

Written Statement of James D. Polk, DO, MMM
Principal Deputy Assistant Secretary and Deputy Chief Medical Officer
Office of Health Affairs
U.S. Department of Homeland Security
Before the House Homeland Security Committee
Subcommittee on Emergency Preparedness, Response, and Communications
April 17, 2012

Good afternoon, Chairman Bilirakis, Ranking Member Richardson and distinguished Members of the Subcommittee. It is an honor to testify before you today on the Department of Homeland Security's (DHS) efforts regarding medical countermeasures (MCM) for first responders.

As you are aware, the Office of Health Affairs (OHA) provides health and medical expertise in support of the DHS mission to prepare for, respond to, and recover from all threats and hazards. OHA's responsibilities include: serving as the principal advisor to the Secretary and the Federal Emergency Management Agency (FEMA) Administrator on medical and public health issues; leading and coordinating biological and chemical defense activities; providing medical and scientific expertise to support DHS preparedness and response efforts; and leading the Department's workforce health and medical oversight activities. OHA also serves as the primary DHS point of contact for state, local, tribal and territorial governments on medical and public health issues.

OHA has four strategic goals that coincide with the strategic goals of the Department:

1. Provide expert health and medical advice to DHS leadership;
2. Build national resilience against health incidents;
3. Enhance national and DHS medical first responder capabilities; and
4. Protect the DHS workforce against health threats.

Today I will discuss a number of MCM and first responder initiatives that support our strategic goals.

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

Executive Order (E.O.) 13527 seeks to mitigate illness and prevent death, sustain critical infrastructure, and complement state, local, tribal and territorial government MCM distribution capacity. 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. A successful anthrax attack could potentially encompass hundreds of square miles, expose hundreds of thousands of people, and cause illness, death, fear, societal disruption and significant economic damage. If untreated, the disease is nearly 100 percent fatal; those exposed must receive life-saving MCM as soon as possible following exposure.

In particular, 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. Due to the nature of the DHS mission, a significant portion of our workforce performs mission essential functions, and others could be exposed during daily activities. As a result, Secretary Napolitano directed DHS 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. OHA leads this effort for DHS and we are pleased to say that DHS is among the first federal agencies to have met this requirement of the E.O.

Stockpiling and Forward Caching of MCM

In the past year, OHA successfully introduced an MCM strategy to mitigate the impact of a biological attack on DHS personnel. As part of this strategy, OHA implemented a plan to purchase and stockpile MCM for all DHS employees, those in DHS care and custody, working animals, and contractor employees with DHS badges. DHS identified regional cache locations for every DHS Component in order to pre-position MCM across the country for employees to have immediate access after a biological incident.

In order to make the plan both cost effective and protect even our most remotely located employees, OHA worked with the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) to draft an Emergency Use Authorization (EUA) that would permit, among other things, the stockpiling and distribution of 10-day courses of doxycycline at Component caches and dispensing of the medication by non-healthcare professionals. This EUA was issued by the FDA Commissioner on July 21, 2011. OHA was then able to forward cache nearly 200,000 courses of MCM to 127 field locations for regional stockpiling, in addition to centrally stockpiling additional MCM that might need to be utilized following an incident. OHA continues to partner with FDA to satisfy regulatory considerations for re-labeling and forward caching of MCM. In addition, pre-EUA submissions are in place to support a possible EUA for ciprofloxacin, an antibiotic that is also effective for post-exposure prophylaxis of inhalational anthrax.

Until an EUA for ciprofloxacin is issued, DHS is restricted to distributing this countermeasure in the currently approved 60-day courses and through a traditional medical dispensing model utilizing DHS healthcare providers, including the Department's more than 3,500 Emergency Medical Service Technicians (EMTs). However, provisions in both House and Senate versions of the Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization bill would, if enacted, facilitate such pre-event and response activities.

In the event of a biological incident, it is important to remember that all affected DHS personnel and their families will also have access to MCM from the Strategic National Stockpile through existing community points of dispensing (PODs).

Advising DHS Leadership on Health and Medical Issues

Serving as the principal advisor to the Secretary and FEMA Administrator on medical and public health issues has afforded OHA the ability to ensure synergistic efforts in implementing a Department-wide strategy for MCM. OHA provides guidance and comprehensive planning information to DHS Components through the Anthrax Operations Plan Department Guidance Statement (DGS) in coordination with the Office of Operations Coordination and Planning, develops and delivers training on dispensing of the MCM, assists operational Components in the development of dispensing plans and conducts DHS points of dispensing (POD) exercises. To supplement the DGS, OHA also provides medical guidance for MCM storage, administration, and non-medical PODs, as well as medical treatment for working and service animals exposed to anthrax spores. We are now in the process of sharing lessons learned and coordinating with the federal interagency to ensure the consistency of plans across the federal government, including our partners at the Department of Health and Human Services (HHS), CDC, and the FDA.

Coordinated medical oversight provided by OHA ensures that the Department's MCM program and medical treatment rendered pursuant to the program is uniform and consistent to national standards. Currently, OHA has a medical liaison officer (MLO) responsible for the provision of medical guidance, support and leadership at FEMA, which has proven to be a very successful model. We are in the process of establishing MLOs with Customs and Border Protection (CBP), the Transportation Security Administration (TSA), and Immigration and Customs Enforcement (ICE) to support their operational workforces. These Components will benefit from coordinated and centralized medical programmatic direction and guidance from OHA, along with an established protocols system that will support and enhance steady state and deployment readiness activities. The Department as a whole will be better situated to prepare for and respond to disasters and significant events through the increased depth in medical leadership this structure provides.

Response Guidance for First Responders

OHA also provides our state, local, tribal and territorial partners with guidance for protection of personnel responding to a wide-area anthrax attack. Through the federal interagency process, OHA and HHS's Office of the Assistant Secretary for Preparedness and Response (ASPR) co-led the effort to develop consensus guidance regarding appropriate protective measures for first 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.

Pre-Event Anthrax Vaccination for Responders

In July 2009, the CDC Advisory Committee on Immunization Practices (ACIP) stated that by priming the immune system before exposure to *Bacillus anthracis* spores, pre-event vaccination might provide more protection than antimicrobial drugs alone to persons at risk for occupational exposure. ACIP recommendations state that, "Emergency and other responders are not recommended to receive routine pre-event anthrax vaccination because of the lack of a calculable risk assessment. However, responder units engaged in response activities that might

lead to exposure to aerosolized *B. anthracis* spores may offer their workers voluntary pre-event vaccination. The vaccination program should be carried out under the direction of a comprehensive occupational health and safety program and decisions for pre-event vaccination should be made based on a calculated risk assessment.” (Centers for Disease Control and Prevention, 2010)

“Responders” refers to a diverse set of individuals who perform critical services necessary to mitigate the potential impact of a wide-area anthrax attack. These responders may either be in the area identified as the point of initial release and/or are called in from elsewhere to provide follow-on activities in a contaminated area performing critical services. Our national response capability to a wide-area anthrax attack would be enhanced by having pre-vaccinated responders, able to deploy immediately and confident that they have been afforded as much protective status as possible for these activities. Pre-event vaccination of these responders will increase the ability to save lives, maintain social order, and ensure continuity of government after a wide-area anthrax attack.

The CDC’s Strategic National Stockpile (SNS) approached OHA in June 2011 with the idea of working collaboratively to determine a use for anthrax vaccine with a short shelf life rather than disposing of the unused vaccine. Anthrax vaccine is currently stockpiled in the CDC’s SNS to support state and local response during a widespread aerosolized anthrax release. Based on DHS threat assessments and the Department’s prioritization of efforts for anthrax preparedness, voluntary pre-event vaccination of responders is deemed to be an appropriate step to prepare for this threat.

Therefore DHS and CDC SNS are developing a program for the provision of expiring anthrax vaccine to federal departments and agencies, as well as state and local jurisdictions for the voluntary pre-event vaccination of responders. Each federal, state, local, tribal or territorial program must meet eligibility requirements, including the existence of a comprehensive occupational health and safety program through which to manage a vaccination program for anthrax vaccine. It is important to note that the federal government is not establishing a federal vaccination program for state and local responders, but rather providing an existing resource to states and localities who will implement the vaccination program within their jurisdictions. No funding or other resources for any administrative programmatic support requirements will be associated or available through DHS or HHS outside of the provision of the physical vaccine. Such a program would distribute anthrax vaccine to responders at greatest risk of exposure and would not impact vaccines needed for Department of Defense (DOD) personnel recommended to receive the vaccine for general use prophylaxis.

As part of the program development process, CDC and OHA formed a federal interagency working group to discuss key decision points regarding voluntary pre-event anthrax vaccination of responders. This working group convened a series of meetings to discuss scientific medical data and policy implications among subject matter expert representatives from over twelve different federal departments. The group developed pre-event anthrax vaccine risk prioritization guidance for use in the event that demand exceeded supply of vaccine. This guidance identifies the categories of responders eligible to receive pre-event anthrax vaccine, contingent on supply and current threat assessment. All categories of responders identified in this guidance are

considered at sufficient risk of future exposure to anthrax to warrant voluntary pre-event vaccination, should the supply be sufficient at the time of the request.

The first step to initiate this pre-event anthrax vaccine distribution program is to pilot the program on a small and manageable scale to ensure the methodology supports responsible vaccine use and to help the U.S. Government understand demand for the vaccine. The pilot program will provide data to allow us to make changes to improve program management and to help scale up the program, as needed, to achieve a safe, reliable, functional and sustainable capability to widely distribute vaccine, within the constraints of existing program capacity. The pilot will include two federal departments or agencies and two state or local jurisdictions (including tribal and territorial jurisdictions) interested in working with DHS OHA and CDC SNS to deliver this program to a pilot cohort of responders. Those selected will manage a voluntary anthrax vaccination program for a minimum of 18 months, in order to accommodate the full 5-dose priming series of vaccine to the volunteer recipients.

Conclusion

Thank you again for the opportunity to testify today. The Department of Homeland Security values the work of the nation's first responders and we are always looking for ways to support them in their critical preparedness and response efforts. I look forward to any questions that you may have.