

FDA states: Anthrax vaccine is safe

SCOTT AIR FORCE BASE, ILL. — Partial truths, misinformation and misinterpretation about anthrax immunization are driving some people to make career-altering decisions based on fear, rather than fact.

People need the facts on this critical force protection issue. The facts are: Anthrax is the most likely biological weapon and poses a real threat to our forces, especially in certain high-risk theaters of operation. Anthrax, as a biological weapon, is nearly 100 percent lethal. The anthrax vaccine is safe and effective. Given these facts, failure to immunize our troops would be unconscionable.

How do you know this vaccine is safe?

Anthrax vaccine has been proven safe during more than 29 years of use. The Food and Drug Administration, which has the strictest quality criteria of any industrialized country, has repeatedly verified that anthrax vaccine is safe and effective.

Every vaccine lot is tested for sterility, safety, purity and potency before distribution.

In her written congressional testimony, Dr. Kathryn Zoon, director of the FDA's Center for Biologics Evaluation and Research stated, "We believe anthrax vaccine is a safe and effective vaccine for the prevention of anthrax disease — an often-fatal disease.

"Our confidence in this vaccine, like all vaccines, is based upon four components: first, the clinical trials and subsequent clinical laboratory experience with the vaccine; second, ongoing inspections of the manufacturing facility; third, our lot release requirements; and fourth, our ongoing collection of adverse event reports.

"We will continue our efforts in all four of these areas, with the anthrax vaccine and all vaccines, to assure that only safe products are on the market."

Rumors say the vaccine stockpile is contaminated; how do you know this isn't true?

No valid scientific or even circumstantial evidence exists to support those rumors. Every lot is inspected and evaluated for sterility, safety, purity and potency. Testing is done at the manufacturer and sometimes the FDA as well. At Defense Department's request, additional testing with independent verification

started in January 1998 on all stockpiled vaccine lots.

Aren't a lot of people having serious adverse reactions to the vaccine?

Although one Air Force base is reporting a larger number of possible reactions than expected, across the Department of Defense, the number of side effects is very small, and mostly very minor.

The intense focus and increased media coverage makes the number seem much higher than it is. Any vaccine can cause some people to have adverse reactions. Even vaccines we give our children produce some adverse reactions.

This vaccine is no different, but the numbers are smaller than most other vaccines and very few serious reactions have occurred.

The FDA has a reporting system to track unexpected adverse reaction and rapidly recall vaccines. This Vaccine Adverse Event Reporting System is a nationwide system, not a military one.

Providers or patients may access this system to report reactions directly to the FDA. Although never intended to report all reactions, it works as an early warning system.

A team of civilian medical experts reviews these reports every four to six weeks, looking for trends or any indication that a vaccine may be causing an unexpected or severe reaction.

As of Oct. 20, only 362 adverse reaction reports have been filed on almost 1.2 million shots given to more than 350,000 people. Of the 98 serious reactions (loss of duty greater than 24 hours or hospitalizations) only 64 have been judged by the expert panel to most probably be due to the vaccine. This is a rate of well less than .1 percent.

Anthrax in a nutshell

Anthrax is a vaccine, just like other vaccines. It protects against a bacteria just like typhoid, tetanus, diphtheria and many other vaccines. It just happens to be a bacterium that not only occurs naturally but also can be



concentrated and used as a biological warfare agent.

All vaccines have some side effects. Usually these reactions are local and mild inflammatory reactions. Sometimes they are allergic and, rarely, are they severe. When looking at the reaction statistics for other vaccines, it becomes clear that anthrax has very low rates of reaction. For example, re-immunization with injectable typhoid vaccine causes tenderness in 98 percent of those immunized, feverish feeling in 4 percent of those vaccinated, malaise (a generalized feeling of illness) in 24 percent, headache in 11 percent and some type of pain in 56 percent.

These rates are much higher rates than anthrax, yet we take it willingly. DPT, a vaccine most people routinely give their children, causes a certain small percentage of those immunized to have reactions ranging from fever to severe neurological disease, and behavioral changes. We take vaccines and we give them to our children because the risks from vaccination are minor compared to the risks from the disease.

The bottom line: Anthrax kills. The anthrax vaccine protects — and it's much safer than many routine immunizations. That's why medics, commanders, senior leaders and others who have researched the scientific facts have lined up to take this shot.

"Anthrax vaccine has been proven safe during more than 29 years of use."

—The Food and Drug Administration