Written Statement of Alexander G. Garza, MD, MPH
Assistant Secretary for Health Affairs and Chief Medical Officer
U.S. Department of Homeland Security
Before the Senate Homeland Security and Governmental Affairs Committee
October 18, 2011

Chairman Lieberman, Ranking Member Collins, and distinguished members of the Committee: thank you for inviting me to testify before you today. Secretary Napolitano highlighted a number of Department of Homeland Security (DHS) activities related to efforts to prepare for and protect against biological attacks in the 2011 Progress Report reviewing DHS and partner efforts to build a country that is stronger, safer and more resilient. I welcome this opportunity to discuss how the Office of Health Affairs (OHA) contributes to this effort.

I would like to begin by providing an overview of OHA and our role within the Homeland Security Enterprise. OHA serves as DHS's principal authority for all medical and health issues. We look at health through the prism of national security, providing medical, public health, and scientific expertise in support of the DHS mission to prepare for, respond to, and recover from all threats. OHA's responsibilities include serving as the principal advisor to the Secretary and FEMA Administrator on medical and public health issues; coordinating DHS biological defense programs; providing medical expertise to support DHS preparedness and response efforts; and leading the Department's workforce health protection and medical support activities. OHA also serves as the primary DHS point of contact for state and local governments on medical and public health issues.

The threat of a biological attack is real and challenging. As you know, the Weapons of Mass Destruction (WMD) Commission reported that we must be vigilant in addressing several urgent threats, especially bioterrorism. Additionally, the Quadrennial Homeland Security Review (QHSR) identified high-consequence biological attacks as a priority threat.

A wide-area attack using aerosolized *Bacillus anthracis*, the bacteria that causes anthrax, is one of the most serious mass casualty threats facing the U.S. A successful anthrax attack could potentially expose hundreds of thousands of people, and cause illness, death, fear, societal disruption and economic damage. Even a small scale attack, such as the Amerithrax attacks of a decade ago, will result in deaths, panic, and economic losses, making this a weapon of mass disruption as well as destruction. The time between exposure and the administration of medical countermeasures (MCM) is the most critical parameter in determining the extent of how many lives are lost in a biological attack.

Since the anthrax attacks 10 years ago, the Department has made progress in protecting the nation from biological attacks, and preparing the nation to respond to such events. OHA lends our expertise to a number of initiatives across the Department that focus on the threat of a biological attack.

The federal government recognizes two critical capabilities must be in place to minimize the effects of a biological attack. First, we must be able to rapidly determine that an attack has occurred. Second, we must have the capability to quickly distribute MCM to the affected population before clinical symptoms appear. This timeline can be as short as one to two days. OHA manages a number of programs and activities designed to improve the government's capabilities in both of these areas.

*Detection*

One of OHA's primary responsibilities is to mitigate the consequences of biological incidents through early detection. Traditional epidemiological surveillance is too delayed to mitigate large scale attack consequences. Therefore early detection is a key tool to make the Nation more resilient against catastrophic health events. Prompt identification of a biological attack has the potential to increase the speed of delivery of medical countermeasures and save lives.

OHA's BioWatch program is a federally-managed, locally-operated, nationwide bio-monitoring system designed to detect the intentional release of aerosolized biological agents. This program deploys collection devices and analytical capability in more than thirty high-risk metropolitan areas throughout the nation. The intent of the BioWatch program is to provide public health experts with a warning of the presence of a biological agent before those who are exposed develop symptoms of illness. This "detect-to-treat" approach gives public health officials an opportunity to respond as quickly as possible in order to mitigate the potentially catastrophic impacts on the population. BioWatch uses risk information provided by the Bioterrorism Risk Assessment (BTRA) developed by the DHS Science and Technology Directorate to inform which agents to detect.

In addition to, and equally import as, providing critical early detection capabilities, the BioWatch program has built a collaborative capacity among the federal government, state and local public health, and emergency management communities that did not previously exist. This partnership is a model of interaction where a rapid, unified response is required.

To become more effective and efficient in detection of threat agents, in 2010 the Department began testing the next generation of automated early-detection systems, known as Generation-3 (Gen-3). Current detection capabilities, termed Gen-1/2, consist of outdoor aerosol collectors whose filters are manually retrieved for transport to and subsequent analysis in a Laboratory Response Network (LRN) facility. This system, while extremely beneficial, is labor intensive with results potentially not available until 12-36 hours after the release of a biological agent. The transition to an automated detection system (Gen-3) is designed to improve the time to detect to 4-6 hours, increase population coverage, and provide greater overall cost effectiveness. Shortening the time to detect is critical because it allows responders more time to distribute countermeasures to the affected population. Therefore this investment in Gen-3 has the potential to greatly enhance our capability to mitigate the effects of a biological attack. Gen-3 field testing

was recently concluded in Chicago, and operational testing and evaluation is scheduled to begin in one city this fiscal year, and three additional cities in FY13.

*Biosurveillance*

Another key element to our approach to addressing biological threats is comprehensive situational awareness of potentially harmful biological events. OHA is focused on developing and maintaining an integrated, near real-time, multidisciplinary common biosurveillance picture that provides the Federal government and state/local partners with an accurate assessment of potential and unfolding biological events which can be used to better inform mitigation and response decisions.

To that end, OHA manages the National Biosurveillance Integration System (NBIS)—a consortium of federal partners that was established to rapidly identify and monitor biological events of national concern. NBIS collaborates among Federal and state partners to collect, analyze, and share human, animal, plant, food, and environmental biosurveillance information as well as threat information to provide early warning and situational awareness of a possible biological attack or pandemic. By identifying those bio-events that have reached reporting thresholds and publishing reports using the Biosurveillance Common Operating Picture (BCOP), the National Biosurveillance Integration Center (NBIC) and NBIS enhance recognition of biological events of national concern, reduce response time, support better decision-making, and promote effective response.

While the NBIC and NBIS have been successful in helping us to achieve our biosurveillance mission, there is still much more work to do to achieve a true national capability. OHA is currently partnering with our stakeholders to enhance and improve the NBIC while successfully meeting the statutory requirements and Congressional intent. We will continue to work to increase collaboration and data integration, improve analysis, and ensure high-quality, timely reporting.

*Response and Recovery*

OHA works directly with the Department of Health and Human Services (HHS) and state and local public health, emergency management and emergency medical services leaders to develop capabilities to respond to health security threats, including those posed by biological threats. We have done this by expanding local public health participation in, and coordination with, the national network of fusion centers. Specifically, OHA helped develop a resource document for state and major urban area fusion centers that identifies the recommended actions for fusion centers to integrate the public health and medical communities into the fusion process. Furthermore, we develop guidance for health and medical experts to better access federal grant and training programs to improve public health preparedness capability.

OHA provides health and medical expertise to planning and exercise efforts that advance national preparedness and response capabilities for threats that have potential health

consequences. The Anthrax Response Exercise Series (ARES), which we completed in partnership with FEMA last fall, is an example of this work. The workshops included federal, state, regional and local public health and emergency management professionals and were designed to help coordinate roles, responsibilities and critical response actions following a wide-area anthrax attack. This year we plan to continue to build on the success of ARES by conducting workshops in additional high-threat cities.

In addition to ARES and other exercise activities that allow state and local governments to strengthen their national response capabilities, OHA also sees its role as providing our state and local partners with guidance for protection of personnel. Through the federal interagency process, OHA continues to lead the effort to develop consensus guidance regarding appropriate protective measures for responders in the immediate post-attack environment of a wide-area aerosolized anthrax attack. This guidance will reflect the most current understanding of the unique environment that would exist after a wide-area anthrax release. DHS and its Federal partners are committed to continually updating the guidance to ensure that it reflects the most recent policy and technical developments.

In April 2010, DHS established the Anthrax Preparedness and Response Steering Committee to coordinate and focus Department preparedness and response efforts to an anthrax attack. The Steering Committee leads the Department's efforts in enhancing readiness and immediate response in the event of a wide-area aerosolized anthrax attack and includes senior leaders from across the Department. A number of products have been developed under the leadership of the Steering Committee, including response playbooks and checklists, guidance for newly-elected officials, and exercise protocols to broaden attention to biological defense.

Furthermore, OHA works to provide Department leaders with appropriate subject matter expertise in public health, medicine, food defense, agricultural security, veterinary defense, pandemic influenza preparedness, and other threats. Our Food, Agriculture, and Veterinary Defense (FAVD) Branch initiative leads the coordination of the Department's programs to ensure the security of our nation's food, agriculture, human and animal health. FAVD experts support the Department's efforts to enhance preparedness through capabilities development and facilitate the integration of the emergency management services community into federal, state, local, territorial, and tribal food and agriculture sector disaster preparedness activities.

*Medical Countermeasures*

As discussed earlier, our biodefense activities are aimed at mitigating the effects of a biological attack through early detection and ongoing surveillance. Early detection allows communities to provide MCM to affected persons in a timely manner to protect lives. OHA coordinates routinely with our Federal partners, especially HHS, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA) on medical countermeasures issues and represents DHS as a member of the HHS-led Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

On December 30, 2009, President Obama signed Executive Order (E.O.) 13527, "Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack." The E.O. sought to mitigate illness and prevent death, sustain critical infrastructure, and complement state, local, territorial, and tribal government MCM distribution capacity. OHA participated in a number of interagency and interdepartmental efforts aimed at addressing the requirements of the E.O.

Section 2 of the E.O. directs the development of a National United States Postal Service (USPS) MCM dispensing model for U.S. cities to respond to a large-scale biological attack. In collaboration with the Departments of Justice (DOJ), Defense, HHS, and USPS, DHS supported the development of the USPS model, which was submitted to the National Security Staff on June 30, 2010. Upon request, DHS will work with DOJ who leads the coordination of Emergency Support Function (ESF)-13 to provide required law enforcement support for the U.S. Postal model in those jurisdictions considering this modality of distributing MCM.

Section 3 of the E.O. directs the development of a federal rapid response capacity to supplement state and local governments and the private sector's capabilities to deploy MCM. This effort was co-led by FEMA and HHS, with OHA being a critical partner in providing subject matter expertise during the development of this Federal Interagency Concept of Operations Plan—Medical Countermeasures Dispensing (FICOP – MCM). This concept plan was submitted to the NSS in September 2011. This work culminated in a table top exercise in Los Angeles, California, led by FEMA's National Exercise Division on September 8, 2011. This focused discussion brought together federal, state, and local officials to enhance biological preparedness by codifying common expectations regarding the federal concept to support initial state and local MCM dispensing. The exercise was well received and information gained helped to finalize the FICOP-MCM. FEMA is now developing a regional operations plan to support the greater Los Angeles area, and we expect that federal operational planning will expand to other metropolitan areas as well.

Section 4 of the E.O. directed federal agencies to establish mechanisms for the provision of MCM to personnel to ensure that the mission essential functions of the executive branch departments and agencies continue following a biological attack. In addition, the Department and HHS have the responsibility to develop a plan to provide MCM directly to mission-essential personnel to ensure continuity of operations. OHA leads this effort for DHS and the Department is among the first federal agencies to have met this requirement of the E.O.

<u>DHS Workforce Health Protection</u>

OHA works each day to build resilience across the country and also within the Department. We do so by leading and strengthening our nation's collective efforts to secure our country from the threats we face. We also build resilience by ensuring the protection of our workforce.

As discussed earlier, in Section 4 of the E.O., the President ordered the federal government to establish mechanisms for the provision of MCM to personnel performing mission-essential functions. Secretary Napolitano further directed the Department to develop a plan to provide emergency antibiotics to all DHS employees in an attack area, not just those who are mission-essential.

The DHS workforce includes a wide variety of mission-essential personnel who work in varying geographical locations throughout the U.S. and internationally. Due to the nature of DHS workforce's security mission, some DHS personnel could be exposed during response activities or while performing their duties each day at airports and ports of entry.

Survival is increased if individuals exposed to biological agents take antibiotics quickly. This underlies the importance of the Department's plans to pre-position MCM in caches across the country for employees. Existing community plans will also provide support to DHS employees and their families.

OHA spearheaded the MCM strategy for DHS employees and oversees the purchase and storage of MCM for the DHS workforce. The MCM strategy and implementation plan is a multi-year, multi-layered approach, each building upon the previous to achieve its goal of covering the entire DHS workforce. The focus of our MCM effort for the DHS workforce thus far has been stockpiling anthrax antibiotics, and will expand in the future to protecting against other biological threats. This scalable approach will ensure the sustainability of the program.

Since the program's inception, we have purchased courses of anthrax MCM and stored them at a central location as well as regional locations. OHA, in coordination with DHS components, identified accessible and secure facilities for storage of the anthrax MCM. Additional cache locations will be identified over time to improve coverage and proximity to employees. OHA also built points of dispensing capability to dispense MCM as needed by providing training to appropriate personnel.

We also provide medical guidance and logistical and operational support to DHS component offices as they finalize their MCM plans. OHA has also provided medical guidance in the form of Standard Operating Procedures, including for storage of MCM, administration of MCM for anthrax spore exposure, non-medical points of dispensing for MCM, and working and service animal anthrax spore exposure. OHA now has mechanisms in place to verify the medical credentials of DHS personnel who will provide the medical oversight of MCM storage and dispensing.

## Conclusion

I would like to conclude by thanking this committee for your continued support of OHA's mission and for your guidance. Thank you again for the opportunity to testify today. I look forward to your questions.