (MPSP) has been implemented as part of the JSIG. The MPSP is chaired by the Commander, Army Medical Department Center and School (AMEDDC&S). The purpose of the MPSP is to identify medical program needs and requirements as developed by the AMEDDC&S, CINCs, services, Joint Staff, the Armed Services Biomedical Research Evaluation and Management Committee, and other users. The MPSP coordinates, integrates, and prioritizes all user requirements input. It provides the consolidated, integrated, and prioritized list of medical CB defense requirements to the JSIG. The JSIG then submits an integrated list of medical and non-medical requirements to the

JNBCDB. The JNBCDB and the OSD NBC Defense Steering Committee may make changes to the medical or the non-medical requirements and priorities list.

The Secretary of the Army is the Executive Agent responsible to coordinate, integrate, and review all services' CB defense requirements and programs. The Secretary has delegated this responsibility to the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, who along with the Vice Chief of Staff of the Army, co-chairs the Joint NBC Defense Board. The military departments' acquisition organizations execute the individual CB defense programs according to service and DoD directives.

The services have established procedures to ensure that individual service requirements are identified and integrated within a joint framework for effective development and acquisition of CB defenses. The services' acquisition organizations manage individual CB defense efforts in accordance with service and DoD Directives. Each service has been assigned the lead for the following commodity areas:

- Army - contamination avoidance and CB medical programs;
- Air Force - decontamination;
- Marine Corps - individual protection; and
- Navy - collective protection and modeling & simulation.

The National Defense Authorization Act for Fiscal Year 1997 authorized DARPA to conduct research programs on biological warfare defense but closely coordinated with the CBD Program. To this end, DARPA coordinates its activities with a wide variety of organizations both inside and outside of the DoD, including the CBD Program, and participates in the DoD-wide science and technology planning and review process and the department's Annual Report to Congress on Nuclear, Biological and Chemical Defense Readiness.

IV. Chemical and Biological Defenses: Progress Since Operation Desert Storm

After Operation Desert Storm, critical deficiencies in CB defenses became apparent. Congress enacted Public Law 103-160 in 1994 partially to remedy the deficiencies. The department's CBD Program was established to field improved systems to enhance the capabilities of our forces to defend themselves against the potential threats revealed during Desert Storm. Biological

detection is limited today to point detection for fielded forces; coverage of key air fields, sea ports, and logistics staging areas; and standoff detection of aerosols. The current program is focusing on fielding improved early warning and point detection with improved sensitivity and agent identification. For chemical detection the program focuses on fielding improved point and stand-off detection systems to provide full coverage for individuals, ships, and aircraft with better reliability, enhanced sensitivity, and additional agent detection capability. Future improvements will also include detection of low-levels of chemical agents, detection of a broader number of chemicals (including some toxic industrial chemicals), and reduced size and weight to allow for a greater variety of applications.

The current reporting and warning system is limited to manual systems with no integration into existing command, control, and communication systems and limited battlefield awareness software for timely, accurate incident display. We began fielding innovative equipment to provide digitized and automated warning and reporting capabilities.

Since Operation Desert Storm, one of the most significant areas of improvement was the fielding of improved individual protective clothing that reduces heat and mobility burdens on the individual and extends previous suits' shelf lives. Future protective clothing ensembles will provide lighter weight and more durable and launderable clothing that ultimately can be integrated into the standard duty uniform to provide for continuous protection.

Additionally, we are pursuing a Joint Service general purpose mask for all service applications that will be compatible with both weapons systems optics and communication systems. We possess limited numbers of collective protective shelters that are based on outdated technology and have heavy logistics burdens. New technology addresses needed improvements in collective protection with reduced logistical burdens.

Medical countermeasures for CB threat agents are limited but improving. Vaccines are the most effective and least costly protection from biological agents. The department's FY00 budget request responds to these documented deficiencies and Commander in Chief (CINC) requirements.

A notable achievement has been the initiation of the anthrax vaccinations of the entire force. Since U.S. forces may be deployed worldwide on short notice and since an enemy may

strike deep behind the front lines using terrorists or ballistic missiles, it is imperative to protect all U.S. forces. We know that anthrax exists this very day as a weaponized agent in the arsenals of countries hostile to the United States. As such, it presents a clear and present danger to U.S. forces around the world. Total force vaccination is essential since full immunity takes about 18 months. To date, about one third (378,242) of our military personnel, including 29,663 members of the Reserves, have received anthrax immunizations--totaling nearly one million injections. While side effects do occur in some people, they tend to be temporary, confined to the area around the injection, and mild or moderate in most people. Anthrax is lethal to approximately 95 percent of personnel exposed, if not protected with the vaccine. With the vaccine, fatalities can be expected to drop from 95 percent of personnel exposed to less than ten percent.

V. Future Chemical and Biological Defenses

Following is a summary of key capabilities that are planned for procurement over the future years defense plan in each of the commodity areas within the DoD chemical and biological defense program.

A. Contamination Avoidance Modernization Strategy

The increased lethality and heightened operational tempo of future battlefields demand responsive detection and warning capabilities to reduce force degradation caused by contamination. These capabilities, which also encompass reconnaissance, identification, and reporting, are given high priority within the CBD Program for force readiness.

Early detection and warning is key to avoiding contamination. As a result, CB defense research, development and acquisition efforts are concentrating on providing our forces real-time capabilities to detect, identify, locate, and warn against all CB warfare threats below threshold effects levels. Current emphasis is on multi-agent sensors for biological agent detection and stand-off/remote/early warning detection of CB agents (see Figure 4). To meet the needs of the next three to five years, stand-alone detectors and sensors are being developed for a number of applications. As detection technology matures, development efforts will focus on system miniaturization, improved sensitivity and range, reduced false alarm rates, and decreased operations and support costs. This

focus will integrate CB detection into personal gear (chemical detectors only) and onto various air, sea, and ground platforms. It also will permit CB warnings and messages to be transmitted to commanders throughout the theater via automatic digital communication systems.

Currently fielded biological standoff detection is based on backscatter within the infrared portion of the electromagnetic spectrum. Development work includes approaches for agent identification using fluorescence within the ultraviolet region. New approaches are examining alternatives to standoff identification of biological agents. For example, microwaves may allow agent identification based on molecular rotations and millimeter waves, which may allow the development of next generation capability.

New approaches focus not on individual (and usually expensive) point detectors, but rather on a network of lower cost point identification systems that will increase reliability over any one sensor, improve warning, and allow for forecasting of hazards.

Over the past four years, the Joint Program Office for Biological Defense (JPO-BD) has managed several single-service and joint biological detection programs. Three single-service biodetection programs which have been fielded include:

- the Navy's Interim Biological Agent Detector -- 25 ships were equipped throughout FY96-99;
- the Army's Biological Integrated Detection System Non-Developmental Item (BIDS NDI), which was fielded to the 310th Chemical Company (U.S. Army Reserves); and
- the Army's Long Range Biological Standoff Detection System NDI, which was also fielded to the 310th Chemical Company (three systems).

Key joint systems managed by JPO-BD include:

- the Army's BIDS Pre-Planned Product Improvement, which provides increased automation, doubles the number of agents detected and identified (4 vs. 8), and reduces identification time (<30 min);
- the Joint Biological Point Detection System, which entered the engineering and manufacturing development phase in FY97 and will be the first truly joint

biological detection acquisition program that is built on an approved joint operational requirements document;

- the Air Base/Port Bio Detection (Portal Shield) Advanced Concept Technology Demonstration (ACTD), which has been deployed to key air fields, including several in Korea; and
- the Joint Biological Remote/Early Warning System ACTD, which started development in FY98.

Over the past three years, the JSMG and JSIG, through the contamination avoidance commodity area manager and with assistance from JPO-BD, transformed and consolidated 44 separate contamination avoidance developmental efforts into nine fully coordinated joint projects. These joint programs are listed below:

- Automatic Chemical Agent Detector Alarm
- Joint Chemical Agent Detector
- Joint Service Lightweight Standoff Chemical Agent Detector
- Joint Service Chemical Warning and Identification Light Detection and Ranging (LIDAR) Detector
- Joint Biological Point Detection System
- Joint Biological Remote Early Warning System
- Joint Service Light NBC Reconnaissance System
- Joint Warning And Reporting Network
- Joint Service Agent Water Monitor

DARPA is working on several fronts to develop components of environmental sensors that are physically robust, largely automated, fast, sensitive, small, and low in cost. Some examples include:

- Developing tissue-based sensors -- living cells on chips that can react functionally to the presence of both biological and chemical threat agents to give an indication of attack;
- Modeling and fully characterizing sensor system performance to better understanding and mitigation of false alarms, which are known to plague current sensors;
- Improving sensor collectors to concentrate the often dilute quantities of biological warfare agents; and
- Developing several techniques to identify the specific agents present in environmental samples.

B. Force Protection Modernization Strategy

Forces cannot always avoid NBC hazards. Therefore, personnel must be provided clothing and equipment to protect them from effects of these lethal agents. Protection must be effective against all known threats and not measurably degrade the performance of personnel, weapons, or equipment. Total NBC protective measures, which consist of individual and collective protection, allow joint forces to maintain operational tempo in a contaminated environment.

The goal of the protection area is to provide equipment that allows U.S. forces to operate in a contaminated environment with minimal degradation of their performance. Current programs are aimed at maintaining protection levels while reducing physiological and logistical burdens.

Individual protective equipment (IPE) consists of eye, respiratory, and skin protection, a mask with hood and protective garments, boots, and gloves. The IPE issued to joint forces protects against all known CB threat agents. Its capabilities against chemical agents are routinely demonstrated with actual agents in the Chemical Defense Training Facility, U.S. Army Chemical School, which has recently completed its move to Fort Leonard Wood, Missouri.

Protective masks will be improved to provide greater user comfort, maintainability, and reliability under field conditions and to reduce the breathing resistance currently encountered. Mask systems will require increased survivability and compatibility with combat weapons systems optics or personal equipment. Future respiratory systems, such as improved and common Air Force and Army aircrew masks, will require enhanced compatibility with both life support and tactical systems on fixed and rotary wing aircraft. In the future, the focus will be on integrated respiratory protective ensembles that offer optimal compatibility with personal, tactical, and crew support systems.

Future protective clothing ensembles will be required for land, sea, air, and marine forces to achieve reductions in bulk and weight with minimum loss of protection or durability. To satisfy these needs, the services have consolidated their mission specific requirements into a first truly joint evaluation program for the next generation chemical protective garments--the Joint Service Lightweight Integrated Suit Technology (JSLIST) program. New accessories, such as gloves

and footwear, are also required to execute missions that require greater tactile function and traction. The Joint Protective Aircrew Ensemble will be developed to provide aviators the same advantages and improved protection as JSLIST provides to other ground forces. Among other initiatives, DARPA is developing novel materials for protective clothing that can actually capture and destroy biological agents.

Collective protection equipment development efforts are focused on protection systems at the crew, unit, ship, and aircraft level and will result in items that are smaller, lighter, less costly, and more easily supported logistically. New systems are required to make "clean" environments available for critical operations, *i.e.*, where IPE would place an unacceptable burden upon the service member in performing duties, and to provide essential rest and relief. Modernization concentrates on: (1) improved air filtration methodologies; (2) advanced technologies integrated into power and ventilation for systems that offer a significant improvement in logistics; (3) applications on essential vehicles, vans, and shelters; (4) improvements to current shipboard filters to extend filter life; and (5) benefit applications on essential spaces on ships. Efforts are underway to support major weapons systems developments, such as the V-22 Osprey, Comanche, Crusader, the United States Marine Corps advanced amphibious assault vehicle, and other aircraft and armored systems modernization programs.

C. Medical Support Modernization Strategy

DoD maintains a robust medical R&D program for CB defense. This program has resulted in the fielding of numerous products to protect and treat service members. Specific initiatives programmed to improve CB medical readiness include:

- Continued emphasis on NBC medical countermeasures research,
- A biological defense immunization implementation plan,
- Medical collective protection, and
- Enhanced medical diagnosis of exposure to agents.

The countermeasures for chemical agents include pharmaceuticals, medical equipment, specialized materiel or medical procedures, and concepts for training, doctrine, and organization. Medical countermeasures are designed not only to prevent lethality, but also to preserve and sustain combat effectiveness in the face of combined threats from chemical and conventional munitions on the integrated battlefield by:

- Prevention of the effects of chemical agents (e.g., pretreatments, prophylaxis, topical protectants);
- Far-forward treatment upon exposure to chemical warfare threats (e.g., antidotes); and
- Chemical casualty care (e.g., diagnosis, therapy, and management).

In accomplishing the goals of the medical biological defense research program, efforts are focused on three objectives:

1) Prevent casualties with medical countermeasures (through the use of vaccines, drugs, and other medical treatments);
2) Diagnose disease (through the use of forward deployable diagnostic kits and confirmation assays); and
3) Treat casualties to prevent death and maximize return to duty (through the use of antitoxins, drugs, and other medical treatments).

Critical elements of medical biological defense include the ability to rapidly identify an agent and to provide prophylactic and/or therapeutic protection from the agent. Often, the most effective countermeasure is pre-deployment active immunization.

The current program includes the following research areas for the development of medical biological agent countermeasures:

- Characterize molecular biology and physiology of biological threat agents;
- Investigate the pathogenesis and immunology of the disease;
- Determine the mechanism of action of the threat agent through modeling;
- Identify new medical biological defense products by understanding their interaction with and mechanisms of action against BW agents;
- Establish safety and efficacy data for new medical biological defense products; and
- Establish the validity of new medical biological defense products against battlefield use.

The DARPA Medical Countermeasures program is developing revolutionary, broad-spectrum, approaches against pathogenic microorganisms and their pathogenic products to eliminate their

biological threats. These are developments related to those mentioned previously, but which will be implemented on a longer time scale.

- Defeating a pathogen's ability to enter the body, traverse the bloodstream or lymphatics, and enter target tissues;
- Construction of unique, robust vehicles for the delivery of countermeasures into or within the body;
- Identification of novel pathogen vulnerabilities based on fundamental, critical molecular mechanisms of survival or pathogenesis; and
- Modulation of the advantageous and deleterious aspects of the immune response to significantly pathogenic microorganisms and their pathogenic products in the body.

DARPA is also conducting research in diagnostics that is complementary to the program dealing with medical countermeasures. Early diagnosis is key to providing effective therapy against biological warfare agents since many of these agents cause early, nonspecific flu-like symptoms. Specific areas of interest include:

- Multiagent diagnostics capable of simultaneously identifying a broad range of pathogens;
- Strategies for identifying both known and presently unknown or bioengineered pathogens;
- Strategies for early detection of exposure;
- Capabilities for continuous monitoring or immediate recognition of infection in the body; and
- Wearable diagnostics for noninvasive broad-spectrum detection of infection in the body.

There has been significant progress within the area of biological defense vaccine policy and development. The department has established policy, responsibilities, and procedures for stockpiling biological agent vaccines and determined which personnel should be immunized and when the vaccines should be administered. The DoD has also identified biological agents that constitute critical threats and determined the amount of vaccine that should be stocked for each threat. The department awarded a Prime Systems Contract in November 1997 to manage advanced development of biological defense products, obtain FDA licenses, and produce vaccines using the U.S. pharmaceutical industrial base. The prime contract approach has the advantage of flexibility and allows

the market to respond to DoD requirements. The RDT&E efforts are underway to develop vaccines against all validated threat agents.

Basic science efforts are providing information on the mechanism of action for sulfur mustard (HD). This knowledge led to the development of strategies to counter vesicant agents both before and after exposure to agents. For example, there are first-time treatments to prevent DNA alkylation, proteolytic activation and other mechanisms that cause damage at a biochemical level.

Advances in computer technologies have allowed for the ability to create 3-dimensional designs of individual molecules. This level of detail allows for accurate study, which in turn provides the scientific bases for the development of accurate detection of various agents and for the development of effective and safe vaccines.

D. Decontamination Modernization Strategy

Decontamination systems provide a force restoration capability for units that become contaminated. Existing capabilities rely upon the physical application and rinse down of decontaminants on contaminated surfaces. Existing systems are effective against a wide variety of threat agents, yet are slow and labor intensive; present logistical, environmental, and safety burdens; and cannot be used on sensitive electronic equipment. To improve capabilities in this functional area, the joint services place emphasis upon new decontaminating technologies and materiel which reduce existing manpower and logistics requirements. They are safer to the environment, personnel, and equipment.

Research and development of non-corrosive, all-agent multipurpose decontaminants and decontaminating systems for combat equipment, cargo aircraft and ships, personal gear, and skin remains a priority. Alternative technologies (such as sensitive equipment decontamination methods, large-scale automated decontamination systems, and catalytic coatings and sorbents) attract strong interest across the services. Large area decon systems are needed to support our power projection strategy into foreign airports or seaports, which may be targeted for CB contamination.

The Army has developed the M291 skin decontamination kit as a replacement to the M258A1 decontamination kit for all

services, and they are currently introducing the M295 for improved personal equipment decontamination. The M295 provides our military a fast and non-caustic decontamination system for personal gear. A new adsorbent that is more reactive and has higher capacity is being developed to improve the performance of the M295 kit.

In the near- and mid-term, the DoD continues to research new multi-purpose decontaminants as a replacement for bulk caustic Decontamination Solution 2 and corrosive super tropical bleach. New technologies, such as sorbents, enzymatic foams, and reactive decontaminating systems, are being explored and may offer operational, logistics, cost, safety, and environmental advantages over current decontaminants. It should be noted that present shipboard chlorine-based decontaminant solutions pose an unacceptable corrosion risk to naval aircraft. Current procedures require the use of fresh water and normal aircraft detergent solutions.

In the far-term, the services are seeking non-aqueous decontamination systems to provide for sensitive equipment decontamination at mobile and fixed sites. Additionally, there is interest and research in coatings which can reduce or eliminate the necessity of manual decontamination.

E. Advanced Scientific Efforts

The DARPA BWD Program, as a science and technology effort, has a more far-term focus than the CBD Program. As individual efforts progress, successful technologies and prototype systems are transitioned to the JPO-BD or the military services for further development.

The BWD Program has set very stringent metrics in order to measure success. While projects may start with experiments involving simulants or inactivated pathogens, they must culminate with testing on live pathogens (or toxins) in order to be declared a success. The true measure of success in any program, however, is the integration and utilization of the technology by the military. The cost of this process may be quite steep, however (this is especially true for the development of new therapeutics). To this end, DARPA is actively engaging the commercial biotechnology and pharmaceutical industries for further technical development and manufacturing.

An excellent example of this kind of work is our support of the work on pathogenic genome sequencing. This is a basic research effort that includes the following items:

- Exploit recent advances in high throughput genetic sequencers to obtain complete genetic information on a number of important pathogens and their non-pathogenic nearest neighbors;
- Develop an inventory of genes and proteins that distinguish pathogens from non-pathogens and to identify pathogenic markers in any guise; and
- Provide superior molecular targets and enable new generations of detectors, diagnostics, and therapeutics.

VI. Chemical and Biological Defenses: Areas of Future Emphasis

Two subordinate groups support the Joint NBC Defense Board. The JSIG is responsible for identifying joint CBD requirements and priorities, and for overseeing the development of appropriate training and doctrine. The JSIG also coordinates with the Joint Staff Joint Warfare Capability Assessment process to identify vulnerabilities and prioritize requirements. The JSMG is responsible for identifying materiel solutions to the requirements and coordinating and integrating research, development and acquisition efforts. These groups perform the planning and programming functions for CBD research, development and acquisition and submit appropriate documentation to the Office of the Secretary of Defense throughout the Planning, Programming, Budgeting System (PPBS) cycle. Based on the Joint Warfighting Capability Assessment, CINC priorities, and other information, following are areas of future emphasis:

- Improved biological detection capabilities;
- Integrated sensors and C4I;
- Improved capabilities for protection of fixed sites;
- Improved decontamination technologies;
- NBC contamination survivability for fielded systems;
- Leveraging industrial base for improved drugs, vaccines, and diagnostics; and
- Additional multipurpose licensed medical products (e.g., polyvalent vaccines).

VII. DoD Chemical and Biological Defense Program: Coordination with Related Efforts

The CBD Program is being coordinated with several related efforts, including DARPA's BWD Program, the Department of Energy (DOE), and international cooperative efforts.

The DARPA is charged with seeking breakthrough concepts and technologies. DARPA's BWD Program, which complements the CBD Program by anticipating threats and developing novel defenses against them, is pursuing the development of technologies with broad applicability against classes of threats. The DARPA BWD Program invests primarily in the early, technology development phases of programs, with rapidly decreasing involvement in the succeeding stages that lead to system development. The CBD Program has programmed funding to facilitate the transition to acquisition of any demonstrated DARPA technologies that may meet military needs.

The DOE initiated an effort to develop CB defenses capabilities for first responders and protection against terrorist attacks within the United States. The CBD Program has leveraged the DOE program by funding DOE efforts that may have military applications. Additionally, coordination between the DOE and DoD is achieved by DOE participation as a non-voting member of the Joint NBC Defense Board and in CBD Program science and technology reviews.

The CBD Program also leverages industrial capabilities by briefing industry annually on program technology needs. Further, the CBD Program reviews industry independent research and development efforts and encourages industry participation in joint field trials conducted annually at Dugway Proving Ground, Utah. This provides an independent validation and assessment of capabilities.

The CBD Program has numerous bilateral and multilateral international cooperative efforts. These include working groups with NATO, The Technical Cooperation Program, and data exchange agreements.

VIII. Conclusion

Since deficiencies identified after Operation Desert Storm were detailed in the *Conduct of the Persian Gulf War, Final Report To Congress* (Public Law 102-25), significant progress has been made within the CB defense readiness area. Improvements continue in the near-term. The current developmental program is

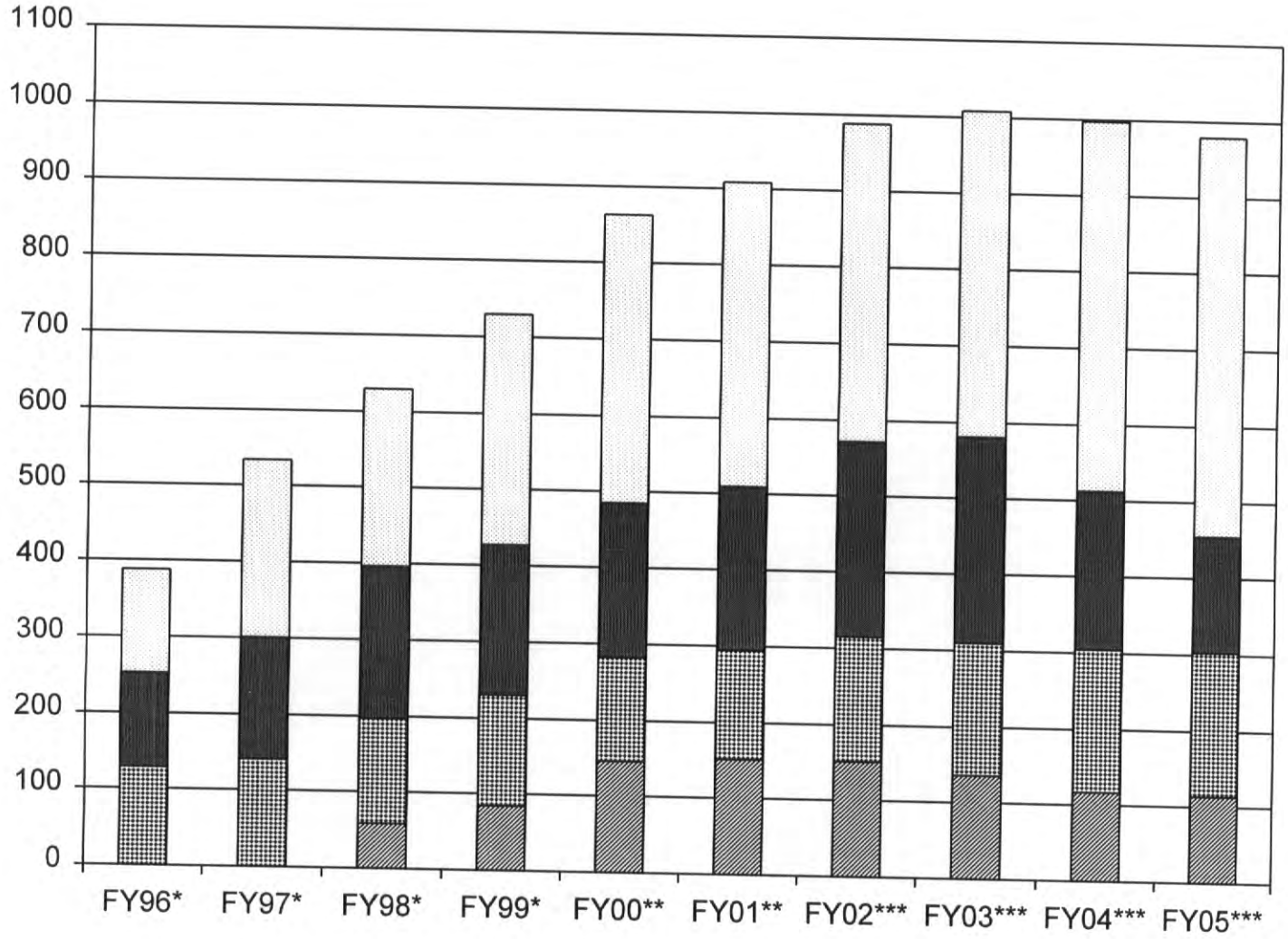
focusing on an integrated, balanced approach to obtaining needed capabilities for joint forces within affordability constraints. Although progress has been made, serious challenges remain with the limitations of our technical understanding to solve CB defense problems. The department is continually analyzing priorities and resources required to execute an effective program. The DoD's chemical and biological defense program, just as the myriad other important DoD programs, will continue to compete for scarce resources in a constrained budget environment. Emphasis on collaborative efforts to eliminate duplication of efforts will result in achieving the most effective use of limited resources.

In summation, the DoD chemical and biological defense program is responding to the requirements, priorities, and resources, as well as taking advantage of newly emergent technologies. Programs are in place to respond to user needs and shortfalls. Oversight and management of the CBD Program continues to improve. Significant progress has been made in implementation of management initiatives. The department is on the right azimuth for progress in fielding needed improved CB defense equipment to our forces as well as developing next-generation technologies and systems. The continued support of Congress and implementation of current plans will continue to improve joint force readiness now and in the future.

Mr. Chairman and members of the committee, this concludes my statement. I would be pleased to answer any questions you might have.

Figure 1.

Figure 2. DoD Chemical and Biological Defense Program Budget



DARPA Bio Warfare Defense Program
Chem/Bio Defense Program (Research thru Advanced Technology Development)
Chem/Bio Defense Program R&D (Dem/Val thru EMD)
Procurement

* Total Obligation Authority
** FY00 President's Budget Request
*** Estimated from FY00 President's Budget Request

Figure 3. Management Structure for the Chemical and Biological Defense Program

This chart illustrates how the chemical and biological defense program is managed. The development of defenses against chemical and biological weapons involves all of the military services, defense agencies, the Department of Energy, and many other agencies and institutions. This circumstance is reflected at the bottom of the chart in the oval, which lists some of the performers. Since the capability to perform the work in support of the chemical and biological defense program is widely distributed, it is not surprising that the management structure is intricate.

The next line above the performers are the two government executive managers of the program, which reflect the two separate tracks along which the effort is directed. The track on the right side of the chart deals with basic, far-term research and is the responsibility of DARPA. The track on the left side of the chart shows the applied research and procurement that comprises the CBD Program. The DARPA portion is headed by Dr. Jane Alexander, who has wide experience in the supervision and management of biological research and who also serves as the Deputy Director of DARPA. The CBD program is headed by Colonel Carmen Spencer, U.S. Army (Retired), who is also the manager of the chemical and biological defense program in the DTRA.

At the management level of the two tracks, which is where the detailed resource judgements are made, we have the DARPA Director, Dr. Frank Fernandez, and the Joint NBC Defense Board. The Joint Board is where the Army's role as the Executive Agent is exercised through the co-chairmanship of the Assistant Secretary of the Army for Acquisition, Logistics, and Technology, the Honorable Paul J. Hoeper and the Vice Chief of Staff of the Army, General John M. Keane. The primary function of the units at the management level is to develop the Program Objectives Memorandum (POM). Each military service is represented on the Joint NBC Defense Board and has one vote. There are also several non-voting members.

At the oversight level, the program elements come together in the Office of the Director of Defense Research and Engineering (DDR&E). The DARPA reports to the DDR&E, and the DDR&E is also the senior member of the NBC Defense Steering Committee in the Office of the Secretary of Defense. Dr. Anna Johnson-Winegar is the Deputy Assistant Secretary of Defense for

Chemical and Biological Defense (DATSD(CBD)). In this capacity, she is the Executive Secretary of the Steering Committee and is also the single person who exercises direct oversight of the NCB program and thus serves as its "focal point". Finally, the entire program is carried out under the leadership of Dr. Jacques S. Gansler, the Under Secretary of Defense for Acquisition, Technology, and Logistics.

Figure 3. Management Structure for the Chemical and Biological Defense Program

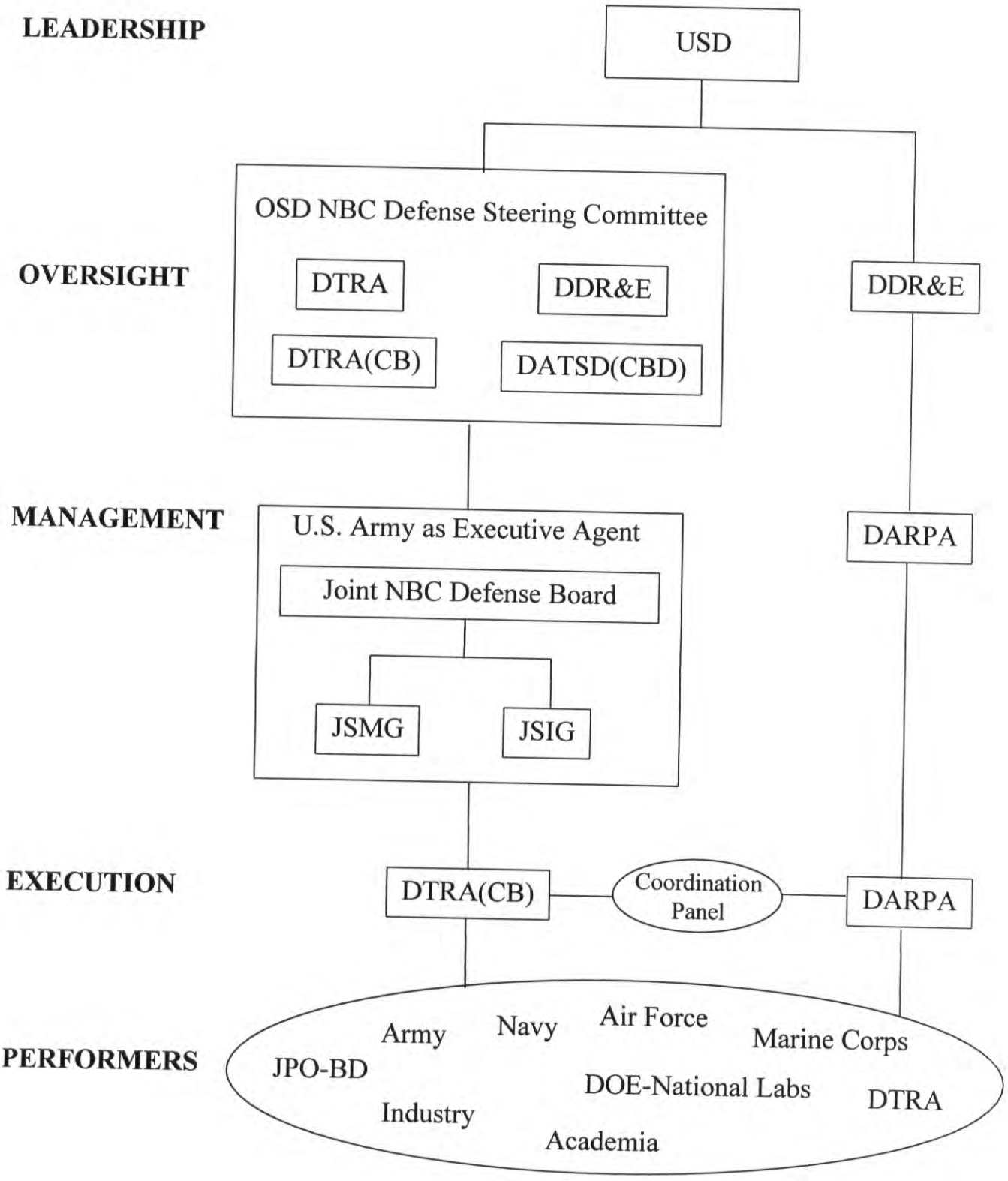


Figure 4.