



DEPUTY SECRETARY OF DEFENSE
1010 DEFENSE PENTAGON
WASHINGTON, DC 20301-1010

APR 25 2005

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
COMMANDERS OF THE COMBATANT COMMANDS
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL OF THE DEPARTMENT OF
DEFENSE
INSPECTOR GENERAL OF THE DEPARTMENT OF
DEFENSE
DIRECTORS OF THE DEFENSE AGENCIES
COMMANDANT OF THE US COAST GUARD

SUBJECT: Resumption of the Anthrax Vaccine Immunization Program (AVIP) Under
Emergency Use Authorization (EUA)

On October 27, 2004, the Secretary of Defense directed DoD to stop administering anthrax vaccinations until further notice. This action resulted from an injunction issued that day by the U.S. District Court for the District of Columbia based on a procedural defect in a Food and Drug Administration (FDA) order classifying licensed anthrax vaccine as safe and effective in preventing inhalation anthrax. On January 27, 2005, the FDA issued an Emergency Use Authorization (EUA) to permit DoD to resume AVIP, conditioned on giving potential vaccine recipients an option to refuse vaccination. On April 6, 2005, the District Court modified its October 27, 2004, injunction to allow program resumption under an EUA. Other initiatives to resolve the legal issues may result in full program resumption later this year, but AVIP resumption under the EUA at this time is needed to counteract the continuing risk to U.S. military forces of attack with anthrax spores.

The Military Services are directed to amend their anthrax vaccination plans to resume the AVIP under conditions set forth by the FDA in the EUA issued January 27, 2005.

Notably, the AVIP will be conducted under the EUA with an option to refuse vaccination. Unit commanders, leaders, and supervisors at all levels will respect the individual's right to refuse anthrax vaccination. Commanders will not order personnel to be vaccinated during this EUA period. Individuals eligible for anthrax vaccination will be provided the approved tri-fold brochure informing them, "You may refuse anthrax

OSD 07425-05

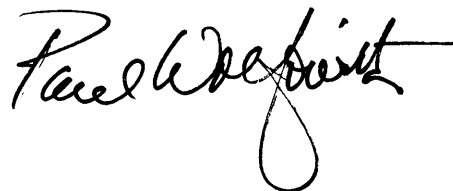


vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.” For categories of personnel previously under the mandatory program and now under the EUA, individuals will be informed that their military and civilian leadership strongly recommend anthrax vaccination, but personnel are not required to be vaccinated under the EUA.

Based on previous AVIP policies, modified to meet all conditions of the EUA, the scope of the AVIP shall encompass military personnel serving in the Central Command Area of Responsibility or with US Forces Korea for 15 or more consecutive days, and those other categories of personnel who prior to October 27, were subject to the mandatory AVIP and who are currently at heightened risk of exposure due to attack with anthrax spores. During the period of the EUA, the policy of continuing the vaccine dosing series of six shots plus boosters for all personnel who begin it is suspended for personnel without a continuing duty assignment associated with the heightened risk of exposure. The Under Secretary of Defense for Personnel and Readiness (USD (P&R)) shall issue detailed instructions to clarify coverage of particular groups and individuals, designate others at heightened risk of exposure due to attack with anthrax spores, and provide other program specifications. All DoD components will implement USD (P&R)’s instructions.

Executive Agency responsibilities, compliance with FDA requirements, and clinical policies (including exception policies and the requirement for accurate electronic recordkeeping) for anthrax vaccination remain in effect. The Court injunction against mandatory vaccinations remains in effect for the time being. Compliance with this injunction is imperative. All personnel implementing the AVIP under the EUA shall carry out reporting procedures established by the Executive Agent to monitor compliance with the injunction and the EUA conditions. This memorandum makes no changes to the smallpox vaccination program or the program of voluntary vaccinations of laboratory personnel against cutaneous anthrax.

The Anthrax Vaccine Immunization Program remains a top priority force health protection requirement. Its resumption, with scrupulous attention to the terms and conditions of the EUA, is essential to the safety of our personnel.

A handwritten signature in black ink, appearing to read "Paul W. Bevilacqua". The signature is written in a cursive style with a large, prominent loop at the end of the last name.