THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

14 Apr 2011

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)

SUBJECT: Department of Defense Participation in BioThrax Post-Licensure Requirements

The U.S. Food and Drug Administration (FDA) licensed BioThrax (Anthrax Vaccine Adsorbed), manufactured by Emergent BioSolutions (Emergent), is the only anthrax vaccine approved in the United States. The anthrax vaccine represents a significant piece of our national and military bio-preparedness strategy. Support and participation in post-licensure vaccine safety studies has national importance.

In December 2008, FDA acknowledged the manufacturer's request to establish a pregnancy registry to collect data on self-reported exposures to BioThrax during pregnancy. The primary objective of the BioThrax Pregnancy Registry is to detect any potential adverse fetal effects, including birth defects, in prospectively enrolled women who were inadvertently exposed to BioThrax during pregnancy. Other objectives include estimating the prevalence of serious adverse pregnancy outcomes and serious adverse events during the first year of life among live births for the registry population. Data obtained from a BioThrax registry may be used to support future labeling changes.

The Military Vaccine Agency will coordinate Department of Defense (DoD) efforts to meet these requirements with the manufacturer and FDA. The Naval Health Research Center will lead the administration of the BioThrax Pregnancy Registry and coordinate protocols through its Institutional Review Board. The registry will fully comply with all human research subject protection rules and FDA regulations. Emergent will fund the registry.

Preserving the health and safety of Service members is our top priority. Participation with the manufacturer in development of this pregnancy registry will support this priority by assuring a safe and effective vaccine for Service members. We endorse efforts between the vaccine manufacturer and DoD for participation in post-licensure safety requirements, and request that the Services support efforts to meet the goals of the registry. The point of contact for this matter is COL James Boles, who may be reached at (703) 578-8444, or James.Boles@ha.osd.mil.

for

Jonathan Woodson, M.D.