THE ASSISTANT SECRETARY OF DEFENSE

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HEALTH AFFAIRS

AUG 1 0 2007

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Department of Defense Pre-pandemic Influenza Vaccine Policy

The most effective method of preventing, or limiting, illness caused by an influenza pandemic is immunization. The inherent delay associated with pandemic specific-vaccine production may result in a significant degradation in Department of Defense (DoD) ability to meet mission requirements. Use of a pre-pandemic vaccine may offer some degree of protection or it may serve as a suitable primer for a pandemic-specific vaccine. This policy provides guidance for the use of pre-pandemic vaccines.

This policy applies to the Office of the Secretary of Defense, the Military Departments, the Chairman of the Joint Chiefs of Staff, the Combatant Commands and non-military individuals under military jurisdiction, elected federal employees, and family members and other people eligible for care within the Military Health System. The term "military Services," as used herein, refers to the Army, the Navy, the Air Force, Marine Corps, and the Coast Guard only when it is operating as a Service within the Navy.

After Food and Drug Administration (FDA) licensing of a specific pre-pandemic vaccine, DoD will offer on a voluntary basis the pre-pandemic vaccine to DoD laboratory personnel working in Bio-surveillance Level 3 (BSL-3) enhanced facilities who are in direct contact with human or avian influenza viral specimens representing strains with pandemic potential and those who are engaged in outbreak evaluation and containment missions involving influenza strains with pandemic potential. It is DoD policy to follow FDA regulations.

Upon receipt of credible information that highly localized small clusters with limited human-to-human transmission (i.e., World Health Organization (WHO) Phase 4 conditions) have emerged in any geographic combatant command area of responsibility, the Assistant Secretary of Defense (Health Affairs) (ASD (HA)) may approve the start of immunization programs involving the general Active Duty population. The precise trigger point for release will be determined by the ASD (HA). The Joint Staff will allocate available pre-pandemic vaccine to the combatant commands and Services based on operational requirements and vaccine supply. Preference should be given to those

who can receive two vaccinations approximately 28 days apart (assuming this is the recommended dosing for the specific vaccine licensed by the FDA), who have a high risk of exposure particularly in operational settings or those likely to have contact with individuals with pandemic influenza. Due to its limited supply, the pre-pandemic vaccine should be used to help preserve operational effectiveness and will not be used by the general beneficiary population. The general beneficiary population will have access to the pandemic-specific vaccine, when developed, as determined by the most current Department of Health and Human Service's guidelines at that time. Prior to administering the pre-pandemic vaccine, commanders should increase efforts to communicate pandemic influenza health risk and mitigation strategies, especially to those beneficiaries not receiving the pre-pandemic vaccine.

The Military Vaccine Agency (MILVAX) will be responsible for tracking overall vaccine administration rates. The Services will monitor implementation via electronic reporting using Service-specific immunization tracking systems and will be responsible to ensure that individuals receive both a priming and booster dose as indicated. The MILVAX, in conjunction with the Vaccine Healthcare Center, will use the Military Vaccine Monitoring System and other monitoring systems determined by MILVAX to track and provide clinical guidance for possible adverse events.

The DoD Global Emerging Infections System's Febrile Respiratory Illness Surveillance Program and the Department of Defense Global Influenza Surveillance System will monitor vaccine effectiveness. Initial immunization programs involving the previously described laboratory and response personnel will include serologic evaluation of immunogenicity conducted by the respective facility in coordination with the US Army Center for Health Promotion and Preventive Medicine, Center for Epidemiology and Serum Surveillance for Pandemic Influenza (CESPI). With large-scale immunization programs initiated following WHO phase 4 conditions, continued serologic evaluation of immunogenicity should be conducted, if possible, though CESPI.

Vaccine storage will be maintained at the manufacturer and/or at Defense Logistics Agency (DLA) facilities in compliance with the manufacturer's guidelines. The Joint Staff will establish the priorities, quantities, and locations (with military and commercial delivery addresses) for vaccine distribution. The DLA will determine the best method of distributing the vaccine in keeping with the Joint-Staff-established priorities. Appropriate cold chain management procedures will be used in the shipment and distribution of vaccines. Geographic Combatant Commanders will ensure expedited transportation of vaccines across borders in their areas of responsibility. Coordination with Department of State or primary agency should be conducted to ensure vaccine delivery access in the event that borders are closed. In accordance with authorities,

geographic Combatant Commanders and Services must plan for the availability of ancillary material to administer the vaccines at the points of administration and ensure confirmation of receipt is reported by ultimate consignees to the Joint Staff and the DLA.

My point of contact on this matter is LTC Wayne Hachey, who can be reached by telephone at (703) 575-2669, or e-mail at *wayne.hachey@ha.osd.mil*.

S. Ward Casscells, MD

cc:
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