

STATEMENT FOR THE RECORD

of

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Regarding a Hearing Entitled

“Six Years After the Anthrax Attack: Are We Better Prepared to Respond to Bioterrorism?”

Before the
U.S. Senate Committee on
Homeland Security and Government Affairs

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INTRODUCTION

Good morning, Chairman Lieberman, Ranking Member Collins, and distinguished members of the Committee. I am honored to appear before you on this solemn occasion of the 6th anniversary of the anthrax attacks against our Nation to report on the progress being made by the Department of Homeland Security's (DHS) Science and Technology (S&T) Directorate. Those events of six years ago served as a wake up call that an adversary could produce or obtain biological agents to use against this country and when juxtaposed with the terrorist attacks on the World Trade Center and the avowed interest of terrorists to create mass casualties greatly raised the concerns about the possibility of potential high consequence acts of bio-terrorism. Recognizing that "biological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies", the President issued Homeland Security Presidential Directive 10 (HSPD-10), *Biodefense for the 21st Century*. HSPD-10 lays out a strategic blueprint for a comprehensive national biodefense built on four pillars: threat awareness, prevention and protection, surveillance and detection, and response and recovery. The activities of the DHS S&T are conducted in support of that integrated interagency strategy and its companion HSPD-9, *Defense of United States Agriculture and Food*.

Reflecting its roles in the National biodefense strategy, DHS S&T's activities emphasize threat awareness, surveillance and detection, response and recovery, and agro-defense, particularly against foreign animal diseases. Our progress in each of these areas is briefly summarized below and detailed more fully in the *DHS Strategic Plan in Support of the National Biodefense Strategy*, which was formally submitted to Congress this summer. These activities are performed in close collaboration with our interagency partners at the Department of Defense (DoD), Department of Health and Human Services (HHS), United States Department of Agriculture (USDA), Department of Justice (DOJ), Environmental Protection Agency (EPA), and the Department of State, whom we gratefully acknowledge.

THREAT AWARENESS

As required under HSPD-10, HSPD-18 (*Medical Countermeasures against Weapons of Mass Destruction*), and the Project BioShield Act of 2004, DHS S&T has played the lead role in conducting assessments of the evolving biological threat "to guide prioritization of our on-going investments in biodefense-related research, development, planning and preparation" (HSPD-10). To date we have:

Established the National Biodefense Analysis and Countermeasures Center (NBACC). Prior to the events of 2001, the Nation lacked a dedicated capability for conducting both unclassified and classified biodefense research and development. The National Academy of Sciences report *Making the Nation Safer* recommended the creation of such a capability. To address this need, in 2003/4 DHS established at interim NBACC capability at Ft. Detrick and other contracted laboratories. It also began construction of a

dedicated NBACC facility on the National Interagency Biodefense Campus located on Ft. Detrick. The construction of the facility is well underway and on track for initial occupancy at the end of 2008 and initial operational capability in 2009.

Conducted the first, formal, quantitative, end-to-end risk assessments. HSPD-10 calls on DHS to provide “a continuous, formal process for conducting routine capabilities assessments to guide prioritization of our on-going investments in biodefense-related research, development, planning and preparedness.” Furthermore, these risk assessments are to integrate “the findings of the intelligence and law enforcement communities with input from the scientific, medical and public health communities” (HSPD-18) The first BioTerrorism Risk Assessment (BTRA) was delivered in FY 2006 as required by HSPD-10 and addressed 28 agents of concern to human health. The BTRA provided the basis for the Secretary of Homeland Security’s decision to issue nine additional Material Threat Determinations in support of Project BioShield and is being used by DHS and the EOP to prioritize other biodefense activities. A draft of the second BTRA has just been completed. The 2008 BTRA expands the list of agents from 28 agents to 40, including representative examples of potential future threats as well as key foreign animal agents and expands the consequence models to also consider economic impacts. This BTRA is on track for delivery to the Homeland Security Council (HSC) in January 2008. Due to the success of the 2006 BTRA, HSPD-18 calls on DHS to perform a similar integrated chemical, radiological, biological, and nuclear (iCBRN) risk assessment by June 1, 2008. This iCBRN risk assessment is also on track.

Issued 14 Material Threat Determinations (MTDs) in support of Project BioShield. The Project BioShield Act of 2004 charges the Secretary of DHS, in consultation with HHS, with determining which CBRN threats posed a significant enough risk to the national security to warrant the need for medical countermeasures. The S&T Directorate, in partnership with our interagency colleagues, have provided the supporting analysis. To date, MTDs have been issued for 14 agents: *Bacillus anthracis* (anthrax), Botulinum toxin, *Burkholderia mallei* (glanders), *Burkholderia pseudomallei* (melioidosis), Ebola virus, *Francisella tularensis* (tularemia), Junin virus, Marburg virus, multidrug resistant *Bacillus Anthracis*, nuclear agents, radiological agents, *Rickettsia prowazekii* (typhus), Variola virus (smallpox), and *Yersenia pestis* (plague). For each of these agents/threats we have provided HHS an associated Population Threat Analysis (PTA) which provides a plausible high consequence scenario along with estimates of the number of individuals exposed to 10, 100, 1000, 10,000 ... threat organisms. This is used by HHS to inform their requirements for medical countermeasures and the associated concepts of operations for delivering those medical countermeasures. It is anticipated that the on-going integrated CBRN Risk Assessment will result in the generation of additional MTDs.

Conducting Laboratory Experiments to address the key scientific gaps identified in the Risk Assessments. These gaps are uncertainties in scientific parameters that have a large impact on policy and operational decisions for protecting the nation against attack, e.g. the amount of an agent necessary to infect a given percentage of the exposed population or the time an agent will persist in the environment or in food supplies upon processing

and cooking. Current efforts seek to close the major gaps in our understanding of traditional agents by FY 2009 and to establish an approach to addressing future threats by FY 2010. Because of the very broad range of potential future threats, this approach is likely to be based on understanding and looking for the basic biological building blocks, often called pathways, that are needed for an organism to make a person sick – for example the pathways that allow it to infect a person, grow, and reproduce.

Undertaken Biodefense Net Assessments to take a broad look at the fundamental assumptions underlying the Nation's biodefense. These assessments are in fulfillment of the HSPD-10 requirement for “a periodic senior-level policy net assessment that evaluates progress in implementing this policy, identifies gaps or vulnerabilities in our biodefense policy posture, and makes recommendations for rebalancing and refining our investments among the pillars of our overall biodefense policy” (HSPD-10). The first *BNA* is due at the end of 2008 and is addressing eight to ten fundamental issues targeted to provide insight regarding the evolution of the Nation's biodefense strategy. Questions range from ‘can deterrence play a greater role in biodefense’ to ‘where will we be if we stay on the current biodefense trajectory for the next 5 years vs. where should we be’.

SURVEILLANCE AND DETECTION

Early detection and characterization of a biological attack is critical to permitting a timely response to mitigate the effects of that attack. HSPD-10 tasks DHS with the lead in coordinating such attack warning amongst our interagency partners. Major progress to date includes:

Deployment and operations of the BioWatch aerosol monitoring system and its subsequent transition to the DHS Office of Health Affairs (OHA). President Bush's State of the Union address on January 28, 2003 included the directive “(we) are deploying the Nation's first early warning network of sensors to detect biological attack.” Following that declaration, it took just 34 days to implement the original BioWatch system, now referred to as Gen 1 (for 1st generation). Gen 1 BioWatch is currently operational in more than 30 cities across the United States. To date, some four million tests for anthrax have been conducted nationally, without a single false positive. Beginning in 2005, we began a two-to-four fold expansion of the number of BioWatch collectors in the top ten threat cities to (a) enable detection of smaller attacks; (b) provide indoor monitoring of selected critical facilities such as transportation hubs; and (c) provide each city with 10-12 collectors to deploy on an as needed basis to special events of their choosing (e.g. conventions, major sports events or celebrations). This expansion, known as Gen 2, will be complete and fully operational by mid FY2008. Given the operational status of Gen 1 and 2 BioWatch these systems were transferred to the DHS Office of Health Affairs (OHA) in 2007.

Development of next generation (Gen 3) BioWatch technology. Current BioWatch operations are limited by the manual labor costs associated with picking up and transporting filter samples and then preparing them for analysis in offsite laboratories. These manual labor costs account for about 75 percent of the BioWatch operational cost

and hence limit the number of detectors that can be deployed and the frequency with which they can be picked up. Since 2004, we have been developing new technology that would allow the samples to be automatically collected and analyzed at the point of collection, with the results of the analysis wirelessly transmitted to the local public health laboratory. As a result, it will be possible to conduct multiple analyses per day (versus the current one per day) at per unit operational cost less than the Gen 1 and 2 systems. Two of the initial eight approaches pursued have successfully made it all the way through fieldable prototypes and are now to begin three months of rigorous independent testing at Edgewood Chemical and Biological Center.

Coordination of National Biomonitoring Activities. Currently, there are three major classes of on-going operational biomonitoring: environmental aerosols; suspicious materials; and mail. Within each of these classes, there are multiple Federal programs, each of which has been independently implemented. Because these programs were quickly deployed by multiple agencies to address their specific detection needs, improved inter-program and interagency coordination is needed to minimize confusion and increase confidence in results following detection of a biothreat agent.

To address this problem, we have led the development of an interagency Memorandum of Understanding (MOU) to coordinate all biomonitoring activities done by, or on behalf of, the signatory agencies. As an outgrowth of this MOU, we and our interagency partners have developed a National Biological Monitoring Architecture (NBMA) that identifies end state visions, transition strategies and multi-year milestones for accomplishing these goals in environmental, mailroom and suspicious material bio-monitoring. We are currently in the process of implementing this architecture including: (1) piloting a process to establish the equivalency of biodetection assays used by the signatories; (2) coordinating interim guidance and concepts of operations for Federal environmental, mailroom and suspicious material monitoring; and (3) establishing agreements to leverage technologies wherever applicable, such as the current and future BioWatch technologies.

Developing processes to make improved detection tools available to the first responder community. Currently, first responders are discouraged from directly testing suspicious materials, e.g. white powders, but instead are instructed to contact the Federal Bureau of Investigations (FBI) who will then take a sample and send it to a Center for Disease Control and Prevention (CDC) Laboratory Response Network (LRN) for testing. The reason for this is two-fold: (1) the performance of a number of commercial assays is not well characterized and historically have been prone to false alarms, and (2) such local testing can often use up much of the sample making it unavailable for subsequent FBI and CDC testing. In spite of these concerns, first responders have a strong desire to locally test suspicious materials and have often continued to do so. DHS S&T has taken three major steps to address these concerns:

Working with the Association of Official Analytical Chemists (AOAC International) we have developed and validated an independent process for testing certain classes of hand held assays for both laboratory and field use and have conducted the first round of these

tests. AOAC established a Task Force on *Bacillus anthracis* that included DHS, DOD, NIST, FDA, EPA, CDC, USDA, FBI and CIA as well as manufacturers of the assays and representatives from state and local emergency responder groups and the National Guard. In short order, this Task Force selected the spore types to be tested, selected US Army Dugway Proving Ground to provide the test materials and conduct the single lab validation of the assays, and chose 12 highly qualified federal and state labs to participate in a multilaboratory validation of the assays. The AOAC task force also established the acceptance criteria for the study and published the criteria in their Journal. Five assays were selected for testing; ultimately only one of the commercial assays met the criteria as judged by the Official Methods Committee of AOAC. This was, however, a successful study in that we achieved consensus on how such assay validations should be conducted, and the manufacturers now know where the bar is set for these assays.

Working with the international standards organization ASTM International, originally the American Society for Testing and Materials, we have developed a set of voluntary standards for local sampling of suspicious materials that preserves sufficient sample for subsequent LRN and FBI analyses. These standards recognize the importance of the official sample that is needed for public health and law enforcement, while still allowing the residual sample material to be used in a prescreening assay by the HAZMAT team. The National Institute of Standards and Technology (NIST) led the interagency team that included again CDC, FBI, DOD, DHS and EPA as well as the National Guard and representatives from state and local responders. Critical measurements to validate the standard were carried out at Dugway using civil defense teams and National Guard. This standard represented a big step forward in forging a consensus between local HAZMAT teams and the law enforcement and public health communities.

We are in the process of piloting a process to make ultra-high, ultra-specific assays, comparable to those used by Federal monitoring systems, available to commercial developers and through them to first responders. In the interim, DHS S&T and OHA are working with other federal agencies and at the state and local level to build on the consensus of the AOAC/ASTM standard to exercise their responses. The states of Georgia and Massachusetts provide two great examples. They are using these standards and the lessons learned from the standards development; they are developing exercises that engage all the players from the local HAZMAT team to the law enforcement and public health labs. At the end of the day, successful response to a biological event will hinge not just on technology, but on cooperation and mutual trust of the responders, incident managers, law enforcement officials, and public health laboratory personnel.

FORENSIC ANALYSIS TO SUPPORT ATTRIBUTION

Prior to the anthrax attacks of 2001, the United States did not have any dedicated facilities for analyzing the samples from biological crimes. The tens of thousands of samples that resulted from just this one relatively small event graphically emphasized the need for such a capability. To respond to this need, in 2003/4 DHS S&T, in partnership with the FBI, established the interim National Bioforensics Analysis Center (NBFAC) in

renovated leased space at the United States Army Medical Research Institute for Infectious Diseases (USAMRIID). This provided the Nation with its first secure, state-of-the-art, contamination free, bio-containment space for the analysis of evidentiary material. The interim NBFAC also includes validated protocols for the biological, chemical, and physical characterization of suspect samples; rigorous “chain of custody” and quality control procedures to ensure the integrity of the sample and its analysis; and remote laboratories to provide specialized capabilities. In 2004, HSPD-10 designated NBFAC “as the lead Federal facility to conduct and facilitate the technical analysis and interpretation of materials following a biological attack in support of the appropriate lead Federal agency”. The NBFAC has recently received initial accreditation by the American Association for Laboratory Accreditation (A2LA) to International Standards Organization (ISO) Standard 17025, similar accreditation to that used by FBI laboratories. Starting with a basic set of forensic protocols, its goal is to have a full set of validated and A2LA accredited assays – culture, genetic, and antibody – for the top 30 biothreat agents by FY 2009 and a comprehensive strain library against which to compare them.

RESPONSE AND RECOVERY

Biological agents have the potential to contaminate large portions of a city, covering multiple city blocks and the facilities therein. Based on our limited experience following the 2001 anthrax events, clean-up of even a few facilities can be extremely expensive and time-consuming. The objective of this program is to provide a more rapid and less expensive post-attack cleanup and restoration in such situations. This work is done in partnership with the EPA, who has overall lead in this area. The DHS emphasis is on developing a systems approach for the restoration of citywide areas and of critical facilities, such as major transportation hubs. Major progress to date includes:

Development of restoration protocols and tools for critical transportation hubs.

Working with the San Francisco International Airport as the initial testbed and in partnership with EPA, CDC, FBI, state and local authorities, we developed improved sampling tools and EPA reviewed protocols for the restoration of airports following a biological attack. The output of these efforts were shared with local users through a series of regional airport workshops and are currently being applied to the restoration of subway (metro) and other transit systems.

Partnering with the DoD to develop protocols for the restoration of wide urban areas following a biological attack.

In FY 2007, DHS S&T initiated the Interagency Biological Restoration Demonstration (IBRD) which focuses on cleaning up an entire neighborhood or district in a major U.S. city following an outdoor biological attack, using the city of Seattle WA and surrounding counties as the initial testbed. IBRD is co-sponsored by the S&T Directorate and the DoD Defense Threat Reduction Agency (DTRA) and involves multiple Federal (e.g. EPA, HHS), State and local stakeholders. Table-top exercises and field demonstrations will be conducted in FY 2008-2009 and will culminate in a set of protocols that are reviewed by the EPA and can be used by other

cities as a template in developing their own protocols for restoration following an outdoor attack.

Leading the interagency development of a validated sampling strategy. In response to the recommendations of the General Accounting Office in its 2005 report entitled *Anthrax Detection*, DHS is leading the interagency development of a coordinated, validated sampling strategy and methodology to determine the extent of contamination and remediation (after a contamination event) for public health determinations.

AGRO-DEFENSE

Recognizing the large potential impacts of agro-terrorism, especially the potential for the intentional introduction of foreign animal diseases into the United States, the Homeland Security Act of 2002 transferred the operations of the Plum Island Animal Disease Center (PIADC) to DHS. HSPD-9 further designates DHS responsibilities in partnership with USDA and others, including the accelerated development of veterinary countermeasures, planning for state-of-the-art biocontainment facilities to support Research Development Test and Evaluation on foreign animal and zoonotic diseases and the establishment of university centers of excellence on agriculture and food defense. Major progress to date includes:

Operation and upgrading of PIADC. Since its transfer under the Homeland Security Act of 2002, DHS has been operating PIADC in close partnership with USDA. DHS is currently in the midst of upgrades to the security, infrastructure, and research capabilities of the facility.

Joint development of veterinary countermeasures with USDA. DHS and USDA have developed and are implementing a joint strategy for the research and development conducted on, and in support of, PIADC (*Report to Congress: A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs*, August, 2004). This strategy emphasizes the development of vaccines, antivirals and high throughput diagnostics for preventing and mitigating outbreaks of foreign animal diseases. Each agency has distinct roles in this development strategy. The USDA's Agricultural Research Service (ARS) has the lead for the basic research portions of these activities, the DHS for the advanced development, and USDA Animal and Plant Health Inspection Service (APHIS) for transition into the field and into the National Veterinary Stockpile (NVS). Together, we have provided improved characterization of the current vaccines for Foot and Mouth Disease (FMD) and have successfully begun the development of next generation vaccines that allows for Differentiation of Infected from Vaccinated Animals (DIVA) – a key issue in resuming trade following an outbreak. The first DIVA vaccine is expected to transition to industry and into the NVS in 2009. In addition, we are now pursuing two candidate vaccines for Rift Valley Fever with the intent to bring one of them to licensure by FY2013.

Planning for the National Bio- and Agro-defense Facility (NBAF). PIADC is now more than 50 years old and is too small to meet the challenges of a greatly expanded

livestock industry with its global markets and with the new threat of agro-terrorism. Defending against FMD alone will require 10 to 14 vaccines to cover the major serotypes and sub-serotypes of FMD – yet the large animal holding space at PIADC will only support development of about one vaccine candidate per year. Further the Nation lacks the capacity for studying zoonotic diseases that affect both large animals and humans. Recognizing these needs, HSPD-9 has tasked the Secretaries of DHS and USDA to develop plans for state-of-the-art biocontainment space for foreign animal and zoonotic diseases and for the accelerated development of countermeasures to address them. To address these needs, DHS, in partnership with USDA, has begun the planning for, and the conceptual design of the National Bio and Agro-defense Facility (NBAF). Expressions of interest were solicited, proposals evaluated, and site visits conducted resulting in narrowing down the selection to five potential sites plus the current Plum Island site. These sites are currently being evaluated as part of the Environmental Impact Statement (EIS) process. Final selection is expected towards the end of 2008 with start of construction in 2010 and initial occupancy in 2013/14.

Established the National Center for Foreign Animal and Zoonotic Disease (FAZD).

As per the direction of HSPD-9, we have also established “university-based centers of excellence in agriculture and food security”. FAZD is a consortium of universities, led by Texas A&M University, focused on conducting some of the more basic R&D needed to address high consequence foreign animal and zoonotic diseases and to train the next generation of agro-defense researcher. FAZD is working closely with partners in academia, industry, and government to address potential threats to animal agriculture, including FMD, Rift Valley fever, avian influenza, and brucellosis.

Established the National Center for Food Protection and Defense (NCFPD). NCFPD is a consortium of universities, led by the University of Minnesota, charged with a mission to defend the safety of the food system through research and education, to establish best practices, develop new tools, and attract new researchers to manage and respond to food contamination events. The NCFPD addresses three major areas: real world modeling of food contamination events to guide response strategies; development of novel detection and decontamination systems to support that response; and establishment of innovative prevention, response and recovery strategies to minimize the consequences of any event.

CONCLUSION

In summary, DHS S&T has taken the ‘wake-up call’ of the 2001 anthrax events very seriously. As part of an integrated National biodefense strategy, we have made significant progress in characterizing and prioritizing the threats this Nation faces; in developing, fielding and operating detection systems to provide the earliest possible detection of an attack and initiation of mitigating measures; in developing frameworks and protocols for recovering from biological attacks; in providing the Nation with the needed bio-forensic capabilities to support attribution; and in partnering with the USDA to defend against foreign animal diseases. Much has been accomplished. However,

because of the evolving nature of the threat, much also remains to be done. We look forward to continuing to support the Nation in responding to this challenge.