Biodefense: Next Steps
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Testimony

INTRODUCTION

Good afternoon, Chairman Burr, Senator Kennedy and distinguished members of the subcommittee. I am pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security is making in the nation's efforts to prevent, protect against, respond to, and recover from acts of bioterrorism against the American people.

President Bush has made strengthening the nation's defenses against biological weapons a critical national priority. Although significant progress has been made to protect America, President Bush instructed Federal departments and agencies to review their efforts and find better ways to secure America from bioattacks.

This review resulted in a Presidential Directive entitled Biodefense for the 21st Century that provides a comprehensive framework for our nation's biodefense. This directive builds upon past accomplishments, defines specifies roles and responsibilities, and integrates the programs and efforts of various communities: national security, medical, public health, intelligence, diplomatic, agricultural and law enforcement into a sustained and focused effort against biological weapons threats.

The Department of Homeland Security (DHS) and the Science and Technology (S&T) Directorate have explicit responsibilities in this integrated national effort. In particular, I want to highlight the strategy, planning and accomplishments to date of the Science and Technology Directorate in the area of biodefense, and the essential collaborations with key Federal partners, including those represented here today.

BIODEFENSE

Before I speak directly to the biodefense efforts of the S&T Directorate, I want to briefly address the role of the DHS's Information Analysis and Infrastructure Protection Directorate (IAIP), and how their work is linked to the S&T Directorate. IAIP assesses intelligence and information about threats and vulnerabilities from other agencies and takes preventative and protective action. They are partners in the total interagency efforts to obtain, assess and disseminate information regarding potential threats to America from terrorist actions. These threat and vulnerability assessments are inputs into the strategy and research, development, testing and evaluation (RDT&E) activities of the Science and Technology Directorate. For example, agriculture and food are two of the multiple

critical infrastructure sectors identified by Homeland Security Presidential Directive 7. As such, they fall within the domain of the IAIP Directorate; they are also within the domain of concern for biological threats and are considered in HSPD-9 and HSPD-10/NSPD-33. In addition, the IAIP Directorate's cooperation with the Science and Technology Directorate is critical to the Department's mission to determine what agents would significantly impact national security if released (Material Threat Determinations).

Mission and Objectives:

HSPD-10 outlines four essential pillars of the nation's biodefense program and provides specific directives to further strengthen the significant gains made in the past three years. The four pillars of the program are:

• Threat Awareness, which includes biological weapons-related intelligence, vulnerability assessments, and anticipation of future threats. New initiatives will improve our ability to collect, analyze, and disseminate intelligence on biological weapons and their potential users.

• Prevention and Protection, which includes interdiction and critical infrastructure protection. New initiatives will improve our ability to detect, interdict, and seize weapons technologies and materials to disrupt the proliferation trade, and to pursue proliferators through strengthened law enforcement cooperation.

• Surveillance and Detection, which includes attack warning and attribution. New initiatives will further strengthen the biosurveillance capabilities being put in place in fiscal year 2005.

• Response and Recovery, which includes response planning, mass casualty care, risk communication, medical countermeasures, and decontamination. New initiatives will strengthen our ability to provide mass casualty care and to decontaminate the site of an attack.

The Department of Homeland Security has a role and responsibility in each of these four pillars of the national biodefense program. The S&T Directorate has the responsibility to lead the Department's RDT&E activities to support the national biodefense objectives and the Department's mission.

Accomplishments and Planned Activities:

In FY 2004 and FY 2005, the Biological Countermeasures portfolio:

• Deployed the BioWatch environmental sensor system to protect our nation's cities from the threat and ramifications of a bioterrorist attack.
• Engaged in creating additional near real-time monitoring (Autonomous Pathogen Detection System) of critical infrastructure facilities such as major transportation hubs.

New infrastructure protection efforts include shorter response time biological agent detection capabilities for BioWatch. This pilot (second generation Bio Watch) is in the process of being deployed in New York City and will join an expansion of the number of collectors in that city.
• Initiated the design of the National Biosurveillance Integration System (NBIS) as part of an interagency process. Recently completed in the first quarter of FY 2005, we will work with the Information Analysis and Infrastructure Protection (IAIP) Directorate to implement this system.
• Conducted preliminary analyses, using the reference scenario approach recommended by Homeland Security Presidential Directive (HSPD)-10 for understanding the requirements of an integrated national biodefense architecture, of four baseline reference cases: a large outdoor release of a non-contagious agent (anthrax); a large indoor release of a contagious agent (smallpox); contamination of a bulk food supply; and two highly virulent agricultural attacks, one on livestock (Foot and Mouth Disease) and the other on crops (soy bean rust).
• Established the Biodefense Knowledge Center, an operational hub for enabling collaboration and communication within the homeland security complex. The Biodefense Knowledge Center will meet the operational and planning requirements of government decision-makers and program planners, the intelligence community, law enforcement officers, public health practitioners, and scientists. Specific capabilities offered to these end-users include knowledge services, modeling and simulation, situational awareness and a pathway to accelerate research and development.
• Certified four "material threats" (anthrax, smallpox, botulinum toxin, and radiological/nuclear); will complete the rest of the Category A bioagents (plague, tularemia) by the end of FY 2005.
• Established the National Bioforensic Analysis Center (NBFAC) to provide a national capability for conducting forensic analyses of evidence from bio-crimes and terrorism to attain a "biological fingerprint" to identify perpetrators and determine the origin and method of attack. The NBFAC was named in HSPD-10 as the lead federal facility to conduct and facilitate the technical forensic analysis of materials recovered following a biological attack in support of the appropriate lead federal agency [in most cases the lead federal agency will be the Federal Bureau of Investigation (FBI)].

In FY 2006, the Biological Countermeasure portfolio plans to:

• Complete the three high-level architectures initiated in FY 2005, identifying key requirements for each major element, a "report card" on the current and projected status in that area and performing detailed design tradeoffs for those areas in which DHS has execution responsibility.
• Complete the first formal risk assessment required under HSPD-10 and close many of the key remaining experimental gaps in our knowledge of the classical biological threat agents. Near-, mid-, and long-term plans for dealing with engineered agents will be developed, and R&D on addressing the gaps in responding to genetically modified organisms (e.g., antibiotic resistant) initiated.
• Complete the deployment of Generation 2 BioWatch systems to additional cities while continuing to operate and optimize already extant BioWatch systems.

• Complete test and evaluation of laboratory prototypes of the Generation 3 BioWatch detection systems for selection of fieldable prototypes for FY 2007.
• Continue operation of the interim National Bioforensic Analysis Center. International Organization for Standardization (ISO) certification is expected to have been achieved, giving the analyses conducted additional credibility and authenticity in both the national and international community and courts of law. R&D will continue on the physical and chemical signatures of the "matrix" materials associated with biological agents so as to develop methods for understanding tell-tale remnants of enrichment media, culture conditions, metabolites, and dispersion technology.
• Continue operation of the Plum Island Animal Disease Center (PIADC) and essential upgrades to the facility and initiate design of the National Bio and Agrodefense Facility (NBAF). R&D will continue on next generation vaccines and antiviral therapeutics for foot and mouth disease (FMD) and other high priority foreign animal diseases.
• Continue to develop bioassays for FMD and look-alike animal diseases. The initial agricultural forensic capability established in FY 2004 at PIADC will be enhanced and epidemiologic capability added. A High Throughput Diagnostics Demonstration will be initiated to work with regional and state laboratories to demonstrate a capability of analyzing thousands of samples per day in support of response to a suspected case or an outbreak. A FMD table top exercise will be conducted, and development of a coupled epidemiological and economic model for FMD will begin. The end-to-end systems study initiated in FY 2004 for Soybean Rust and FMD will be completed, and system studies will be initiated for highly pathogenic avian influenza.

National Bio-Defense Analysis and Countermeasures Center (NBACC)

The NBACC, a key component of the National Strategy for Homeland Security, addresses the need for scientific research to better anticipate, prevent, and mitigate the consequences of biological attacks. The need for the NBACC facility is further defined in HSPD-10, the Nation's blueprint for future biodefense programs. The NBACC's mission will support two pillars of this blueprint – threat awareness and surveillance and detection. The NBACC is made up of two centers, the Biological Threat Characterization Center and the National Bioforensic Analysis Center to carry out these missions. Specifically, NBACC's mission is to:

• Understand current and future biological threats, assess vulnerabilities, and determine potential impacts to guide the research, development, and acquisition of biodefense countermeasures such as detectors, drugs, vaccines and decontamination technologies; and
• Provide a national capability for conducting forensic analysis of evidence from bio-crimes and terrorism to attain a "biological fingerprint" to identify perpetrators and determine the origin and method of attack.

In FY 2004, the Department completed the planning and conceptual design of the NBACC facility. Additionally, the Department has been working through the National Environmental Policy Act (NEPA) process during the year, which culminated in the signing of the Record of Decision in January 2005 of the Final Environmental Impact

Statement (EIS) for the construction project and subsequent operations. It was decided to delay the award of any contracts for design and construction until further in the EIS process. As the public concerns are analyzed and considered it is anticipated that contracts will be awarded in FY 2005 to initiate design and construction of the NBACC facility

In FY 2005, the solicitations of contracts for the design and construction of the NBACC facility are expected to be awarded. The design of the NBACC facility will commence in March 2005. Congress appropriated $35 million in obligated funds for award of the construction contract in the fourth quarter of FY 2005. Construction of the facility is planned for completion by the fourth quarter of FY 2008.

University Centers of Excellence

The mission of the University Programs is to stimulate, coordinate, leverage and utilize the unique intellectual capital in the academic community to address current and future homeland security challenges, and to educate and inspire the next generation of scientists and engineers dedicated to homeland security.

Within the University Programs in the S&T Directorate, the Homeland Security (HS) Centers of Excellence provide independent, cutting-edge research in academia for focused areas of homeland security Research and Development (R&D). Established centers include: the Homeland Security Center for Risk and Economic Analysis of Terrorism Events, the National Center for Foreign Animal Disease and Zoonotic Defense, and the National Center for Food Protection and Defense. In the next few months, the S&T Directorate expects to establish the Homeland Security Center for Behavioral and Social Aspects of Terrorism and Counter-Terrorism. Each Center is selected on a competitive basis, and each grant is for three years. Each Center has a role in addressing bioterrorism and two are specifically aligned with addressing bioterrorism.

DHS awarded funds, over three years, to the University of Southern California (USC) and its major partners, University of Wisconsin at Madison, New York University and Structured Decisions Corporation (affiliated with MIT) to establish the Center on Risk and Economic Analysis of Terrorism Events. The mission objectives are to evaluate the risks, costs and consequences of terrorism and to guide economically viable investments in countermeasures. Specifically, the Center will develop risk assessment and economic modeling capabilities that cut across general threats and targets, in application areas such as electrical power, transportation and telecommunications. Additionally, USC and their partners will develop tools for planning responses to emergencies, to minimize the threat to human life and reduce economic impacts of terrorist attacks.

Texas A&M University and its partners from the University of Texas Medical Branch, University of California at Davis, and the University of Southern California expect to receive funds over the course of the next three years for the study of foreign animal and zoonotic diseases. The Center, which will be known as the National Center for Foreign Animal and Zoonotic Disease Defense, will work closely with partners in academia,

industry and government to address potential threats to animal agriculture including Foot and Mouth Disease, Rift Valley fever, Avian influenza and Brucellosis. The Foot and Mouth Disease research will be conducted in close collaboration with DHS's Plum Island Animal Disease Center.

The Department of Homeland Security expects to provide the University of Minnesota and its partners, Michigan State University, University of Wisconsin at Madison, North Dakota State University, Georgia Institute of Technology, and the University of Tennessee at Knoxville with funds over the course of the next three years to establish best practices and attract new researchers to manage and respond to food contamination events, both intentional and naturally occurring. The University of Minnesota's National Center for Food Protection and Defense, will address agricultural security issues related to post-harvest food protection.

Negotiations began January 10, 2005, for a three-year grant with the University of Maryland for a fourth Center on Behavioral and Social Research on Terrorism and Counter-Terrorism. We expect its mission objectives to be to provide strategies for intervention of terrorists and terrorist organizations and to embolden the resilience of U.S. citizens. Major domestic partners include, the University of California at Los Angeles, University of Colorado, Monterey Institute of International Studies, University of Pennsylvania, and the University of South Carolina.

A broad agency announcement was released in mid-January for proposals for a fifth DHS Center of Excellence on the topic of High Consequence Event Preparedness and Response.

In addition to the University Centers of Excellence, the Department of Homeland Security's University Programs and the Environmental Protection Agency's Science to Achieve Results (STAR) Program are reviewing proposals for a research Center of Excellence focused on an area of high priority to both Agencies, Microbial Risk Assessment (MRA) for Category A bio-threat agents.

Interagency Collaboration:

Ensuring that all relevant Federal Departments and agencies coordinate in the area of Biodefense is critical to protecting the nation from biological threats. The previously mentioned HSPD-10, as well as other directives including HSPD-9, Defense of United States Agriculture and Food; HSPD-8, National Preparedness; HSPD-4, National Strategy to Combat Weapons of Mass Destruction; and HSPD-7, Critical Infrastructure Identification, Prioritization, and Protection, identify national objectives and priorities, and departmental and agencies' roles in addressing these national objectives.

The S&T Directorate has been, and continues to be an active participant in these interagency activities as illustrated by our participation in the biodefense program. At the highest level HSPD-10/NSPD-33 laid out the overall strategy, department and agency roles, as well as specific objectives and called for periodic reviews to plan, monitor and

revise implementation. This was followed by an interagency review, of specific FY 2006-FY 2010 science and technology needs to support the national biodefense strategy as articulated in HSPD-10.

The National Science and Technology Council's Weapons of Mass Destruction Medical Countermeasures Subcommittee (WMD-MCM), co-chaired by the Assistant Secretary of the S&T Directorate, provides an interagency forum for discussing and prioritizing medical countermeasure needs to be pursued under BioShield. At still the next level of coordination, there are strong bilateral efforts around key elements of the strategy. Examples of this coordination including strong and frequent collaborations on Bioshield (HHS/DHS), the development of coordinated civilian and military surveillance and detection systems (DHS/DoD), the development and execution of a National Strategy for Agricultural Biosecurity (DHS/USDA), and development and assessment of decontamination technologies (DHS/EPA).

In addressing these activities, DHS has a leadership role in several key areas and partners with lead agencies in others. Those areas in which the S&T Directorate provides significant leadership are:

• Providing an overall end-to-end understanding of an integrated biodefense strategy, so as to guide the Secretary and the rest of the Department in its responsibility to coordinate the nation's efforts to deter, detect, and respond to biological acts of terrorism.

• Providing scientific support to the intelligence community and the IAIP Directorate in prioritizing the bio-threats.

• Developing early warning and detection systems to permit timely response to mitigate the consequence of a biological attack.

• Conducting technical forensics to analyze and interpret materials recovered from an attack to support attribution.

• Operation of the Plum Island Animal Disease Center to support both research and development (R&D) and operational response to foreign animal diseases such as foot and mouth disease.

DHS also supports our partnering departments and agencies with their leads in other key areas of an integrated biodefense: the Department of Health and Human Services (HHS) on medical countermeasures and mass casualty response; the U.S. Department of Agriculture (USDA) on agriculture biosecurity; USDA and HHS on food security and the Environmental Protection Agency (EPA) on decontamination and on water security.

In addition, the Science and Technology Directorate has engaged with other Federal Agencies in the following efforts:
• The S&T Directorate worked with DOS (STAS), USDA, OSTP, NSF to create and support the US-Japan Safe and Secure Society forum.

• The Directorate and DOS (OES) jointly created and negotiated the US-UK S&T Memorandum of Agreement (MOA). The resulting MOA supports collaboration on Homeland Security research, development, testing, and evaluation between the US and the UK.
• Currently leads a partnership with CDC, EPA, and FBI on the deployment of BioWatch, a bioaerosol detection system deployed to many of this nation's cities.
• Funds BioNet - DTRA executed pilot program to integrate civilian and military domestic biodetection and consequence management, using San Diego as a pilot city.
• Leading an interagency effort with HHS, DoD, and USPS to develop a National Integrated Biomonitoring System, part of HSPD-10 responsibility.
• Primary participant in the establishment of the National Interagency Biodefense Campus being developed at Ft. Detrick.
• The National Bioforensics Analysis Center (NBFAC) is a joint Science and Technology Directorate-FBI program
• In a joint effort with USDA, have developed an integrated national agrodefense strategy, with especial emphasis on foreign animal disease. The Directorate and USDA also conduct joint research and development programs at the Plum Island Animal Disease Center

Presidential Initiatives:

Three Presidential Initiatives address the needs of an integrated biodefense strategy and DHS plays a key role in each one. These three initiatives are:

BioShield: Signed into law July 21, 2004, BioShield is a program coordinated by the Secretary for Homeland Security and the Secretary for Health and Human Services that provides $5.6 billion over 10 years for the purchase and development of countermeasures to WMD. DHS's S&T Directorate plays a significant role in this in determining which agents constitute "material threats" and in developing scenarios that inform decisions on the quantity of countermeasures required. We have certified four "material threats" (anthrax, smallpox, botulinum toxin and radiological/nuclear and the rest of the Category A bioagents should be completed by FY 2006.

Biosurveillance Initiative: A program that seeks to enhance systems that monitor the nation's health (human, animal and plant) and its environment (air, food, water) and to integrate these with intelligence data to provide early detection of an attack and the situational understanding needed to guide an effective response. The S&T Directorate plays a major role in the Biosurveillance Initiative in operating its 1st Generation BioWatch System, in deploying a 2nd Generation system and significantly expanding the number of collectors in the highest threat cities and at key facilities (e.g. transportation systems), and in continuing to develop advanced detection systems to further increase the capabilities. We are also designing the information system that will be used to integrate health and environmental monitoring information from the sector specific agencies with intelligence data from the IAIP Directorate. Implementation of this system will actually

be initiated by the IAIP Directorate in FY 2005, but the S&T Directorate will continue to supply subject matter expertise in biological threat and defense.

Food and Agricultural Initiative: Seeks to enhance the security of our agricultural and food infrastructures. DHS activities in this area are led by the IAIP Directorate – but the S&T Directorate brings significant contributions in end-to-end studies of key agricultural and food threats, through the development of advanced diagnostics, and through R&D conducted jointly with USDA at the Plum Island Animal Disease Center.

CONCLUSION

The Science and Technology Directorate's programs conducted within the Department of Homeland Security fully support the national biodefense program as stated in the presidential directive Biodefense for the 21st Century, and other Homeland Security Presidential Directives. Moreover, they are conducted in an active collaboration with other Federal departments and agencies having a role in meeting this national priority, and are focused on reducing the threat of a biological attack against this nation's population and its agriculture and food critical agricultural infrastructures, and supports a science-based forensics and attribution capability.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Senator Kennedy, and Members of the Subcommittee, I thank you for the opportunity to appear before you and I will be happy to answer any questions that you may have.