

STATEMENT BY

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Mr. Chairman and members of the subcommittee, thank you for the opportunity to speak to you today on behalf of the Office of the Assistant Secretary of Defense for Health Affairs (Health Affairs) and the Military Health System (MHS). Today, I will speak on the roles and responsibilities of the Assistant Secretary of Defense for Health Affairs in the use of medical countermeasures against biological warfare agents and other infectious disease threats. In addition, I will summarize Department of Defense (DoD) preparedness efforts for countering a potential influenza pandemic.

The mission of the MHS is to provide health services in support of our nation's military mission – anytime, anywhere. This includes military operations, responding to natural disasters, and humanitarian crises around the globe, and delivery of world-class healthcare to all Service members, retirees, and other beneficiaries. The MHS promotes a fit, healthy, and protected force to reduce non-combat losses, optimize healthy behaviors and physical performance, and provide comprehensive casualty care. Health Affairs is responsible for ensuring the medical readiness of our soldiers, sailors, airmen, and Marines, including protecting them against biological warfare agents, and militarily-relevant infectious disease threats that could affect operational readiness.

The research, advanced development, and procurement of chemical, biological, radiological, and nuclear medical countermeasures is the responsibility of DoD's Chemical Biological Defense Program (CBDP). Health Affairs provides medical consultation to the CBDP on all aspects of the program, including development of the requirements for medical countermeasures. Health Affairs has the primary responsibility within DoD for developing medical policy and guidance to the Services for the use of Food and Drug Administration (FDA) approved

medical countermeasures against routine infectious diseases and biological warfare threats.

The Joint Staff recognizes anthrax and smallpox as lethal biological weapon threats. The Department's Anthrax Vaccine Immunization Program began in March 1998. Since then, more than 1.9 million Service members have received more than 7.4 million doses of anthrax vaccine. In October 2006, DoD directed a resumption of mandatory anthrax vaccinations for higher threat areas, and voluntary anthrax immunizations for individuals who are not in the mandatory category, but who have previously received one or more doses. Military Service members, emergency-essential DoD civilians, mission-essential contractors deployed to higher threat areas for 15 or more consecutive days, and units with special missions, will receive mandatory anthrax vaccinations. These higher threat areas include the United States Central Command's area of responsibility, and Korea.

The Department's Smallpox Immunization Program began in 2002 when the President announced that DoD would vaccinate selected units and personnel against smallpox to preserve critical mission capabilities. The policy includes military personnel, emergency-essential DoD civilians, and mission-essential contractors deployed to higher threat areas for 15 or more consecutive days, and units with special missions. Since December 2002, more than 1.5 million Service members have been immunized against smallpox.

On April 1, 2008, DoD transitioned from use of the Dryvax smallpox vaccine to the newly-licensed ACAM2000 smallpox vaccine. DoD made this transition to ensure a continuous supply of smallpox vaccine that is manufactured using modern cell-culture techniques, which are designed to comply

with current vaccine manufacturing standards. As with all DoD immunization programs, medical personnel and vaccine recipients were informed of changes in the vaccine program through extensive communication, education, and training initiatives. We continue to use the latest advances in technology to distribute our education materials to our healthcare providers, Service members, families, and other beneficiaries around the world. We continue to provide online educational briefings, products, and training videos designed towards each individual group, as well as providing detailed vaccine information at the time of the vaccinations. We are now using live, interactive, webcasts in support of the vaccinations programs. This provides valuable education through briefings by clinical staff and the ability to provide customized interactive question and answer sessions for specific issues.

DoD has implemented a robust surveillance program for monitoring the safety and efficacy of its immunization programs. These range from clinical studies, which increase scientific understanding of the vaccines, to large database surveillance programs, which provide early indicators of vaccine safety. As an example, for the current anthrax vaccine, the DoD has supported continuing research into the scientific understanding of this vaccine resulting in 26 published studies, numerous ongoing studies, and the concurrence of eight independent reviews. The Armed Forces Health Surveillance Center collects serious adverse event data for vaccinations as part of its mission to provide continuous surveillance for the MHS. The primary tool for this study is the Defense Medical Surveillance System, an executive information system whose database contains up-to-date and historical data on diseases and medical events (e.g., hospitalizations, ambulatory visits, reportable diseases, acute respiratory diseases, and health risk appraisals) and longitudinal data on personnel and deployments.

The Vaccine Healthcare Center Network is an initiative the DoD that

fulfills Section 751 of the National Defense Authorization Act of 2001 to support Service members and other beneficiaries. Established in 2002 with four centers, this Network provides educational assistance to individuals who are concerned about their vaccinations, and they assist individuals who experience a rare adverse event. With every anthrax and smallpox vaccination, the Service member is provided an educational brochure that details the possible adverse events and provides contact information for clinical services, such as the Vaccine Healthcare Centers Network.

Since May 2005, an Interagency Agreement has existed between the DoD and the Department of Health and Human Services (HHS) for support of contingency medical materiel requirements. The agreement establishes a framework to coordinate mutual support in the event of a shortfall in critical medical materiel (pharmaceuticals, biologics, medical/surgical supplies, and equipment) when responding to, or recovering from the public health and medical consequences of a domestic catastrophic incident or incident of national significance. The agreement establishes procedures by which HHS can request delivery and transfer of DoD contingency materiel assets. HHS maintains contingency materiel in the Strategic National Stockpile. Health Affairs provides technical expertise and advice to identify, establish, and recommend DoD priorities regarding allocation of Strategic National Stockpile assets from HHS.

DoD is making extensive preparations to ensure its ability to continue its mission in the event of an influenza pandemic. In 2006, in concert with the Implementation Plan for the National Strategy for Pandemic Influenza, Health Affairs issued policies and guidance on preparation and response to a pandemic caused by the bird flu virus. This included policy guidance for the use of stockpiled anti-viral medications during an influenza pandemic, such as

oseltamivir phosphate (commercially sold as “Tamiflu”), as well as policy guidance for the use of pre-pandemic influenza vaccines.

Since Fiscal Year 2004, as part of its responsibilities outlined in the President’s National Implementation Plan for Pandemic Influenza, DoD has made significant investments in materiel readiness for pandemic influenza, including pre-pandemic vaccines, antiviral medications, personal protective equipment, and antibiotics. DoD medical preparedness planning for pandemic influenza has been based on the projected clinical requirements, industry capacity to satisfy those requirements in the event of a pandemic, and DoD’s ability to store materiel. DoD has positioned quantities of oseltamivir at military medical treatment facilities worldwide, and is expanding supplies for the immediate use of the overseas Geographic Combatant Commands. DoD has positioned additional quantities of oseltamivir at strategic storage sites in the Pacific, Europe, and Pennsylvania, which could be distributed to specific points of need, as required. Approximately one-third of military medical treatment facilities hold stocks of antibiotics specifically allocated to treat bacterial infections secondary to pandemic influenza. DoD is also assisting the Department of Health and Human Services by storing a cache of antivirals in the U.S. Pacific Command, which could be used in an attempt to contain a potential outbreak in Asia. Last August, Health Affairs worked with the DoD Personnel community to conduct a pandemic influenza exercise where 1,500 individuals simulated a 40% absenteeism rate and tested its ability to continue its mission by implementing social distancing and telework.

Military personnel deployed to specific military operations could be potentially exposed to a range of chemical, biological, and radiological weapons, as well as to endemic diseases specific to that area. It is DoD’s policy to provide military personnel with safe and effective vaccines, antidotes, and treatments that

will eliminate or minimize the effects of these potential health threats. DoD also stockpiles these countermeasures as part of contingency planning.

Mr. Chairman, protecting and preserving the health of our Service men and women is one of our highest priorities, second only to our military mission. Thank you for the opportunity to provide you with an overview of Health Affairs' role in the use of medical countermeasures.