

ANTHRAX VACCINE

The disease anthrax is caused by spores which may enter the body through ingestion, inhalation or through the skin. The spores occur naturally in the soil. The potency of anthrax spores does not diminish over time. Most cases of human anthrax infection occur through handling infected animals or animal products. The anthrax vaccine was originally developed to protect livestock, people who work with animal hair or hides and veterinarians. Due to advances in vaccine availability, development of antibiotics and quarantines, incidence of anthrax in both humans and animals has dropped since the 1950s. (IOM, *Gulf War and Health, Volume 1*)

Anthrax Chronology by Alan Milstein: <http://www.sskrplaw.com/vaccine/anthchrono.html>

Military Perspective – First known use of Anthrax as a biological weapon was against the Chinese by the occupying Japanese army in the 1930s. In response, the United States, Canada and the United Kingdom developed and experimented with anthrax weapons in 1941. After signing the Biological and Toxic Weapons Convention in 1972, the US stopped development of anthrax weapons.

The Vaccine: Although some form of Anthrax vaccine has been used since 1881, when Louis Pasteur developed the first successful vaccine for veterinary purposes, there are still many questions and problems about its use:

- Several formulations have been developed; some have proved fatal to recipients, others ineffective at preventing disease.
- The anthrax vaccine approved by the FDA is only for skin-contact (cutaneous) exposure; inhalation and ingestion exposures remain unprotected. Ingestion anthrax is rare, but inhalation anthrax seems like a more logical delivery for a bioterrorist to use than cutaneous delivery. The FDA eventually approved the same vaccine for all forms of anthrax, leaving many to doubt the entire process of FDA approval.
- For the 150,000 troops who were inoculated against anthrax in 1990-91, records kept by the DOD were incomplete and inconsistent. Therefore, there is no record to show who received the DOD vaccine, when it was given, or which lots of vaccines were used. According to the DOD, records were not kept due to a mistaken belief by some military healthcare providers that the anthrax vaccine was a classified matter;
- Some lots of the vaccine may have been contaminated;
- Some shot recipients did not deploy to the Persian Gulf, but did develop illnesses similar to other veterans who had shots and other toxic exposures in theater;
- Hundreds of service personnel have reported adverse reactions, some severe and life threatening;
- There have been no studies regarding the long-term effects of the anthrax vaccine.
- The DOD contracts with one company, Emergent BioSolutions, Inc., which has had issues meeting FDA standards at their production facility.

Mandatory Vaccination: In 1998, DOD made the vaccine program mandatory for all 2.4 million active duty, reserve, and guard troops. This program is still highly controversial for the reasons listed above. From the beginning of the order, military personnel have refused to take the shots, and many more resigned or retired rather than face it. For reports of current refusals, see http://www.prisonplanet.com/articles/september2007/170907_b_anthrax.htm and <http://www.washingtonpost.com/ac2/wp-dyn/A28133-2004Mar26>.

Synthetic Squalene: Another issue results from the DOD's damaged credibility over the issue, the possibility that an experimental delivery substance (adjuvant) was used. General Accounting Office (GAO) records indicate that the DOD may have used synthetic squalene in the vaccine. The DOD denies tampering with the vaccines. The synthetic additive is not FDA approved. This matter remains under investigation.

Reactions: Following are a few of the more than 2000 documented short term adverse reactions reported by recipients of the anthrax vaccine:

- extreme fatigue;
- local pain at the injection site with swelling and pain extending into other parts of the body;
- muscle and body weakness;
- dizziness;
- heart failure;
- nausea and vomiting;
- fever;
- blurred vision; and
- general malaise.

Documented long-term side effects reported by some recipients of the anthrax vaccine include:

- extreme fatigue;
- concentration and memory impairment;
- dizziness;
- joint and muscle pain;
- nausea;
- muscle and body weakness;
- blurred vision; and
- general malaise.

Status of Investigations and Epidemiological Research – On 29 June 2002, the Assistant Secretary of Defense for Health Affairs, Dr. William Winkenwerder announced the resumption of mandatory anthrax vaccine shots for service members after a year hiatus caused by a quarantine of contaminated lots and a pending FDA approval for the manufacturer's facility license. After the shots resumed in earnest in November/December 2002, the NGWRC received several calls per week from troops, their family members, or the media, on the third major military use of anthrax shots (Anthrax Vaccine Adsorbed, or AVA). This ongoing issue remains unresolved for many veterans and military personnel.

The following subtopics report on developments in important areas relevant to anthrax shot concerns of Gulf War veterans, their families, and current service members.

Lawsuits:

Ruling against military personnel who refused to take the anthrax shot because of its inappropriate FDA classification, 2004:

<http://query.nytimes.com/gst/fullpage.html?sec=health&res=9A06E0DB1131F93BA35752C0A9629C8B63>.

Groups with severe illness after receiving anthrax shot: <http://www.sskrplaw.com/publications/newguinea.html>

A Qui Tam (whistleblower) lawsuit against the manufacturer for making false claims about the anthrax vaccine that caused personal harm to the plaintiff's job: <http://www.pubklaw.com/rd/courts/03-1841.pdf>,
http://www.arentfox.com/publications/index.cfm?fa=legalUpdateDisp&content_id=1064.

Press Coverage: Press coverage regarding problems within BioPort, the sole US manufacturer of the vaccine is available at <http://www.wired.com/politics/law/news/2001/10/47410#>. Background information on Bioport can be obtained at <http://educate-yourself.org/vcd/vcdanthraxvacsanfu10oct01.shtml>.

Petition to the FDA: On October 12, 2001, several key opponents of the Anthrax Vaccine Immunization Program (AVIP) policy (service members, attorneys and a retired FDA official) filed a petition with the FDA to declare the vaccine unsafe, misbranded, or ineffective, as well as adulterated and experimental given the DOD's use for inhalation exposure. Additionally, the petition requested the FDA enforce its regulations prohibiting distribution of an adulterated product to government or commercial markets and to revoke the manufacturer's license for such violations. <http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/cp00001.pdf>

In their October 2002 response to the petition, FDA admitted the current vaccine's license is improper and that the FDA had not enforced its own regulations. In spite of these glaring admissions, the FDA refused to grant any of the petitioner's requests, thus setting the stage for an appeal or action in federal court, both of which are currently under consideration. <http://www.fda.gov/OHRMS/DOCKETS/dailys/02/Sep02/091102/80027a9f.pdf>

There is also a petition to BioPort to destroy quarantined stock of the vaccine:

<http://www.petitiononline.com/robi2662/petition.html>. More information at:
<http://www.mvrd.org/AVN/fdahal~1.htm>.

VA Developments: On 14 May 2002, the VA General Counsel issued a legal finding specifically establishing service-connected disability solely for the anthrax vaccine by redefining the meaning of the word "injury":
http://www.va.gov/ogc/docs/2002/PREC_4-2002.doc.

Citation: If evidence establishes that an individual suffers from a disabling condition as a result of administration of an anthrax vaccination during inactive duty training, the individual may be considered disabled by an "injury" incurred during such training as the term is used in 38 U.S.C. § 101 (24), which defines "active military, naval, or air service" to include any period of inactive duty training during which the individual was disabled or died from an injury incurred or aggravated in line of duty.

Consequently, such an individual may be found to have incurred disability in active military, naval, or air service for purposes of disability compensation under 38 U.S.C. § 1110 or 1131.

Several cases of Gulf War and post-Gulf War veterans are being awarded disability ratings that indicate the VA is following through on its position.

Shot Reactions: Approximately 2000 reactions to the anthrax shot have been filed with the FDA's Vaccine Adverse Event Reporting System, or VAERS. These reactions, filed mostly by service members from 1998-2001,

make the anthrax vaccine the most reactogenic shot in use. Additionally, the vaccine's package insert published by the manufacturer (Bioport), no longer claims a systemic reaction rate of .2%, but acknowledges it could be as high as 35%. The insert also lists nearly 60 different types of reactions and 6 deaths associated with the shot. See <http://www.fda.gov/cber/label/biopava0131022LB.pdf>. [Not sure if this is documented properly – PSG]

Other FDA Developments: The FDA approved the vaccine for use against all forms of anthrax, inhalation, ingestion and cutaneous: <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-24223.pdf>. However, the 1/31/02 information on BioThrax mentions only cutaneous exposure: <http://www.fda.gov/cber/label/biopava0131022LB.pdf>.

GAO/Congress: Dr. Sue Bailey, Assistant Secretary for Health Affairs, Department of Defense, reported to House Subcommittee on National Security, Veterans' Affairs and International Relations of the Committee on Government Reform, March 24, 1999: http://www.avip2001.net/DOCS/106_17.pdf. She participated in a press conference: http://www.fas.org/spp/starwars/program/news00/t02172000_t0217asd.htm. She was recently named to the Board of Directors of BioPort – June 14, 2007: <http://www.smartmoney.com/ws/briefingbooks/doPrint.cfm?page=executives&origin=wsj&symbol=EBS&type=usstock>.

Women's/Birth Issues: Early in the AVIP program, the Army injected 600 medical workers at its Tripler Army Medical Center in Hawaii with the anthrax shot. Statistics there showed women getting reactions at twice the rate of men. The Army's top immunologist declared at a May 1999 Ft. Detrick meeting that attendees might regret pushing this vaccine given the women's immune system differences. This warning became reality as the September 2001 issue of *Self* magazine documented several severe cases of women's reactions.

Also in 1999, three congresswomen wrote Secretary of Defense Cohen requesting shots be made voluntary for women (<http://www.anthraxvaccine.org/congwom.htm>).

These concerns were further verified when *The Wall Street Journal* and *Army Times* published stories on preliminary Navy studies indicating problems for women: <http://www.ph.ucla.edu/epi/bioter/anthraxvacbirthdefects.html>

Synthetic Squalene: Some Gulf War veterans have long suspected the use of this experimental adjuvant in the anthrax shot is the root cause of their ailments. Dr. Pamela Asa and colleagues created a test to detect antibodies to squalene and discovered all sick Gulf War veterans had these antibodies, while none in the control group had the antibodies. Several GAO reports indicated that squalene issues could be resolved given more cooperation from the Pentagon that was not forthcoming. After years of total denial about squalene, the FDA discovered squalene in all eight anthrax lots tested in 1999. This information was revealed in a House Government Reform Committee hearing on 3 October 2000 in a 3-year report from Representative Metcalf (State of Washington) who was retiring. The *Washington Times* weekly news magazine "Insight on the News" covered the entire history of the squalene controversy, containing this poignant statement by an unnamed FDA official:

"Something is wrong when we find a contaminant in the vaccine [lots tested] that shouldn't be there," an FDA official tells Insight. "That tells me an investigation should have been launched. It wasn't, because of pressure, and that's not right; this vaccine should not be used until DOD finds out how squalene got into those tested batches, whether other batches are contaminated and what are the health consequences from the contamination."

In a recent bizarre twist to this issue, deploying British service members dumped thousands of anthrax vaccine vials overboard as they proceeded to the current Iraqi conflict. Some of those vials of new production lots got tested for squalene and came up positive. Given this irrefutable proof of experimentation above and beyond the Asa squalene antibody presence in sick British Gulf War veterans, there can no longer be any doubt that squalene was indeed put into their bodies without their permission. The new U. S. lots should also be tested for squalene, and the FDA indicated in a letter to Representative Metcalf that this could be done. However, neither the Congress nor the DOD have followed up on this offer that would clear up the question of squalene presence. http://www.jamesmadisonproject.org/press.php?press_id=6

The NGWRC continues to take every opportunity to shine the light on this vaccine, hoping to attain recognition, diagnosis, and treatment for Gulf War veterans, and better force protection for the future.

Other Resources:

http://anthraxvaccine.blogspot.com/2007_07_01_archive.html#6806076506901379532;

<http://www.gulfwarvets.com/anthrax.htm>, <http://www.thepowerhour.com/articles/anthrax.htm>

For legal arguments, see: <http://www.law.duke.edu/shell/cite.pl?50+Duke+L.+J.+1835#H1N7>.

What the DOD says: <http://www.anthrax.mil/whatsnew/FDAorder.asp>