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Anthrax Vaccine Immunization Program

The **Anthrax Vaccine Immunization Program** (AVIP), is the name of the policy set forth by the U.S. federal government to immunize its military and certain civilian personnel with the *BioThrax* anthrax vaccine. It began in earnest in 1997 by the Clinton administration. Thereafter it ran into Food and Drug Administration (FDA) and judicial obstacles (mainly concerning the methods and viability of the vaccine manufactured by BioPort, a subsidiary of Emergent BioSolutions Inc.). Over 8 million doses of *BioThrax* were administered to over 2 million U.S. military personnel as part of the program between March 1998 and June 2008.

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Senior Chief Petty Officer John Parkhurst administers the first in a series of anthrax vaccinations to one of 6,200 sailors aboard the aircraft carrier USS John C. Stennis (CVN 74) on March 17, 1998. Stennis and its embarked Carrier Air Wing 7 are on station in the Persian Gulf in support of Operation Southern Watch, which is the U.S. and coalition enforcement of the no-fly-zone over Southern Iraq. Parkhurst, from Virginia Beach, VA, is a Navy hospital corpsmen. The Stennis is now homeported in Bremerton, WA. DoD photo by Petty Officer 3rd Class Mike Larson, U.S. Navy.

History

1990s

In 1998, the Clinton administration required the inoculation of all military members with the anthrax vaccine known as Anthrax Vaccine Adsorbed (AVA) and by the trade name *BioThrax*.[1][2] In June 2001, the DoD halted vaccinations due to non-FDA approved changes in BioPort's manufacturing process.[3]

In 1999 at Offutt Air Force Base, the first ever Anthrax refusal court-martial in the United States Air Force was prosecuted. In the case of U.S. v. Bickley, Captain Jeffrey A. Lustick, USAF, prosecuted an airman's refusal to submit to the immunization. The airman was convicted and later administratively separated from the U.S. Air Force.[4]

2000s

On October 15, 2001, military members filed a FDA Citizen Petition highlighting the fact that the license for AVA had never formally been finalized by the FDA in accordance with the requirements of 21 CFR § 10.30 as Docket # 01P-0471.[5] The Petition was later utilized as the foundational basis for a Preliminary Injunction by a Federal Court to temporarily halt the program [*Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003)].

On June 28, 2002, in the wake of the 2001 anthrax attacks and leading up to the 2003 invasion of Iraq, all military personnel were required to receive AVA in addition to their other vaccinations of smallpox.[6] The military does give this vaccination regularly as well as Japanese encephalitis (JEV) when the service member is to be deployed to Southeast Asia, and other vaccines such as pneumococcal, tetanus, among others.[7]

> While some military personnel had questions about the safety of the vaccine, it was considered a lawful order at that time, and this made refusing the vaccine at peril of the subordinate, including possible discharge (i.e., losing their job and any benefits depending on the type of discharge). This pressure, at least for the National Guard and Reserve pilots and crewmembers, became a deciding retention factor.[8]
>
> Later that month, the DOD made it policy to include any personnel spending 15 days or more in high anthrax-risk areas, such as the Persian Gulf or the Korean peninsula.[9]

In December 2003, Judge Emmet G. Sullivan of the U.S. District Court for the District of Columbia ruled that the Department of Defense could not force military personnel to take the vaccine unless through a special order by the president.[10]

In October 2004, for about 8 days in (October 20–28), anthrax vaccinations were resumed,[11] but then an injunction against mandatory vaccination was filed on the basis that AVA was not proven to work against inhalation anthrax.[12] The ruling held that the mandatory program was illegal. The DoD was now required to either let the individual member choose under an informed consent policy, or allowed the president to bypass this requirement by executive order (*Doe v. Rumsfeld*, 341 F. Supp. 2d 1, 6 (D.D.C. 2004)).[13] For military members who had started the vaccination (which usually takes build-up and booster shots), they tended to continue the vaccination program under informed consent. For those who had a choice, they usually decided against it. [14] Deborah Funk, July 25, 2005.[15] The government stated that they will resume the vaccination program under informed consent in April 2005.

On December 15, 2005, the FDA re-issued a Final Rule & Order[16] on the license status of AVA, clearing the way for mandatory vaccination reinstatement. After reviewing extensive scientific evidence and carefully considering comments from the public, the FDA again determined that the vaccine is licensed for the prevention of anthrax, regardless of the route of exposure. Pertaining to the previous ruling, the DC District Federal Appeals Court declined to vacate or overturn the injunction in 2006, instead mooting the case based on the FDA's new 2005 licensing of the vaccine.[*Doe v. Rumsfeld*, 127 Fed. App'x 327 (D.C. Cir. 2006)]

On October 16, 2006 the military announced intentions to resume vaccinations for select personnel again, but the vaccinations remained voluntary until further guidance by the DoD.[17] The DoD's official resumption status of the program awaited publication of service messages.[18]

On December 13, 2006, a new class-action lawsuit,[19] filed on behalf of six unnamed plaintiffs, revived the legal battle over the military's mandatory anthrax immunization program. According to court documents, the basic premise of the lawsuit is the plaintiffs' claim that the vaccine is "unapproved for its applied/intended use". The lawsuit says that "plaintiffs will suffer substantial and irreparable injury if they are forced to take the vaccine", which the suit says has not been properly approved by the government, despite the FDA issuing its "final rule" on the vaccine on December 15, 2005. The suit also says the DOD has failed to follow presidential orders and federal laws that require the government to obtain informed consent before giving an unapproved and experimental vaccine to anyone.

On February 8, 2007, the military has resumed mandatory vaccinations of certain troops. Specific policies and troop selection varies according to branch of service.[20]

By August 2007, the original court affirmed that the AVIP was not substantially justified prior to the consequent FDA licensure and requisite rule making for the vaccine in December 2005. The Court ultimately granted "prevailing party" status for the plaintiffs against defendants DoD and FDA [Doe v. Rumsfeld, 501 F. Supp. 2d 186, 188 (D.D.C. 2007)].

By March 2008, a different Federal Judge affirmed the prior ruling in its opinion regarding corrections of records writing, "Taken as a whole, Judge Sullivan's decisions in *Doe v. Rumsfeld* conclude that, prior to the FDA's December 2005 rulemaking, it was a violation of federal law for military personnel to be subjected to involuntary AVA inoculation because the vaccine was neither the subject of a presidential waiver nor licensed for use against inhalation anthrax."[21]

By August 6, 2008, an FBI press briefing theorized that the "failing" anthrax vaccine immunization program led as the primary motivator in the fall 2001 anthrax letter attacks allegedly perpetrated by U.S. Army scientist Bruce Ivins. FBI documents reveal the FDA "suspended further production" of anthrax vaccine just prior to the attacks (Ivins' emails and FBI analysis available on pp. 12–16 of affidavit).[22] Failed potency tests prevented FDA approval. FBI released emails by Ivins showing the vaccine "isn't passing the potency test" and that "no approved lots" were available just prior to the letter attacks. The FBI explained Ivins' involvement with the failed potency tests. FBI affidavits also documented Ivins receiving the highest Defense Department honors for "getting the anthrax vaccine back into production". The U.S. Department of Justice press statements theorized Ivins' anthrax letter attack motive: "by launching these attacks, he creates a situation, a scenario, where people all of a sudden realize the need to have this vaccine".[23]

On October 1, 2008, Michael O. Leavitt, Secretary of Health and Human Services, declared a need "to provide targeted liability protections for anthrax countermeasures" because "I have determined there is a credible risk that the threat of exposure of *B. anthracis* and the resulting disease constitutes a public health emergency" until the year 2015.[24] Emergent BioSolutions immediately prepared to supply 14.5 million doses of anthrax vaccine by 2011.[25]

2010s

On February 19, 2010, the FBI released its final summary on the Amerithrax investigation. The "motive", according to the FBI, was detailed on page 8 of the report: "Motive. According to his e-mails and statements to friends, in the months leading up to the anthrax attacks in the fall of 2001, Dr. Ivins was under intense personal and professional pressure. The anthrax vaccine program to which he had devoted his entire career of more than 20 years was failing. The anthrax vaccines were receiving criticism in several scientific circles, because of both potency problems and allegations that the anthrax vaccine contributed to Gulf War syndrome. Short of some major breakthrough or intervention, he feared that the vaccine research program was going to be discontinued. Following the anthrax attacks, however, his program was suddenly rejuvenated." The FBI continued on page 39 finding, "within a few months of the anthrax attacks, the FDA fast-tracked the approval process and approved the Anthrax Vaccine Adsorbed ("AVA"), even though it didn't meet the original potency standards. This was a significant development for the anthrax researchers."[26]

To date, the DOD has not announced a reevaluation of the AVIP, nor consideration of correcting the records of previously punished soldiers, in light of the above-mentioned legislative, legal and criminal findings related to the anthrax vaccine.

Pamphlet

This is a pamphlet distributed to military members regarding their vaccinations after the Emergency Use Authorization from the FDA after April 4, 2005.



What about long-term side effects?

✓ This vaccine has been used for over 30 years. Like other vaccines, rarely has death or serious illness been reported after vaccination. Each case is reviewed by CDC, FDA, and DoD, to make vaccinations as safe as possible.

If I have a health problem or adverse event after vaccination, what do I do?

✓ First, if a health problem occurs following any vaccine, seek medical care to take care of your immediate health problem! If your symptoms persist, you or your provider may contact the DoD Clinical Call Center at **866.210.6469**. Then follow the information below to file a report with the Vaccine Adverse Event Reporting System (VAERS). We are committed to giving you the best care, no matter what caused the problem.

When do I file a VAERS report?

✓ Adverse events after vaccination are reported to the Vaccine Adverse Event Reporting System (VAERS). VAERS forms are available at **www.vaers.org** or call **800.822.7967**. Healthcare workers and vaccine recipients are encouraged to report any severe events that require medical treatment and/or interfere with work or recreation. DoD requires VAERS reporting by healthcare workers for adverse events that cause hospitalization or loss of work for 24 hours or more.

✓ You or any healthcare provider (civilian or military) treating you may contact the Vaccine Healthcare Center (VHC) for help with preparing a VAERS report or vaccine adverse event consultation.

If I started anthrax vaccinations, but had doses delayed, do I have to restart the series?

✓ No, you will not have to restart the series. You will simply pick up where you left off. This is consistent with national guidelines from the CDC's Advisory Committee on Immunization Practices (ACIP).

✓ The protection of each additional dose builds on the immune response to earlier doses. This is like climbing steps on a ladder towards full protection. Six doses are needed for full protection.

What about Reserve Component (RC) units that drill every month?

✓ Your unit commander, in coordination with the medical authority responsible for immunizations, will schedule your vaccinations in a timely manner.

I'm in the Reserves or National Guard. If I have an adverse event, can I go to a military hospital or clinic?

✓ Adverse events after military-directed vaccinations are in "line-of-duty" (LOD). Some RC members may seek medical care from their private physicians, while others may seek medical care at a local military Medical Treatment Facility (MTF).

✓ Those who seek treatment for an adverse event related to an official immunization will be treated. Any necessary line-of-duty (LOD) documents shall be completed after the person is treated. If you see a NON-military provider, be sure to notify your commander for the proper paperwork for an LOD or Notice of Eligibility determination.

✓ Evaluation or treatment will not be denied or delayed, pending a line-of-duty determination.

✓ For civilian health services outside a military Medical Treatment Facility call: **888.MHS.MMSO (888.647.6676).**

What if I'm pregnant?

✓ Good medical practice defers vaccination during pregnancy, unless clearly needed. If you are unsure if you are pregnant, you may request a pregnancy test from your medical provider.

✓ A study at Fort Stewart found that vaccinated women get pregnant and give birth at the same rate as unvaccinated women. Outcomes of pregnancies are comparable in vaccinated and unvaccinated women.

✓ Preliminary results suggest that anthrax vaccine may be linked with birth defects if given during pregnancy. These data are unconfirmed. Pregnant women should not be vaccinated against anthrax unless the potential benefits of vaccination outweigh the potential risk to the fetus.

Anthrax Vaccine Immunization Program

- For information about vaccine or policy.
  Military Vaccine (MILVAX) Agency:
  Websites: www.anthrax.mil www.vaccines.mil
  E-Mail: vaccines@amedd.army.mil Toll-Free: 877.GET.VACC
- For medical advice about your vaccination.
  DoD Vaccine Clinical Call Center: Toll-Free: 866.210.6469
- For clinical consultation or exemption assistance.
  DoD Vaccine Healthcare Centers: www.vhcinfo.org
  E-Mail: askvhc@amedd.army.mil Phone: 202.782.6411
- CDC National Immunization Hotline: 800.232.2522

To Civilian Healthcare Providers: If a Reservist or Active Duty Service Member presents to you for a condition that may be an adverse event caused by a military vaccination, please provide appropriate care. For authorization and payment, contact the **Military Treatment Facility (MTF)** where the member is enrolled. OR contact the **Military Medical Support Office (MMSO), 888-647-6676)** if not enrolled to an MTF.

WHAT YOU NEED TO KNOW ABOUT ANTHRAX VACCINE

5 April 2005
EUA Edition

US military forces are at risk of attack with anthrax spores. A significant potential for a military emergency exists.
The FDA Commissioner granted an Emergency Use Authorization (EUA) for anthrax vaccine to prevent inhalation anthrax.
Your military and civilian leaders strongly recommend anthrax vaccination.

For more information:
www.anthrax.mil www.vaccines.mil
vaccines@amedd.army.mil
877-GET-VACC, DSN 761-4245

- In January 2005, the Food and Drug Administration (FDA) granted an Emergency Use Authorization (EUA) for anthrax vaccine to prevent inhalation anthrax. This permits vaccinations to resume.
- The FDA determined that the known and potential benefits outweigh the known and potential risks for this use.
- A study in mill workers showed that anthrax vaccine was 92.5% effective in preventing anthrax (including cutaneous [skin] and inhalation anthrax cases).
- U.S. anthrax vaccine has been FDA-licensed to prevent anthrax since 1970.

THE THREAT FROM ANTHRAX SPORES IS DEADLY AND REAL

- The most deadly form of anthrax is inhalation anthrax.
- You can be infected with anthrax and not know it, until it's too late.
- No other product is approved by FDA to prevent anthrax before exposure.

- Without vaccination, you would be more vulnerable to lethal anthrax infection.
- If you get infected with anthrax, your loss could endanger other people in your unit who depend on you.
- If you get infected with anthrax, it could endanger your mission.

➢ **You may refuse anthrax 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.**

➢ The consequences of refusing anthrax vaccine include that you will be more vulnerable to lethal anthrax infection. Your loss could threaten the lives of others in your unit who depend on you, and could jeopardize the success of the mission.

➢ **On October 27, 2004, the U.S. District Court for the District of Columbia issued an Order declaring unlawful and prohibiting mandatory anthrax vaccinations to protect against inhalation anthrax, pending further FDA action. The Court's injunction means you have the right to refuse to take the vaccine without fear of retaliation. A copy of the Court's Order and Opinion is available at www.anthrax.mil or from the vaccination clinic.**

➢ **The issue of mandatory vaccination will be reconsidered after the FDA completes its administrative review, which DoD expects to occur later in 2005.**

Information about anthrax vaccine...
➢ The FDA-licensed dosing schedule is 0-2-4 weeks, 6-12-18 months, plus annual boosters, given subcutaneously.
➢ Injection site reactions, like burning, redness and swelling are common. Local reactions occur in 30% of men and 60% of women. Anthrax vaccine can cause a lump under the skin where injected. These lumps can last a few weeks, but they go away on their own.
➢ Systemic reactions, such as headaches or a fever, are less common than injection-site reactions. These occur at rates similar to other vaccines: 5% to 35%.
➢ Report adverse events to the Vaccine Adverse Event Reporting System (VAERS). Get VAERS forms at www.vaers.org or call 800.822.7967. Healthcare workers and vaccine recipients are encouraged to report via VAERS any severe events within 30 days of vaccination, that require medical treatment and/or interfere with work or recreation. DoD requires healthcare workers report adverse events that cause hospitalization or loss of work for 24 hours or more.

Who should not get anthrax vaccine?

✓ Some people should not get anthrax vaccine or should wait:

- People who had a serious allergic reaction or other serious reaction to a prior dose
- People who have a moderate or severe illness
- Women who are pregnant
- People with a possible history of latex sensitivity
- HIV-infected and immune-suppressed people
- People who had Guillain-Barré Syndrome (GBS)
- People who recovered from anthrax infection

✓ You can request an evaluation for a medical exemption from your provider. If you or your provider need assistance with medical exemption questions, the Vaccine Healthcare Center (VHC) is available for consultation services or referral for a second opinion.

What side effects can I expect?

✓ A burning sensation may occur immediately after getting anthrax vaccine and can last about a minute.

✓ Like other vaccines, anthrax vaccine may cause soreness, redness, itching, and swelling at the injection site.

✓ Up to 30% of men and 60% of women report small local reactions, but these reactions usually last only a few days. A lump at the site occurs commonly, up to 50% of the time, lasting for a few weeks.

✓ Larger injection-site reactions occur in about 1% to 4% of vaccinees.

✓ Beyond the injection site, 5% to 35% may notice such symptoms as muscle or joint aches, headaches, rashes, chills, low-grade fever or nausea. These symptoms usually go away in less than a week.

✓ Any vaccine, like any prescription drug, can cause serious reactions including those requiring hospitalization or medical care. Severe allergic reactions occur less than once per 100,000 doses.

How many shots will I get?

✓ The FDA-licensed schedule for anthrax vaccine is 6 doses given over 18 months: 0-2-4 weeks, 6-12-18 months, plus annual boosters. Six doses are needed for full protection. Do not get a dose earlier than your due date. If your risk of exposure to anthrax changes, we will reconsider the need for you to continue vaccination.

U.S. Department of Defense 5 April 05

See also

- Anthrax

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    Docket No. 1980N-0208
    Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Anthrax Vaccine Adsorbed; Final Order.
    AGENCY: Food and Drug Administration, HHS.
    ACTION: Notice.
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External links

- Official U.S. Department of Defense web site (http://www.anthrax.osd.mil/) for AVIP.
- Vaccination Timeline (https://web.archive.org/web/20070928014609/http://www.estripes.com/article.asp?section=104&article=39847&archive=true) at Stars and Stripes.
- The Military Vaccine Resource Directory (https://web.archive.org/web/20071008042434/http://www.mvrd.org/AVN/timeline.html) maintained by Kathryn D. Hubbell (https://web.archive.org/web/20061210070637/http://www.mvrd.org/showpage.cfm?ID=25), former Air Force parent.
- Q&A from the Navy (https://web.archive.org/web/20030321034454/http://www-nehc.med.navy.mil/prevmed/epi/AVIP%20Q%26A%2027Jun02.doc) regarding anthrax vaccination from 2002.

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