Prepared Statement

of

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on

Anthrax Protection: Progress or Problems

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Mr. Chairman and members of this distinguished subcommittee, it is an honor to be here today to discuss the Department of Defense's programs to prevent, mitigate and respond to anthrax incidents. Today, we have approximately 236 thousand service men and women deployed in support of our nation's defenses, including those serving in Afghanistan and Iraq. Protecting and preserving the health of our service members, before, during and after deployments is our primary mission.

As the Deputy Assistant Secretary of Defense for Force Health Protection and Readiness, I am responsible for supporting the Assistant Secretary of Defense for Health Affairs in his role as the principal health and medical advisor to the Secretary of Defense on all aspects of the DoD's military health care system, including protecting, preserving, and restoring the health of our service members against not only endemic disease but also weapons of mass destruction (WMD). In the WMD arena, DoD Directive 6205.3, DoD Immunization Program for Biological Warfare Defense, provides policy guidance on vaccines and vaccination policies for defense against biological warfare threats, to include the agent that causes anthrax. Vaccination is an essential layer of protection, supplemented by antibiotics and other measures, for members of the armed forces, emergency-essential DoD civilians and contractor personnel carrying out mission-essential services.

Medical Countermeasures

The Department of Defense (DoD) currently uses two forms of medical countermeasures against anthrax: vaccines and antibiotics. Vaccines provide an effective means of preventing disease, and offer the advantage of providing around-the-clock protection even in the absence of biologic agent detectors. Antibiotics have value if given

shortly after exposure. However, if prevention, detection, and treatment are delayed, people can still develop dangerous anthrax disease.

Anthrax vaccine adsorbed (BioThrax™) is an FDA-licensed vaccine. On December 19, 2005, the Food & Drug Administration, after a review of all available scientific information and consideration of extensive public comments, published a final order reaffirming previous conclusions that anthrax vaccine adsorbed prevents anthrax resulting from any route of exposure, including inhalation.

The DoD works closely with BioPort Corporation, manufacturer of the only anthrax vaccine licensed by the Food and Drug Administration, to ensure a consistent supply of vaccine to meet the requirements of DoD's anthrax immunization program. Since 2002, BioPort has doubled its production capacity and delivered more than 8.4 million FDA-licensed doses of Anthrax Vaccine Adsorbed (AVA) to DoD. Inventory levels are sufficient to meet current DoD anthrax immunization program requirements.

The current contract with BioPort expires in September 2006. DoD is negotiating with BioPort for a new contract starting in FY07 to meet DoD anthrax vaccination program requirements. We anticipate needing to buy AVA through at least FY09 and possibly longer, depending on when a new anthrax vaccine may be licensed. A decision to switch to a new vaccine will be supported by science and a thorough business case analysis.

The anthrax vaccine is safe and effective, facts that are fully supported by the Food and Drug Administration and other national experts and based on sound science. The National Academy of Sciences and its Institute of Medicine (IOM) comprehensively reviewed the safety of anthrax vaccine in an April 2002 report commissioned by the U.S.

Congress. The IOM stated that adverse events after anthrax immunization are "comparable to those observed with other vaccines regularly administered to adults." As with all vaccines and pharmaceuticals that have a benefit, there are some risks, but most adverse events after vaccination are minor and temporary. Anthrax immunization may have associated temporary pain, swelling, headache, muscle aches, and other side effects, similar to all immunizations. There are several grounds for medical exemption, including pregnancy. Serious events, such as those requiring hospitalization, are extremely rare. The DoD has established four sites in the Vaccine Healthcare Center Network, a network of specialty clinics, to provide the best possible care in rare situations where serious adverse events follow vaccination. DoD assesses the safety of vaccines using a multi-faceted program using various scientific study designs.

Anthrax immunization remains the single most effective countermeasure to prevent anthrax disease. Between March 1998 and March 2006, over 1.5 million personnel received over 5.5 million doses of anthrax vaccine. Currently, DoD personnel deploying to high-risk areas, principally Korea and areas under Central Command, are eligible for anthrax immunization and have the option to decline. In addition, effective antibiotics against anthrax disease and other biological agents are pre-positioned strategically around the world for rapid delivery in the event of an emergency. The DoD is collaborating with the Department of Health and Human Services to develop plans for the use of post-exposure anthrax immunization combined with antibiotics in those personnel not previously immunized. This is consistent with the prevailing medical recommendation for the best clinical response to anthrax exposure.

Although anthrax vaccine is licensed by the FDA, its approved labeling does not include post-exposure use to prevent anthrax disease. However, section 564 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 360bbb-3), part of the Project BioShield Act of 2004 (Public Law 108-276), allows the FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency involving an actual or heightened risk of attack on the public or U.S. military forces. Based on an emergency declaration by the Secretary of Human Health Services (HHS), the FDA Commissioner can authorize emergency use of a product if: the product is used for a serious or life-threatening condition; there is no adequate, approved, and sufficiently available alternative; the preponderance of scientific evidence indicates that the product may be effective; and the product's known and potential benefits outweigh its known and potential risks. It is likely that, in the event of an anthrax attack that results in unvaccinated individuals being exposed to the anthrax bacteria, the public health authorities responsible for helping those individuals would ask the FDA for an Emergency Use Authorization (EUA) for post exposure administration of anthrax vaccine in conjunction with antibiotics. To be ready for a potential emergency, both DoD and the CDC are developing draft EUA requests and working with the FDA to establish the most effective and scientifically valid clinical response.

In closing, I want to reiterate that the health and safety of all service members are the top concerns of the Department. Our medical program to protect service members from this deadly biological disease is based on the best medical and scientific information available as well as by independent review of the world's best experts in the field. The Department bases its decisions on strong science and best medical practices. Our program

supports FDA regulations and is consistent with all legal requirements. It has the full support of the DoD military and civilian leadership.