

COMMENTS ABOUT ANTHRAX VACCINE

SAFETY AND EFFECTIVENESS

“The committee finds that the available evidence from studies with humans and animals, coupled with reasonable assumptions of analogy, shows that AVA [anthrax vaccine adsorbed] as licensed is an effective vaccine for the protection of humans against anthrax, including inhalational anthrax, caused by all known or plausible engineered strains of *B. anthracis*.”

Institute of Medicine Report: *The Anthrax Vaccine: Is it Safe? Does it Work?* Washington, DC: National Academy of Sciences, March 6, 2002.

“The committee found no evidence that people face an increased risk of experiencing life-threatening or permanently disabling adverse events immediately after receiving AVA, when compared with the general population. Nor did it find any convincing evidence that people face elevated risk of developing adverse health effects over the longer term, although data are limited in this regard (as they are for all vaccines).”

Institute of Medicine Report: *The Anthrax Vaccine: Is it Safe? Does it Work?* Washington, DC: National Academy of Sciences, March 6, 2002.

“The range of reported side effects experienced by recipients of the anthrax vaccine are in line with previously published reports and compatible with similar vaccines. There are no convincing data demonstrating long-term adverse health impacts to recipients of anthrax vaccine, although additional studies are in progress.”

Armed Forces Epidemiological Board (AFEB), civilian physicians and scientists advising the Surgeons General, report of March 1, 2002.

“The Food and Drug Administration's approval to resume production of the anthrax vaccine is welcome news for our fight against bioterrorism. For more than 30 years, the anthrax vaccine has been a safe and effective way to protect people from this deadly disease. Health officials did the right thing in providing vaccine to Congressional and postal workers. Anthrax spores can remain in the lungs for extended periods.”

Louis W. Sullivan, M.D., President of the Morehouse School of Medicine, former Secretary of Health and Human Services from 1989-93, as published in *New York Times*, February 10, 2002.

"Evidence indicates that this vaccine is effective in preventing cutaneous and inhalational anthrax; it is recommended for laboratory workers who routinely work with *B. anthracis* and workers who handle potentially contaminated industrial raw materials. It may also be used to protect military personnel against potential exposure to anthrax used as a biological warfare agent. Annual booster injections are recommended if the risk of exposure continues."

James Chin, MD, MPH, Editor, *Control of Communicable Diseases Manual*, 17th Edition, 2000.

"The AFEB was concerned and somewhat surprised at the criticism surrounding the program given the high level of professionalism that had characterized this effort. ... Anthrax vaccine is a fully licensed FDA vaccine. The vaccine does cause local side effects, but has an excellent safety profile. The Anthrax Vaccine Immunization Program has carefully tabulated person-specific immunization data and has assiduously investigated reported complications associated with receipt of anthrax vaccine. These data have been regularly reviewed by the board and attest to the safety of the vaccine."

Armed Forces Epidemiological Board (AFEB), civilian physicians and scientists advising the Surgeons General (<http://www.tricare.osd.mil/afeb/>), report of March 29, 2000.

"I think what we can talk about is the vaccine and the studies that have been done to show both its safety and efficacy, and the FDA has been involved in those studies, and it is on that basis that we can say the vaccine is safe, and it's also effective."

David Satcher, MD, PhD, former Surgeon General of the United States, to U.S. House of Representatives Committee On Government Reform, August 3, 1999.

"The only known effective prevention against anthrax is the anthrax vaccine. Treatment of cutaneous anthrax infection involves administration of antibiotics. In the case of pulmonary anthrax infection, therapy has been of limited benefit, except when given immediately after exposure."

Later, **"Mr. Chairman, 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.”

Kathryn C. Zoon, Ph.D., Director, Center For Biologics Evaluation And Research (CBER), Food & Drug Administration (FDA), To U.S. House of Representatives Subcommittee on National Security, Veterans Affairs and International Relations Committee on Government Reform, Hearing on DoD’s Anthrax Vaccine Immunization Program, April 29, 1999.

“Mr. Chairman, we are aware that some people question the safety and efficacy of the anthrax vaccine. Let me be clear. We believe that for persons at high risk the licensed anthrax vaccine is safe and effective for the prevention of the often-fatal anthrax disease.”

Kathryn C. Zoon, Ph.D., Director, Center for Biologics Evaluation and Research (CBER), Food & Drug Administration (FDA), to U.S. House of Representatives Committee on Government Reform Subcommittee on National Security of Veterans Affairs and International Relations, Hearing on Anthrax Vaccine, April 29, 1999.

“Killed anthrax vaccines appear to be effective in reducing the risk of contracting anthrax with a relatively low rate of adverse effects. Further research should be restricted to testing new vaccines only.”

The Cochrane Collaboration, internationally respected group of scientists who apply principles called evidence-based medicine (<http://www.cochrane.org>), “The Effectiveness and Safety of Vaccines Against Human Anthrax: A Systematic Review,” *Vaccine* 1998; volume 16: pages 880-884.

THREAT

“Anthrax represents the primary biological warfare threat to United States forces and interest. It is the most widely adopted agent in foreign biological warfare programs. An attack will likely come with little to no warning with potential catastrophic impact. Because of this, anthrax deserves its reputation as an effective and deadly biological warfare agent.”

Rear Admiral Lowell Jacoby, United States Navy, Director of Intelligence, Joint Staff J2, to Senate Committee on Armed Services, Hearing on the Anthrax Biological Warfare Threat, April 13, 2000.

CONGRESSIONAL SUPPORT

“And in my view, there’s no question when you move into an area of possible risk with anthrax that you should vaccinate.”

Later, “I’ve supported this program from that—from my perspective, my training and what I know about the disease. I think it would be unconscionable for us to knowingly allow our troops to be at risk from a credible, military threat of weaponized anthrax simply because misinformation and fear have seized control of this issue.”

Senator Wayne Allard, a veterinarian, U.S. Senate Armed Services Committee, Hearing to Review the DoD Anthrax Vaccine Immunization Program, April 13, 2000.

COMMENTS FROM THE TROOPS

“I view the anthrax vaccine is similar to any other force protection measure that I receive or use. I may not need the protection every day, but I never know when I’ll need it. Consequently, for my safety and the safety of my teammates, I want all the protection I can get.”

Later, “From my personal standpoint, and what I’ve observed in my team, taking the anthrax vaccine has not been an issue. I’m aware that there is information out that attempts to discredit this vaccine, however, I’m also aware that this is an FDA-approved vaccine and has been used successfully for years.”

Lieutenant (Junior Grade) Chris Rohrbach, United States Navy, Assistant Officer in Charge, Bravo Platoon, Special Warfare Group 8, Little Creek Virginia, to U.S. House Armed Services Subcommittee on Military Personnel, Hearing on the Anthrax Vaccine Immunization Program, September 30, 1999.

“I believe it’s [the threat’s] very real. In fact, I’d feel very uncomfortable going into, going in harm’s way with a teammate of mine that hasn’t been vaccinated against the anthrax. That is one more casualty I’ll have to worry about. If he gets vaccinated for anthrax, that’s, as far as I’m concerned, that’s one less thing that I need to worry about.”

Lieutenant James Randall, United States Navy, Head, Training Department, Special Warfare Group, to House Armed Services Subcommittee on Military Personnel, Hearing on the Anthrax Vaccine Immunization Program, September 30, 1999.