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Before the House Homeland Security Committee
Subcommittee on Emergency Preparedness, Response, and Communications

May 12, 2011

Good afternoon, Chairman Bilirakis, Ranking Member Richardson and distinguished Members of the Subcommittee. Thank you for inviting me to testify before you today. It is an honor to be here to discuss the Office of Health Affairs' (OHA) programs that support the Department of Homeland Security's efforts in medical countermeasures (MCM) distribution and dispensing.

Today I will discuss a number of OHA initiatives that help to mitigate biological threats and help prepare the nation to quickly detect and respond to a biological attack. I will also speak about how DHS assists and coordinates with state and local governments, our activities relating to Executive Order (E.O.) 13527, and how we work every day to ensure a resilient nation and DHS workforce.

OHA Initiatives that Help Mitigate Biological Threats and Help Prepare the Nation to Quickly Detect and Respond to Biological Events

OHA supports and coordinates routinely with our federal partners, especially the Department of Health and Human Services (HHS), including 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. OHA and the DHS Science and Technology Directorate (S&T) represent DHS as ex officio members of the HHS-led interagency Public Health Emergency Medical Countermeasures Enterprise Senior Council, which is the primary conduit for communication among entities involved in the MCM mission.

OHA also works closely with S&T, which has the DHS lead to assess current and emerging threats that occur naturally or are chemical, biological, radiological, or nuclear agents, and to determine which agents present a significant threat to the U.S. population. S&T produces the Bioterrorism Risk Assessment (BTRA), a strategic assessment of bioterrorism risk, updated biennially, that integrates the findings of the intelligence and law enforcement communities with input from the scientific, medical, and public health communities. OHA provides subject matter expertise to S&T in developing the BTRA, and has worked closely with the BTRA program managers to develop tailored assessments designed to address specific knowledge gaps or areas of uncertainty identified within OHA programs. OHA applies these assessments when operating, managing, and supporting the Department's biodefense programs.

The threat of an attack using a biological agent is real and requires that we remain vigilant. A wide-area attack using aerosolized *Bacillus anthracis*, the bacteria that causes anthrax, is one of the most serious mass casualty biological threats facing the U.S. An anthrax attack could

potentially encompass hundreds of square miles, expose hundreds of thousands of people, and cause illness, death, fear, societal disruption and economic damage. If untreated, the disease is nearly 100 percent fatal, which means that those exposed must receive life-saving MCM as soon as possible.

The federal government recognizes two critical capabilities must be in place in order to minimize the effects of a biological attack. First, the nation must be able to rapidly determine that an attack has occurred. Second, we must have the capability to quickly distribute MCM to the entire affected population before clinical symptoms appear.

Through early detection, OHA works to mitigate the consequences of a biological incident. OHA's Biowatch program is a federally managed, locally operated, nationwide environmental surveillance system that detects the release of certain aerosolized biological agents before exposed individuals develop symptoms of illness. This "detect to treat" approach provides the public health community with an opportunity to respond to a release of a biological agent as quickly as possible in order to mitigate the potentially catastrophic impact on the population. Early detection allows communities to provide medical countermeasures to affected persons in a timely manner in order to save more lives.

For this reason, OHA is investing in the development of advanced detection technology that aims to significantly reduce the time between a release of a biothreat agent and confirmation of the release by Biowatch technology. The transition to an automated detection system, called "Generation 3", is intended to confirm a release within four to six hours in the locations that Biowatch covers. Reducing the time it takes to properly detect and confirm a release is critical because earlier detection allows for earlier distribution of lifesaving MCM to effectively protect the exposed population.

DHS Assists and Coordinates with State and Local Governments

OHA works directly with state and local leaders to develop capabilities to respond to health threats. We have done this by expanding local public health participation in, and coordination with, the national network of BioWatch jurisdictional advisory committees as well as state and urban area fusion centers.

Furthermore, OHA provides health and medical expertise to planning and exercise efforts that advance national preparedness and response capabilities. To increase preparedness for and resilience to biological threats, Secretary Napolitano initiated the Anthrax Response Exercise Series (ARES) exercises, which are comprehensive anthrax response exercises conducted in each of the 10 Federal Emergency Management Agency (FEMA) regions in coordination with state and local governments. Completed in fall 2010, the ARES series was valuable to state, local and regional stakeholders for a number of reasons. It increased awareness in the areas of biodetection, notification, and early response protocols. It also provided the opportunity to combine exercise program requirements (biodetection strategies, including BioWatch and state exercise plans) while engaging both large and small metropolitan areas throughout the U.S.

ARES successfully provided an opportunity for federal, state, local, and regional partners to come together and better understand their roles and responsibilities supporting biodetection,

notification and response. ARES created an opportunity for all levels of government to define and refine their MCM programs and plans. We plan to continue to build on the success of ARES by conducting workshops in additional cities for 2011 and 2012.

In addition to ARES and other exercise activities that allow state and local governments to strengthen their national response capabilities, OHA also provides our state and local partners with guidance for protection of personnel responding to a wide-area anthrax attack. Through the federal interagency process, OHA led the effort to develop consensus guidance regarding appropriate protective measures for responders in the immediate post-attack environment of an aerosolized anthrax attack. The guidance reflects the most current understanding of the unique environment that would exist after a wide-area anthrax release. The guidance is a prudent step to provide to first responders the best information on protective measures currently available. The responder community had requested guidance in this area, and DHS and federal partners are committed to continually updating the guidance to ensure that it reflects the best science.

Executive Order 13527: Establishing Federal Capability for the Timely Provision of Medical Countermeasures Following a Biological Attack.

In addition to assisting and coordinating with state and local governments, OHA also actively engages in federal interagency efforts to strengthen the nation's ability to prepare for, respond to, and recover from natural disasters and terrorist attacks. 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. seeks to mitigate illness and prevent death, sustain critical infrastructure, and complement state, local, territorial, and tribal government MCM distribution capacity.

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. This model has the capacity for rapid residential delivery of MCM for self administration across all U.S. communities. In collaboration with the Departments of Justice, Defense, HHS, and USPS, DHS supported the development of the USPS model. Upon request, DHS will assist state and local governments through 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 is being co-led by FEMA and ASPR, and OHA has provided subject matter expertise.

Section 4 of the E.O. directs 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 to be performed 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. We are pleased to say that DHS is among the first federal agencies to have met this requirement of the E.O.

In April 2010, DHS established the Anthrax Preparedness and Response Steering Committee to develop specific products to improve preparedness and response efforts that include the activities mandated in the E.O. The Steering Committee leads the Department's efforts in enhancing readiness and immediate response in the event of wide-area aerosolized anthrax attack and includes senior leaders from across the Department.

DHS Workforce and Health Protection

OHA works each day to build resilience across the country and 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 mandated in Section 4 of the E.O.

In Section 4, 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 and seek funding for a capacity to provide emergency antibiotics to all DHS employees in an attacked 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 in their interactions with millions of people each day at airports and ports of entry.

As previously discussed, individuals exposed to anthrax spores can survive if they take antibiotics quickly, underlining the importance of the Department's plans to pre-position MCM in caches across the country for employees. In the event of an anthrax attack, all affected DHS personnel and their families will also have access to MCM through existing community MCM dispensing plans.

OHA spearheaded an MCM strategy for DHS employees and oversees the purchase and storage of MCM for the DHS workforce. This includes all employees and personnel and individuals in the custody and care of DHS. The MCM strategy and implementation plan is a multi-year, multi-layered approach which consists of four phases, each building upon the previous and is subjected to the availability of funding to achieve its goal of covering the entire DHS workforce. This scalable approach will ensure the sustainability of the program.

The goal of the first phase is to protect and mitigate the effect of an anthrax exposure by delivering MCMs post-event to employees. This phase is currently underway. We purchased courses of MCM that are stored at a central location and at regional locations to cover federal employees and those in DHS's care and custody. OHA, in coordination with DHS components, identified accessible and secure facilities for storage of MCM. Additional cache locations will be identified over time to improve coverage and proximity to employees. OHA also builds points of dispensing capability to dispense MCM as needed by providing training to appropriate personnel.

Leading by example and pushing forward the federal interagency effort for MCM dispensing and distribution, OHA collaborates routinely with various offices within DHS to ensure synergistic efforts in implementing this Department-wide strategy. OHA provided guidance and comprehensive planning information to DHS components through the Anthrax Operations Plans Department Guidance Statement (DGS). We also provide medical guidance and logistical and operational support to DHS component offices as they finalize their MCM plans. To supplement the DGS, 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 is now in the process of credentialing DHS personnel who will provide the medical oversight of MCM storage and dispensing.

Among the first departments to fulfill the mandates required by the E.O., OHA is also sharing lessons learned and coordinating with the interagency process to ensure the consistency of plans across the federal government, including our partners at HHS, CDC, and FDA. Along with ASPR, we co-chair a working group to protect mission essential employees of executive branch departments and agencies in the event of a wide-area aerosol anthrax attack.

Conclusion

OHA manages and oversees the DHS MCM program and works to mitigate biological threats by preparing the nation to quickly detect and respond to a biological attack through early detection and rapid distribution of MCM. DHS leads and strengthens our nation's collective efforts to secure our country from threats, assisting and coordinating with state and local governments and helping to ensure a resilient DHS workforce. Thank you again for the opportunity to testify today. I look forward to any questions that you may have.