Joint Statement of

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Regarding

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Introduction

Mr. Chairman, Ranking Member McCaul, and Members of the Subcommittee, thank you for the opportunity to testify today on the Department of Homeland Security's (DHS) biosurveillance efforts. I serve as the Deputy Assistant Secretary for WMD and Biodefense, a division within the Department of Homeland Security's Office of Health Affairs (OHA). I appreciate your interest in our biosurveillance programs, and trust that my testimony today will provide valuable insight into the Department's biosurveillance initiatives to safeguard the Nation against a biological attack or other biological incidents that threaten the security of the Homeland.

The Nation continues to face the risk of a major biological event that could cause catastrophic loss of human life, severe economic damages, and significant harm to our Nation's critical infrastructures and key resources. As you so vividly remember the nation already experienced a form of bioterrorism in late 2001 with the deadly anthrax mailings that cost the lives of 5 individuals, injured 17, and caused severe disruptions to many of our government activities, including operations of the U.S. Postal Service and numerous other functions.

The challenges we face in assessing current terrorist capabilities and identifying plots make it unlikely that we will receive actionable, specific warning of an impending bioterrorist attack. Furthermore, many of these deadly biological agents are accessible in nature, relatively easy to procure, develop and transport without an advanced background in the biological sciences. Unlike nuclear weapons, few people with advanced laboratory knowledge in the biological sciences are needed to weaponize many of these deadly pathogens. As such, it is incredibly difficult to predict and prevent a biological attack from taking place. The threat of bioterrorism has not subsided, and the impact of a large-scale bioterrorism event, such as the wide-spread dissemination of an aerosolized form of anthrax or other deadly biological pathogen, would have a serious effect on the health and security of the Nation.

A bioterrorist plot may not have detectable signals, thus, there may be little or no warning of an impending biological attack, presenting significant challenges to the identification, detection, and disruption of such plots. Our first indication of a bioterrorist attack will likely be through early detection and warning systems, such as BioWatch and the National Biosurveillance Integration Center (NBIC). Their detection capabilities will drive the subsequent response and significantly influence the number of individuals affected by an attack.

In the event that a threat does reach, or occur in, the Homeland, a comprehensive biosurveillance capability can minimize the impact and duration of the event via early detection and characterization, broad situational awareness and by facilitating early intervention and mitigation.

Biosurveillance

An integrated biosurveillance program is vital to help protect the homeland from bioterrorism: unintentional introductions (e.g. Foot-and-Mouth Disease); and naturally occurring biological events, such as pandemic influenza. *Biosurveillance* refers to monitoring for potential signs of biological events with the intent of early detection of that event to permit the timely response to

mitigate consequences. Should an event occur, biosurveillance and detection allows the monitoring of an outbreak as it happens and provides accurate situational awareness to first responders. Biosurveillance is one of the critical components of our Nation's biodefense strategy, as outlined in Homeland Security Presidential Directive (HSPD) – 10: *Biodefense for the 21st Century*.

Biosurveillance includes many different components that work in complementary fashion to achieve a comprehensive awareness. This takes the form of both traditional and novel methods of early event detection including environmental detection systems, clinical syndromic surveillance, reportable disease and laboratory-based surveillance, monitoring of agricultural and wildlife activity, testing of the food supply, and monitoring mail and open-source analysis to name a few. Each is a necessary and valuable component of a comprehensive biosurveillance strategy. I would like to discuss two biosurveillance programs that the Department is leading as part of the Federal government's larger biosurveillance strategy: NBIC and the Biowatch Early Detection System.

National Biosurveillance Integration Center (NBIC)

Recognizing the need to create a new biological threat surveillance capability across multiple sectors and domains to provide early awareness and warning of emerging biological events, Secretary Chertoff, in collaboration with the other appropriate Federal Departments and agencies, established the National Biosurveillance Integration System (NBIS), which serves as the platform for information exchange between senior leaders and partners agencies and facilitates the early recognition of biological events, including natural disease outbreaks, accidental or intentional use of biological agents, and emergent biohazards.

Currently, twelve Federal Member Agencies comprise the NBIS community. Eventually, this community will evolve to include State, local and tribal entities, and potentially the private sector and, international stakeholders. The NBIS community provides situational awareness through the acquisition, integration, analysis and dissemination of information from existing human disease, food, agriculture, water, meteorological, and environmental surveillance systems and relevant threat and intelligence information.

In 2007, Congress passed and President Bush signed P.L. 110-53, The Implementing of the 9/11 Commission Recommendations Act of 2007 which formally authorized the establishment of the National Biosurveillance Integration Center (NBIC), which serves as the hub of operations and personnel to which the NBIS community contributes information. The NBIC is located in the DHS Nebraska Avenue Center and is charged with the primary mission to rapidly identify, characterize, localize, and track a biological event of national concern; integrate and analyze data relating to human health, animal, plant, food, water; and disseminate alerts and pertinent information. NBIC seeks to provide information to allow early recognition of biological events of national concern, both natural and man-made, in order to make a timely response possible. No other entity in government serves to integrate this biological threat information from across the spectrum of public and private, domestic and international, open or protected sources.

As an operating center, the vital component parts of NBIC are:

- A corps of highly-trained subject matter experts (SMEs) and analysts, including a 24 hour/7 day OHA Watch Desk within the DHS National Operations Center;
- Tailored customer products resulting from integrative analysis of biosurveillance information;
- A culture of cooperation, trust and mutual support across the Federal government and other partners; and
- A robust information management system capable of handling large quantities of structured and unstructured information.

Developing an Interagency Information Sharing Capability

Developing interagency cross-domain biosurveillance capability is a difficult and complicated task that has not been previously attempted. Coordination with our Federal partners to obtain data, personnel, and information sharing agreements requires new processes and procedures. Additionally, building a new IT system to coordinate the information sharing, as well as creating new analytical tools to assist analysts in identifying trends, patterns, and anomalies quickly and accurately as is necessary for forward looking and cueing capability has taken time. However, we are still scheduled to meet our full operational capability (FOC) goals by September 30, 2008.

NBIC has formalized its relationship with a number of Federal partners, and continues to make progress on obtaining formal agreements with the remaining relevant Federal Agencies in order to promote a robust interagency biosurveillance capability. MOUs are in place with Departments of Defense, State, Agriculture, Interior, Health and Human Services, and Transportation. We are also working closely with the Department of Veterans Affairs, FBI, Environmental Protection Agency, U.S. Postal Service, and the Department of Commerce and other components within DHS. While final details of some of these agreements are being resolved, these Departments and agencies are currently contributing to the NBIC mission and providing valuable information on current bio-events.

NBIC has established the NBIS Interagency Working Group (NIWG) which meets monthly to provide an open forum among NBIS members to discuss interagency collaboration, develop detailed operational procedures and offer recommendations to enhance the capability of NBIS. The NIWG representatives possess a detailed knowledge of their respective organization's biosurveillance-relevant capabilities, programs and activities that can contribute to the integrated effort. This collaboration has produced the first version of the NBIS Concept of Operations which lays out the details of how the mission of NBIS is being implemented and executed. This document is significant in that it describes the steps NBIS will take to accomplish the unprecedented task of Biosurveillance cross-domain integration and analysis.

Further, NBIC has developed a governance structure to provide senior-level oversight of operations to ensure that interagency goals and objectives are met. The National Biosurveillance Integration System Interagency Oversight Council is made up of representatives at the Assistant Secretary level from each NBIS member agency and acts as the senior oversight body to provide guidance and direction for the efficient operation and evolution of NBIS.

NBIC Information Integration and Analysis
To accomplish the biosurveillance mission, the NBIC monitors over 530 information feeds. Monitoring of these information feeds is facilitated by the NBIS 2.0 IT system. These sources include interagency communications and165 open source sites. These open source sites include 20 organizational sites, 14 federal government sites, 85 State, local, or territorial government health and agriculture sites, 35 foreign government sites, and 2 commercial sites.

Using its information feeds, NBIS develops and shares a Biosurveillance Common Operating Picture (BCOP) with the NBIS community. The BCOP is a comprehensive electronic picture with assessments of current biological events, trends and their potential impacts on the Nation's homeland security. The BCOP provides a secure platform for cross domain information analysis by NBIS subject matter experts to learn more about and collectively evaluate current situations. An impact assessment of an event constitutes a major portion of the NBIS BCOP information dissemination.

As an example of the NBIC capability, several NBIS member agencies continue to work closely together to provide comprehensive situational awareness to Federal agencies on the current *Salmonella* stereotype Saintpaul event. NBIC remains thoroughly engaged in the tracking of this event, and regularly posts Situational Reports (SITREPs) on the BCOP. Thus far, NBIS has released 11 national SITREPs on this event.

NBIC Full Operating Capability
NBIC has developed a set of goals to address the highest priority requirements to achieve FOC by September 30, 2008, which assumes the current reprogramming request before Congress. We continue to progress toward the following to achieve full operational capability:

- Install interagency staff and enhanced space resources for NBIC;
- Enhance IT Infrastructure for biosurveillance;
- Expand the NBIS Interagency Community;
- Further develop NBIC Intra-Agency Collaboration;
- Continue NBIC Collaborative Analysis and Production;
- Refine the NBIC Five Year Strategic Plan with modified objectives; and
- Refine the NBIC Contingency Operations Plans with updated strategies.

BioWatch
I would also like to discuss the Department's BioWatch Program, which was established in January 2003, and is currently managed by OHA. The BioWatch mission is to deploy and maintain a national 24/7 early warning system capable of detecting the intentional release of select aerosolized biological agents in order to speed response and recovery efforts. The purpose of this early detection and warning capability is to mitigate the consequences of a catastrophic attack, which could affect tens of thousands of people if, for example, aerosolized anthrax were released.

The goals of the BioWatch Program include:

- Early detection and characterization of biological attacks against the Nation's cities, high value assets, and mass gatherings to allow for the rapid distribution of life-saving countermeasures;
- Cost-effectively improving bio-aerosol threat monitoring capability and increasing its capacity to cover a greater portion of the general population;
- Providing operational and consequence management guidance and assistance to Federal, State, local, and tribal entities; and
- Integrating BioWatch capabilities into a national bio-threat monitoring and response system.

BioWatch is part of a national biodefense strategy that includes intelligence, law enforcement, bio-monitoring, situational awareness, decision support, response, and recovery activities. Within this strategy, BioWatch is an essential component of bio-monitoring, along with astute clinicians, syndromic surveillance, food and agriculture monitoring, veterinary surveillance, and mailroom monitoring. BioWatch technical and operational capabilities are integrated with military capabilities at installations to the benefit of both the Department of Defense and DHS.

Bio-monitoring of infectious agents will enable earlier treatment of affected populations than would otherwise be possible, and contribute to the prevention of secondary transmission, thereby reducing morbidity, mortality, and the associated health care costs from a biological terrorist attack. Each component of bio-monitoring relies on different technologies and techniques that are optimized for their intended purpose. It is through situational awareness and decision support that bio-monitoring is linked with the public health and medical response communities that must respond in the event of a biological terrorist event.

Current BioWatch Capability

The current generation BioWatch system, which is operating in over 30 of the Nation’s largest metropolitan areas, is composed of aerosol collectors, secondary sampling kits, laboratories, guidance documents, concepts of operation, communications protocols, an internet-based information portal, subject matter experts, and a small number of early-generation indoor detectors. System operation requires the integration and coordination of Federal, State, and local authorities whom all play an active role in the program. The system is tested routinely at each of the local jurisdictions where it is deployed.

The BioWatch program has established and strengthened existing local infrastructure. Laboratory procedures and field operations have been standardized and are reviewed periodically for quality assurance by the BioWatch program. Detailed environmental sampling plans have been developed that could be used to gather information about the viability and distribution of a bio-agent detected by the system.

BioWatch laboratories that analyze filters taken each day from the aerosol collectors are part of the Laboratory Response Network (LRN). Laboratory personnel follow strict protocols using laboratory assays that were developed jointly by the CDC and Lawrence Livermore National Laboratory to analyze the filters for the presence of biological threat agents. The BioWatch

laboratories have been in continuous operation since 2003, having analyzed more than 7 million samples without a single laboratory false positive result.

If BioWatch detects the presence of a bio-agent of concern, it issues a signal known as a BioWatch Actionable Result (or BAR). Since the Program's inception, dozens of BARs have been reported by multiple BioWatch State and local jurisdictions. These valid laboratory findings have been attributed in all cases to naturally occurring environmental sources.

BioWatch operational readiness is essential for the system to be effective. Readiness involves planning, preparedness, detection, and initial response. Representatives from these agencies, along with State and local public health and response personnel, have created guidance documents for local jurisdictions to use in developing operational plans for BioWatch.

These guidance documents cover preparedness, response, environmental sampling, and indoor operations. They are reviewed and updated periodically by the Federal BioWatch Working Group to take advantage of lessons learned through training, exercises, and real-world execution of operational plans in response to positive laboratory results from environmental sources.

The operational response plans for each jurisdiction are triggered by a BAR and implemented by a local BioWatch Advisory Committee (or BAC). A BAR triggers a formal notification process whereby the local public health official notifies local, State and Federal partners. The public health official convenes the BAC via conference call to begin situational assessment; Federal and State partners join BAC members in a national teleconference within two hours of notification. The initial call may be followed by others as more pertinent information becomes known. Investigation and discussions continue until consensus is reached about the significance of the BAR, which is used to inform protective action decisions on the part of the local public health official.

Each environmental BAR has provided local, State, and Federal government personnel an opportunity to exercise its preparedness plans and coordination activities that are fundamental to an effective response to a bioterrorism event or some other incident of public health significance. These real world events have been a catalyst for collaboration among local, regional, State, and Federal authorities, resulting in greater integration of public health, medical, veterinary, laboratory, emergency response, and critical infrastructure personnel responsible for consequence management across the full spectrum of public health threats facing our Nation.

BioWatch technical and operational capabilities are also integrated with related military capabilities at installations around the country to the benefit of both DHS and the Department of Defense. It is through situational awareness and decision support that bio-monitoring is linked with the public health and medical response communities that must respond in the event of a biological terrorist event.

Developing Future BioWatch Capability

The BioWatch system continues to evolve with new technologies, new partnerships with other bio-monitoring activities in the government and private sector, and a refined national bio-monitoring architecture. We are striving to further the BioWatch system technologies and

improve procedures to reduce the time-to-detect between biological agent release, detection and follow-on response. We are also working to increase the number of biological agents that are detected and to increase the population coverage in existing BioWatch jurisdictions, including in the highest risk indoor facilities.

We are striving to improve the detection capabilities of the system, while ensuring that appropriate testing and evaluation control processes are in place. We are working with DHS's Testing and Evaluation team on future technology developments to ensure the appropriate level of independent oversight to make informed decisions regarding deploying improved technologies and reducing risk of technological shortcomings.

One of our high-priority initiatives is to replace collectors - the filters of which require formal laboratory analysis - with automated detectors, wherein the analysis is performed within the unit itself. The primary objective of the Generation 3 system is the development of automated detectors that will significantly reduce the time to detect a biological agent from the current 10 to 34 hours down to between 4 and 6 hours which will potentially save thousands of lives for each day an attack, such as anthrax, is detected ahead of human syndromic surveillance and other public health indicators.

The BioWatch operational requirements (e.g., logistics, readiness and interoperability) stem from OHA's experience operating the system. Detailed requirements are captured in the Generation 3 Operational Requirements Document. That document is our guide for ensuring that the best automated detection system will be selected and fielded. The responsibilities for technical improvements and supporting R&D are jointly shared by DHS's Science and Technology (S&T) Directorate and OHA. Technologies under consideration must meet operational requirements for performance, operability, and reliability. As with any upgrade to a complex system, it is not as simple as plugging in a new component and assuming that the technology will work well and integrate properly with all other material and non-material elements of the system. To ensure new technology deployments are successful, candidate detectors need to be thoroughly tested under real-world operational conditions.

The operational test and evaluation of automated detectors under consideration for inclusion in the BioWatch Generation 3 system are scheduled to begin in April 2009. The tests will be conducted in two BioWatch jurisdictions over a period of 3 to 6 months. A procurement decision will then be made; the initial deployment of the BioWatch Generation 3 system is planned for fall 2010. The Generation 3 system will be operated along side Generation 2 systems for a period of 60 to 90 days to facilitate the transition to the enhanced system.

BioWatch deployment strategies are derived from risk-based analyses that account for threat, vulnerability, and consequences. Our plan is to continue increasing the population coverage in existing BioWatch jurisdictions, as well as expand coverage to new locations or facilities when the risk is determined to be high enough to warrant 24/7 environmental monitoring.

Given the current system's lag time between an attack and detection, DHS believes it is necessary to procure and deploy an interim automated system which we call Generation 2.5 designed to reduce notification times to as little as four to six hours. This interim system will be

deployed in high-consequence indoor environments to provide coverage of the highest risk facilities before the Generation 3 system will be ready for deployment.

The BioWatch program will continue to reduce the risks associated with bioterrorism and continues to develop future technology options and best deployment options. This will provide increased safety to the American public through early detection of biological pathogens that threaten our public health.

Conclusion

Biological threats to the Homeland continue to be of concern. We are facing persistent and evolving terrorist threats with potentially catastrophic consequences. A catastrophic biological event, such as a WMD terrorist attack, or a naturally occurring pandemic or emerging disease outbreak, could cause hundreds of thousands of casualties, damage our economy and the public's confidence, and threaten the security of our homeland. As I stated earlier, the challenge of detecting an invisible footprint of an impending bioterrorist plot and preventing an attack or the emergence of a pandemic is daunting. That is why DHS is taking the approach of enhancing early detection systems and building a national biosurveillance capability for situational awareness – to prevent a biological event from becoming a Nation-changing catastrophic event.

Our goal is to generate timely and comprehensive information about a biological event and put it into the hands of decision makers responsible for the continuity of society and government. I have observed in today's vernacular that "time zero" when a response can be initiated is often referred to as the time an event is *known* to have occurred, not when the event actually occurred. The time lag between the true "time zero" when an event occurs and when it is recognized is critical in determining how successful a response will be in mitigating loss of life and suffering. DHS is committed to improving the Nation's biodetection and biosurveillance capabilities so that we can achieve a "time zero" as close to the true time of the actual event as possible.

I appreciate the opportunity to share the vision, status and direction of the NBIC and BioWatch biosurveillance programs with you and look forward to your comments and guidance on how to better shape the programs to protect the American public against intentional and natural biological events. Thank for the opportunity to testify. I would be happy to provide answers to any questions that you may have.