

Department of Defense

# Anthrax Vaccine Immunization Program Information



**“ ...I have a message for our military: Be Ready.”**

President Bush, September 20, 2001  
speech to the Joint Session of Congress  
following attacks on America

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*Dec 19, 2005*

# Department of Defense Policy

The Department of Defense conducts the Anthrax Vaccine Immunization Program (AVIP) consistent with Food and Drug Administration (FDA) licensed labeling and the best practice of medicine. With regard to inhalation anthrax, DoD complies with a Final Order issued by FDA on December 15, 2005.

## Frequently Asked Questions

### What Is Anthrax?

- Anthrax is a robust spore-forming bacterium (*Bacillus anthracis*) that can be stored for years, loaded into a variety of weapons, and produced in large quantities without sophisticated equipment. Inhalation anthrax is 99% lethal in an unprotected, unvaccinated population, left untreated.

### Is Anthrax A Biological Warfare Threat?

- The threat is real and failure to prepare would result in grave consequences. A former Director of the Central Intelligence Agency, James Woolsey, referred to it as “the single most dangerous threat to our national security in the foreseeable future.”
- Several countries have or are developing an offensive biological warfare capability using anthrax.
- Anthrax is a deadly infection. In the fall of 2001, 22 cases of anthrax resulted from attacks with anthrax spores. Five people died in these attacks.
- Iraq conducted weapons tests in 1990; biological warfare bombs and warheads were moved to forward locations during the Gulf War; thousands of pounds of anthrax spores were loaded into missiles, aerial bombs, and spray tanks.
- Admissions in the post-Cold War era of the former Soviet Union’s massive biological warfare capability confirmed their anthrax and smallpox programs were highly developed.

### How Can Service Members Protect Themselves From Anthrax Infection?

- To prevent an anthrax infection, anthrax vaccine is the safest means of protection for high risk personnel. After an anthrax attack, antibiotics would be given to increase survival even further. Antibiotics plus vaccination would be given to get survival as close to 100% as possible. Nonetheless, anthrax vaccine is the best round-the-clock protection available.

### Is the Anthrax Vaccination Program Still Voluntary for Service Members?

- Military services will continue anthrax vaccinations as they have since April 2005, with the same people eligible and the same option to refuse, until DoD completes its review of the FDA’s Final Order. As with the EUA, if vaccination is refused, no disciplinary action or adverse personnel action will be taken. They will not be processed for separation, and they will still be deployable.
- The consequences of refusing anthrax vaccine include that service members will be more vulnerable to lethal anthrax infection. Their loss could threaten the lives of others in their unit who depend on them, and could jeopardize the success of the mission.
- The issue of mandatory vaccination will be reconsidered after further review of the FDA’s Final Order.

## **Dose Anthrax Vaccine Provide Protection Against Anthrax?**

- Field studies conducted in the 1950s by Centers for Disease Control researchers demonstrated more than 92 percent vaccine effectiveness in humans (jointly against cutaneous and inhalational anthrax).
- The Food and Drug Administration licensed anthrax vaccine as a safe and effective prevention against *Bacillus anthracis*—the bacteria causing anthrax. The FDA reaffirmed this position to Congressional committees over multiple years, including a December 15, 2005, Final Order stating that anthrax vaccine prevents anthrax resulting from any route of exposure, including inhalation. Based on human and animal data, the National Academy of Sciences' Institute of Medicine concluded in March 2002 that anthrax vaccine is "an effective vaccine for the protection of humans against anthrax, including inhalational anthrax."
- Animal studies consistently demonstrate protection—non-human primates with only one or two vaccinations survived lethal challenges with many times over the median lethal dose (LD<sub>50</sub>) up to 2 years later. In all, 62 of 65 vaccinated monkeys (95 percent) survived inhalation challenge, but 0 of 18 unvaccinated monkeys (0 percent) survived. Similarly, 114 of 117 vaccinated rabbits survived, but unvaccinated rabbits died. Correlates of immunity that allow comparisons from animals to humans have not been fully developed.

## **Are There Vaccine-Resistant Strains of Anthrax?**

- No, every disease-causing strain of *Bacillus anthracis* produces the same protein, a protein that is required to cause disease. The vaccine induces the body to produce antibodies that neutralize that protein.

## **Is Anthrax Vaccine As Safe As Other Vaccines?**

- 20 safety studies of more than 800,000 vaccine recipients establish the safety of anthrax vaccine. This vaccine has been used for over 35 years.
- As with any vaccine, injection-site reactions do occur. Mild injection-site reactions, such as redness, swelling, and tenderness (less than one inch), occur in up to 30 percent of men and 60 percent of women. About 1 in 100 develops a reaction five inches or larger. Such symptoms resolve on their own in a few days.
- The rate of side effects away from the injection site—fatigue, headache, muscle or joint pain—occur in 5% to 35% of vaccine recipients; again, they typically resolve within 24 to 48 hours. As the National Academy of Sciences noted in their March 2002 report, these rates are similar to other vaccines.
- If a service member has a serious reaction to anthrax vaccine, he/she will be exempted from further doses and will receive full medical care. This policy is the same as for any vaccination.
- Anthrax vaccine is as safe as other vaccines. Multi-year studies found no patterns of long-term health problems due to anthrax vaccination. A vaccine, like any medicine, could possibly cause serious problems. The risk of anthrax vaccine causing serious harm, or death, is extremely small.
- The National Academy of Sciences' Institute of Medicine reported in March 2002, "There is no evidence that life-threatening or permanently disabling immediate-onset adverse events occur at higher rates in individuals who have received AVA [U.S. anthrax vaccine] than in the general population." In rare cases, patients experience serious adverse effects; these are treated and followed appropriately.

- Between March 1998 and Dec 2005, more than 1.3 million people have been vaccinated against anthrax.
- The anthrax vaccine was invented using mid-century technology that also led to highly successful vaccines against influenza, tetanus, diphtheria, and other infectious diseases.
- The license to manufacture anthrax vaccine has been valid without interruption since 1970. BioPort's license was amended and approved by the FDA to reflect the renovated facilities and processes.
- An October 2004 review of over 716,000 active-duty service members discharge rates shows anthrax vaccination does not increase risk of disability. Overall, the disability evaluation rate in the Army was very low for the 4.25 years covered by this study, and there appeared to be no effect of exposure to anthrax vaccine on the risk of disability evaluation.

### **Have Long-Term Cancer or Fertility Studies Been Conducted?**

- Virtually no vaccine is studied for cancer or effects on reproductive health, largely because such problems have not previously been seen with any vaccine. Prevailing scientific knowledge, based on literally billions of vaccinations administered since 1796, is that vaccines do not cause such problems; the manufacturing process and constituents of anthrax vaccine are similar to other vaccines.
- A 2005 study of male fertility found a diagnosis of male-factor infertility was less common in anthrax-vaccinated men than in unvaccinated men. Vaccination didn't impair semen parameters, fertilization rate, embryo quality or clinical pregnancy rates.
- A study suggests that anthrax vaccine may be linked with birth defects if given during pregnancy. Pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination outweigh the potential risk.
- We know from large database studies that vaccinated and unvaccinated service members have the same likelihood of cancer or fertility problems. There is no vaccine effect.

### **Does DoD Control the Nation's Supply of Anthrax Vaccine?**

- No. BioPort has been manufacturing sufficient anthrax vaccine licensed by the FDA to fulfill commercial sales.

### **What About Squalene?**

- Squalene (a substance naturally produced by the human body) has never been added to anthrax vaccine. Food and Drug Administration (FDA) scientists found trace quantities of squalene in anthrax, diphtheria, and tetanus vaccines (less than the natural level of squalene in the human bloodstream). But other tests did not confirm this finding. The FDA notes that these minute quantities could have come from processing during FDA tests (squalene is present in the oil in fingerprints). The FDA called squalene in vaccines "naturally occurring and safe."