

**U.S. DISTRICT COURT ISSUES INJUNCTION;
DoD TEMPORARILY STOPS ANTHRAX VACCINATIONS;
FDA RULES ANTHRAX VACCINE PROTECTIVE REGARDLESS OF ROUTE**

31 Dec 03

POLICY

What is DoD's current anthrax vaccination policy?

The Department has stopped giving anthrax vaccinations until the legal situation is clarified. To continue protecting troops against the lethal threat of anthrax, DoD hopes this temporary pause or interruption in giving anthrax vaccinations is short. However, although shots are on hold for now, the Anthrax Vaccine Immunization Program (AVIP) has not been cancelled.

What did the US District Court do?

On 22 Dec 03, the United States District Court for the District of Columbia issued a preliminary injunction against the current operation of the AVIP. Safety of the vaccine is not the focus of the injunction. The judge ruled based on concerns about the completeness of the Food and Drug Administration's (FDA) process to approve the vaccine for use against inhalational anthrax.

What is FDA's position about the effectiveness of anthrax vaccine?

For years, FDA has held that anthrax vaccine prevents anthrax, regardless of the route of exposure. On 30 Dec 03, the FDA codified this position in a "Final Rule and Order" that is scheduled to be published in the Federal Register on 5 Jan 04. The FDA press release appears at: www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html. The full text of the FDA final rule appears at www.fda.gov/OHRMS/DOCKETS/98fr/80n-0208-nfr0001.pdf.

What is DoD doing in response to the court injunction?

The Department of Justice has filed several motions on behalf of DoD in response to the preliminary injunction recently granted by the U.S. District Court. One motion requests the injunction be limited to the six plaintiffs. Another requests the injunction be vacated based on the FDA's ruling of 30 Dec 03. Questions regarding the litigation itself should be addressed to the Department of Justice.

DoD is committed to protecting American troops and continues to feel that anthrax vaccinations provide the best protection against a lethal weapon. Anthrax vaccinations are the best round-the-clock measure to protect our troops.

Why can't you allow personnel to choose voluntarily to be vaccinated?

The implications of the judge's order would preclude anthrax vaccinations except under the extremely detailed and time-consuming requirements of the FDA's "investigational new drug" provisions. DoD does not consider anthrax vaccine an investigational drug to protect the troops. Because of this, voluntary anthrax vaccinations are not available at this time.

When will anthrax vaccinations under this policy stop?

We have already given the order to cease providing the vaccination.

What about all those people who received anthrax vaccinations in the past? Will they be allowed to continue the six-dose series?

The Department will stop giving anthrax vaccinations until the legal situation is clarified.

What happens to those of us who have received several doses and cannot continue the series?

Individuals who already started the series will be in deferral and not receive further doses at this time. There is no reason for concern that stopping the anthrax series will cause you any harm. The concern is that your immunity level will not increase because of delayed doses. However, at such a time that anthrax vaccine is reintroduced to your body (you get your next dose), published evidence shows that your body has a good immune memory and will have a good antibody response. Each dose of anthrax vaccine is like walking up a set of stairs. You may remain on one step longer than originally planned, but the next dose of vaccine will resume development of protective immunity (climbing further up the stair case).

What happens to those individuals who were court-martialed or given non-judicial punishment for refusing to take anthrax vaccine?

This is a matter for appeals processes and the Board for the Correction of Military (or Naval) Records.

How many servicemembers have been vaccinated?

We have vaccinated over 1 million service members since the beginning of the AVIP program in March 1998. Since June 2002, when the program was re-initiated after it had been slowed down because of a period of constrained vaccine supply, we have vaccinated over 600,000 service members.

Does DoD experiment on service members or use them as "guinea pigs"?

Absolutely not. The purpose of military vaccination programs is to keep our troops healthy and help them return home safe.

Do you still intend to vaccinate the total force over the long term?

Those plans are dependent upon a number of factors. In the near-term, however, we want to protect our personnel at higher risk whose performance is essential for certain mission critical capabilities. Immunizations may be expanded at a future date to provide similar protection as the threat demands and existing supplies allow. Over the long term, our goal is to have an easily administered vaccine, which utilizes the latest technology and is easily scalable to produce large quantities. We are working together with the Department of Health and Human Services and private industry to produce such a “next generation vaccine.”

COURT CASE

What was the court ruling regarding anthrax vaccinations?

Six anonymous men and women are suing the Secretaries of Defense and Health & Human Services (HHS) and the Commissioner of Food & Drugs in the U.S. District Court for the District of Columbia. The six allege anthrax vaccine is an investigational new drug (IND) according to Title 10 United States Code section 1107, necessitating informed consent before vaccination. DoD, HHS, and FDA respond that the FDA has determined that because the approved label is nonspecific as to route of exposure to anthrax spores, it includes inhalation exposure; consequently, informed consent is not required. On December 22, 2003, Judge Emmet G. Sullivan ordered a preliminary injunction. He wrote: “In the absence of a presidential waiver [of informed consent], defendants [DoD, HHS, FDA] are enjoined from inoculating service members without their consent....”

Does the Department of Defense agree with the ruling?

DoD will comply with the law. DoD will take appropriate action to protect service members against the lethal threat of anthrax attack. DoD hopes a legal remedy will permit resumption of anthrax vaccinations as soon as possible.

Is DoD considering appeals or requests to the President or other remedies?

DoD is considering all its options and is acting vigorously to resume anthrax vaccinations as soon as possible. The interests of the Department of Defense are represented in court by counsel from the Department of Justice (DoJ). Questions about the litigation itself should be directed to the Department of Justice.

What was the basis of the ruling?

The District Court ruling questions the legal status of anthrax vaccine when used to protect individuals against inhalational anthrax. Safety of the vaccine is not the focus of

the ruling. The FDA's official position regarding the licensed uses of anthrax vaccine appear in a "Final Rule and Order" scheduled to be published in the Federal Register on 5 Jan 04. The FDA press release appears at: www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html. The full text of the FDA final rule appears at www.fda.gov/OHRMS/DOCKETS/98fr/80n-0208-nfr0001.pdf.

PROTECTION

What is the threat of anthrax used against our military?

Anthrax is an attractive weapon of mass destruction for our enemies. It is highly lethal, relatively easy to produce in large quantities and to develop as a weapon, easily spread in the air over a large area and it can be stored and remain dangerous for a long time. For this reason, anthrax may be the most important biological warfare threat facing U.S. forces. The intelligence community believes several countries currently have or are developing an offensive biological warfare capability using anthrax. Given the ease with which anthrax can be produced, U.S. forces may have little or no warning before an anthrax attack, which could be delivered by unconventional means.

How will DoD ensure people are protected against weaponized anthrax during this interruption in vaccinations?

DoD is concerned about the health and safety of all service members, including those assigned or deployed in high threat areas. That is why it is important to use the other pillars of Force Health Protection including protective masks and suits, detection equipment, ongoing surveillance and intelligence gathering and stockpiling antibiotics in the event of exposure.

Why doesn't DoD use antibiotics rather than anthrax vaccine?

There is no better round-the-clock protection against anthrax infection than the anthrax vaccine. Antibiotics are effective when started immediately or very soon after exposure. However, not all exposures can be predicted in advance or even determined in very early stages, particularly in certain military situations. In such situations, the consequences for military personnel and their mission could be dire. This is not a risk we can afford to take. DoD therefore believes the best method to ensure the safety and protection of the force is to vaccinate ahead of time.

Does anthrax vaccine protect people against inhalational anthrax?

Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is effective against inhalational anthrax.

Is anthrax vaccine safe?

Yes. The DoD shares the repeated findings of the FDA, the National Academy of Sciences, and numerous other authoritative experts that anthrax vaccine is safe.