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Department of Defense Anthrax Vaccination

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Summary

The Department of Defense (DOD) intends to immunize 1.4 million active duty and 900,000 Selected Reserve personnel against anthrax. The vaccine, approved by the Food and Drug Administration (FDA), has been in use since 1970. About 455,000 personnel have started the vaccination series, and, according to DOD, at least 442 have refused the vaccine. DOD deems the immunization to be mandatory, and active duty personnel who have refused have been subject to administrative discharge or court martial for failure to obey a lawful order. Some Reserve and National Guard personnel have resigned rather than take the vaccine. Legislation was introduced in the 106th Congress to delay the program pending further research (H.R. 2543, H.R. 2548), however these bill have not been reported from committee. Congress also addressed the anthrax vaccination program in the DOD FY2001 Authorization Act (P.L. 106-398, Sec. 217, 218, 751), establishing a broad range of reporting requirements and monitoring efforts.

Questions have been raised about the vaccine's efficacy against all forms of anthrax, possible long-term adverse effects, the reliability of the adverse reaction reporting system, the reliability of the manufacturer, and DOD's contractual arrangements with the manufacturer. The House Government Reform Committee and its Subcommittee on National Security, Veteran's Affairs, and International Relations; the House Armed Service's Military Personnel Subcommittee; and the Senate Armed Services Committee have held hearings, with representatives from DOD, the Food and Drug Administration (FDA), and the General Accounting Office (GAO). Members of the military who believe their anthrax vaccination caused a variety of medical ailments, and members who refused the vaccination and received disciplinary action or chose to leave the service also testified. The House Committee on Government Reform has also issued a report prepared by the majority staff summarizing its conclusions regarding the program.[1]. The Department of Defense and the U.S. Food and Drug Administration continue to maintain that the vaccine is safe and the most effective medical protection currently available against anthrax, and that adverse reactions to the vaccine remain at a lower rate than other widely-administered vaccines.

This report will not be updated, unless there are significant new developments.

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[1] *The Department of Defense Anthrax Vaccine Immunization program – Unproven Force Protection*, House Committee on Government Reform. February 17, 2000. [http://www.house.gov/reform/]

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Department of Defense Anthrax Vaccination

On December 15, 1997, the Department of Defense announced plans to vaccinate all active duty personnel against anthrax, a highly lethal disease caused by the bacterium *Bacillus Anthracis*. At least 10 countries are suspected of having developed or trying to develop anthrax as a biological weapon. In testimony before the Senate Armed Services Committee, the Joint Chiefs of Staff Director of Intelligence identified seven of these countries: Russia, China, Iran, Iraq, Libya, North Korea, and Syria.[2]

The vaccinations began in March 1998 with an advance program for the 48,000 troops assigned to the Persian Gulf region. On May 18, 1998, Secretary Cohen approved the total force vaccination program, and the full program began in September with troops in Korea being a priority. It was expected to take about seven years to vaccinate all 1.4 million active duty and 900,000 Selected Reserve personnel, however difficulties in obtaining sufficient supplies of vaccine will probably extend this estimate.[3] Prior to this program over 3,000 civilian and military personnel associated with DOD's biological warfare defense activities were routinely vaccinated. An abbreviated immunization series of injections was also given to about 150,000 troops deployed to Southwest Asia during the Persian Gulf conflict in 1990-91.[4]

The U.S. Food and Drug Administration first approved the vaccine for use in 1970. Anthrax primarily infects grazing animals, such as sheep and cattle, and the vaccine is given to veterinarian and livestock workers who are at risk from exposure to the disease. The full immunization process currently involves six injections delivered over 18 months, followed by annual booster shots. If the vaccination series is interrupted, the FDA does not require re-starting the series from the beginning, but rather approves continuing with the remaining shots. This is in keeping with the recommendation of the Centers for Disease Control and Prevention's Advisory Committee for Immunization Practices. The vaccine does not contain live *Anthracis* bacteria; it is a "killed bacteria" vaccine.

As of July 2000, about 447,000 personnel had started the vaccination series. According to DOD data, 442 personnel have refused the vaccination, and have received punishments ranging from a general discharge under honorable conditions to courts-martial resulting in bad conduct discharges for failing to obey a lawful order.

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[2] *Proliferation: Threat and Response,* Department of Defense, November 1997.

[3] Department of Defense *Overview: DOD Biological Warfare Defense Immunization Program.* [http://www.defenselink.mil/other_info/overview.html]

[4] The vaccination series was abbreviated owing to a lack of available vaccine and lack of time prior to deployment.

This is in keeping with DOD policy regarding all FDA-licensed immunizations given to military personnel. The disparity in punishment has received criticism, but DOD maintains that the disciplinary actions remain at the discretion of the local commander, and that no DOD-wide policy will be imposed on the services. Critics of the program maintain that significant numbers of personnel, particularly among the reserves, are choosing to leave the service rather than take the vaccine, and DOD has acknowledged that its records would not reflect those individuals. This has raised concerns over the program's effect on personnel retention and readiness, although DOD maintains that the effect has been minimal. In response to this, the FY2001 DOD Authorization Act (P.L. 106-398) requires a GAO report by April 2002 on the impact of this program on personnel recruitment and retention.

Secretary of Defense Cohen directed that the DOD vaccination program be preceded by:

- Testing, in accordance with FDA standards, to assure the safety, potency, and purity of the vaccine.
- Implementation of a personnel tracking system for those who are vaccinated.
- Operational plans for vaccine administration and for informing military personnel about the program.
- Review of the health and medical issues by an independent expert.

Mitretek Systems Inc. is conducting supplemental testing of vaccine lots previously approved for release by the FDA to assure safety and potency. As discussed below, not all these lots have been re-approved for release, thereby creating a shortage of vaccine that will extend into 2001 (See **Vaccine Production and Testing**). Personnel data on those vaccinated is currently being entered in the Defense Enrollment Eligibility Reporting System (DEERS), and eventually will be entered in a newly developed joint-service Preventative Health Care System for long-term tracking of immunization status.

The independent review of the immunization program was conducted by Dr. Gerard M. Burrows, David Page Smith Professor of Medicine at Yale Medical School and Special Advisor to the President for Health Affairs. He completed his independent review of the anthrax vaccination program on February 19, 1998, concluding that "the anthrax vaccine appears to be safe and offers the best available protection against anthrax as a biological warfare agent" and that, aside from not vaccinating pregnant personnel and those with immune systems deficiency, "there would not seem to be the need for special considerations."[5] There has been criticism, however, that Dr. Burrows is not a specialist in immunology or biological warfare, and consequently the value of his review is limited.

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[5] *Report on the DOD Anthrax Vaccination Program*, Department of Defense. [http://www.defenselink.mil/other_info/burrows.html] ; Testimony of Rear Admiral Lowell Jacoby, Director of Intelligence, Joint Staff before the Senate Committee on Armed Forces, April 13, 2000. [http://www.senate.gov/~armed_services/hearings/2000/c000413.htm]

Concerns about the Anthrax Vaccine Program

The anthrax vaccination program has become a focus of controversy and congressional concern for a variety of reasons. Questions have been raised about the vaccine's efficacy against all forms of anthrax, possible long-term adverse effects, the reliability of the adverse reaction reporting system, the reliability of the manufacturer, and DOD's contractual arrangements with the manufacturer. The House Government Reform Subcommittee on National Security, Veteran's Affairs, and International Relations, the House Armed Services Subcommittee on Military Personnel, and the Senate Armed Services Committee have held hearings, providing testimony from a broad range of witnesses, including representatives from DOD, the Food and Drug Administration (FDA), and the General Accounting Office (GAO). Members of the military who believe their anthrax vaccination has caused a variety of medical ailments, and members who have refused the vaccination and have received disciplinary action or chosen to leave the service have also testified. The House Government Reform Committee has also published a report detailing its National Security Subcommittee's critique of the vaccination program.[6]

Some members of the U.S. Air National Guard and Air Force Reserve have been among the vocal of opponents to the vaccination program, and significant numbers have left the service rather than participate. The General Accounting Office provided preliminary results of a study to the House Committee on Government Reform, indicating that the program was indeed a serious consideration among those pilots leaving the Guard and Reserve.[7]

The Department of Defense and the Food and Drug Administration in their testimony continue to maintain that the vaccine is safe and the most effective medical protection currently available against anthrax. [8] Charles Cragin, Acting Assistant Secretary of Defense for Reserve Affairs has noted that in addition to the FDA, the United Nations World Health Organization, the American Public Health Association, the American College of Physicians, and the National Institutes of Health have endorsed the vaccine.[9]

Vaccine Effectiveness. The controversy over the vaccine's effectiveness centers on its ability to protect against inhalation anthrax and its ability to protect against genetically-engineered strains that could be developed as a biological weapon. Anthrax is naturally most often contracted through cuts or abrasions in the skin which come in contact with contaminated animal products, or through ingestion of contaminated meat. As a biological weapon, however, anthrax is far more likely to be delivered as a spore aerosol that would be inhaled. Critics of the vaccine program

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[6] *Department of Defense Anthrax Vaccine Immunization Program: Unproven Force Protection, H.Rept. 106-556.*
[http://www.house.gov/reform/ns/reports/subcommittee_reports.htm]

[7] Testimony before House Committee on Government Reform, October 11, 2000.

[8] Testimony from these hearings is available on the Subcommittee's website. [http://www.house.gov/reform/ns/hearings/subcommittee_hearing_testimony2.htm]

[9] Department of Defense, American Forces Press Service Release, August 18, 1999.

point out that there is very little data based upon human studies upon which to judge the vaccine's effectiveness against inhalation anthrax.[10] Given that anthrax is a fatal disease, "challenge" studies (i.e. exposing vaccinated subjects to anthrax spores to determine immunity) cannot be performed. Consequently, the only public study involving humans was based upon observation of a limited group of wool workers, and though none of the vaccinated workers contracted anthrax and unvaccinated ones did, the small number of people involved limits the value of the study. DOD's assessment of the vaccine's effectiveness against inhalation anthrax is based upon studies conducted with rhesus monkeys. Dr. Arthur Friedlander, Chief Bacteriologist at the Army Medical Research Institute of Infectious Diseases, has testified that the vaccine protected 95% of the test subject Rhesus monkeys exposed to anthrax doses "hundreds of times greater than the amount that kills an unprotected population."[11] The General Accounting Office has noted, however, that there is inadequate data on correlating the effectiveness of this vaccine in monkeys to its effectiveness in humans.[12] DOD and the FDA are currently working to develop the data required for this correlation.

Concerns have also been repeatedly raised that the vaccine may not protect against all 31 known strains of anthrax, and that it would be possible to develop a genetically engineered strain against which the vaccine would not be effective. On September 30, 1999, Lt. Gen. Robert R. Blanck, Surgeon-General of the Army testified before the House Armed Services Military Personnel Subcommittee that "we have solid evidence that this [vaccine] will protect against all natural strains of anthrax." At the same hearing, Deputy Secretary of Defense Hamre testified "we have no evidence that anyone has genetically engineered an anthrax strain to the point that it can be weaponized and is a threat", but acknowledged that were this to occur there is the possibility that the current vaccine would not be effective. With this in mind, critics of the program insist that the vaccine's possible limitations be openly acknowledged. The vaccination program's supporters maintain that the question of the vaccine's effectiveness against potential new anthrax strains should not overshadow its effectiveness against the current anthrax threat agents.

The Health and Human Services Department, in cooperation with DOD, is currently working to develop an improved anthrax vaccine, and one which could reduce the number of shots required to achieve immunization. Although the FDA-approved protocol currently requires 6 shots, it has been suggested that data supporting this requirement is not conclusive, and that a protocol requiring fewer shots could be approved. The FDA is currently reviewing development of a new protocol.[13]

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[10] House Government Reform Subcommittee on National Security, Veteran's Affairs, and International Relations, Hearing , July 21, 1999. [http://www.house.gov/reform/ns/hearings/testimony/july_21.htm]

[11] U.S. General Accounting Office, *Medical Readiness: Safety and Efficacy of the Anthrax Vaccine.* GAO/T-NSIAD-99-148. p. 4..

[12] Ibid.

[13] Testimony before the House Government Reform Subcommittee on National Security, (continued...)

Vaccine Safety. The manufacturer, the FDA, and DOD maintain that, in the twenty-nine years of administering the vaccine, no permanent or chronic adverse reaction has been reported.[14] Although the anthrax vaccine has been in use since the 1970's, there has been no study conducted that actively followed the long-term medical conditions of those receiving the vaccine. The FDA's assertion that there have been no long-term or chronic adverse health effects from the vaccine is based upon data received through the Vaccine Adverse Events Reporting System (VAERS). This system relies upon physicians or patients taking the initiative to report effects believed to be caused by any vaccination. Because it is not a system of active medical surveillance of those receiving vaccinations, it has been criticized as under-reporting adverse events, particularly those could occur long after the vaccination and therefore not obviously connected. It should be noted that there is a distinction between an "adverse event", which is any medical event or condition that occurs after the vaccination and may or may not be associated with the vaccination, and an "adverse reaction", which is a medical event or condition that can be directly attributed to the vaccination.

From 1990 through September 2000, 1,561 adverse events associated with the anthrax vaccine have been reported to the FDA through the VAERS – a lower than average number of reports for vaccines, according to the FDA, given that during this period 2 million doses of the vaccine were administered. Of the 1,404 adverse events, 76 were judged serious (i.e. life-threatening, requiring hospitalization, or resulting in permanent disability), but diverse in nature with no clear patterns emerging. Of the 76 reports, 55 were judged to be reactions to the vaccination, and all personnel have recovered and returned to duty. The FDA has testified that, aside from injection site reactions (e.g. swelling, localized pain), "none of these events...can be attributed to the vaccine with a high level of confidence, nor can contribution of the vaccine be entirely ruled out".[15] The FDA has concluded that "the reports on the anthrax vaccine received thus far do not raise any specific concerns about the safety of the vaccine."[16] Army Surgeon-General Blanck has also noted that over the last 20 years more than 3,000 personnel working in the Army's biological warfare defense program have

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[13] (...continued)
Veteran's Affairs, and International Affairs, July 21, 1999.

[14] "Amid Concerns over Anthrax Immunization Plan, DOD Remains Confident", *Inside the Pentagon*, January 28, 1998, p. 1.

[15] Testimony of Kathryn Zoon, Director of the FDA Center for Biologics Evaluation and Research before the Senate Committee on Armed Services on July 12, 2000, and testimony of Mark Elengold, Deputy Director of the FDA Center for Biologics Evaluation and Research before the House Government Reform Committee, October 3, 2000.
[http://www.senate.gov/~armed_services/hearings/2000/c000712.htm] Testimony of Army Surgeon-General Blanck before the House Govermental Reform Subcommittee on National Security, Veterans Affairs, and International Affairs, March 24, 1999.
[http://www.house.gov/reform/ns/hearings/testimony/witnesslistfor3-24.htm]

[16] Ibid

received the vaccinations and that they routinely undergo regular physical examinations which have detected no long term medical effects.[17]

A number of Service members testifying before the House Government Reform Subcommittee on National Security, Veteran's Affairs, and International Affairs maintain that military physicians have been reluctant to report their medical complaints through VAERS because their symptoms do not conform to anticipated vaccine reactions. Consequently, they maintain that there is a "filtering" effect inherent in the VAERS which would also contribute to under-reporting. They strongly believe that their on-going medical conditions are a direct result of their vaccinations, and believe their cases should not be excluded from consideration of the vaccine's safety.[18]

Some service personnel and members of the public have associated the anthrax vaccine with the controversy over illnesses experienced by veterans of the Persian Gulf War. The independent Presidential Advisory Committee on Gulf War Veteran's Illnesses determined that no evidence could be found connecting the vaccine with subsequent illnesses.[19]

On September 28, 2000 another issue arose when a Michigan county medical examiner told a local newspaper that a reaction to the anthrax vaccine had contributed to a 61-year old Bioport employee's death. The pathologist who actually performed the autopsy disagreed with that assessment, asserting that the employee died of a ventricular arrhythmia, a cardiac artery inflammation, which could not be definitely linked to the vaccine. Both the FDA and the Department of Defense have obtained copies of the autopsy report, and will conduct independent investigations.[20]

Vaccine Production and Testing. There have been some concerns raised about the vaccine production facility and the retesting of stockpiled vaccine. The vaccine was originally manufactured by the Michigan Biologic Products Institute (MBPI), the only licensed manufacturer of human anthrax vaccine in the United States. Food and Drug Administration inspectors repeatedly cited this facility for quality control and record-keeping deficiencies during 1993-97. With MBPI having failed to take corrective action, the FDA issued a warning of license revocation in March 1997. The revocation, however, did not take place, and the facility passed subsequent FDA inspections. In the Spring 1998, the state of Michigan sold MBPI to a private corporation, Bioport, Inc. The facility was then shut down for renovations, partially funded by DOD, to increase its production capacity. Renovated from the ground up, the new Bioport facility underwent an initial FDA inspection in November 1999. The FDA found shortcomings in a number of areas, including: deviation reporting, filling

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[17] Testimony before the House Armed Services Subcommittee on Military Personnel, September 30, 1999.

[18] Testimony before the House Government Reform Subcommittee on National Security, Veteran's Affairs, and International Affairs, March 24, 1999.

[19] *Presidential Advisory Committee on Gulf War Veteran's Illnesses Final Report*., p. 112

[20] "Pathologist Cannot Confirm Anthrax Vaccine Link to Death of Bioport Corp. Employee", PRNewswire, September 29, 2000.

operations, stability testing, and environmental operations. [21] Bioport and independent consultants are currently working with the FDA to bring the facility into compliance. FDA officials have estimated that this will take until early or mid-2001. In the interim, Bioport is manufacturing only test lots of vaccine.

This lack of production created a vaccine shortage and forced DOD to alter its policy of vaccinating all personnel deploying to Korea and Southwest Asia. Now only those who will be deployed to those regions for more than 30 days will be vaccinated. On this reduced schedule, DOD estimates there is sufficient stockpiled vaccine to last until March 2001. DOD had expected that stockpiled vaccine that was being re-tested by independent consultants and the FDA to ensure its safety and potency would be sufficient to carry through Bioport's shutdown for renovations. However, the retesting is taking longer than expected, and some vaccine lots have been rejected for lack of potency.

Concerns about Bioport's financial stability also arose when the company, in order to remain solvent, required a renegotiation of the vaccine procurement contract which raises the per dose price from $4.36 to $10.64, raising the contract price from $25.7 million to $49.8 million, including an $18 million advance payment. The renegotiation was requested by Bioport, Inc., which maintained that the facility's former financial sponsorship by the state of Michigan led to an inaccurate initial estimate of production costs, and without additional DOD support the facility would have to close. The Army Contract Adjustment Board approved the renegotiation on July 27, 1999.

These difficulties with the Bioport facility have led DOD to explore ways to establish a second production source. The U.S. pharmaceutical industry is being canvassed, though the industry has shown little interest, owing to the relative lack of profitability in an anthrax vaccine. Consequently, DOD will request funding in FY2002 for a study to determine the advisability of building a government-owned, contractor-operated (GO-CO) facility.[22] Neither option will, however, provide a second production facility in the short term. Estimates range from 4 to 7 years to establish a fully licensed, functioning second facility, depending on whether an existing plant is converted or a new one built.

Congressional Action. Congress addressed the anthrax vaccination program in the DOD FY2001 Authorization Act (P.L. 106-398, Sec. 217, 218, 751) requiring DOD to provide:

- Notification of FDA certification of the vaccine production facility.
- A report on the contingencies associated with relying on the current vaccine manufacturer.
- A report, no later than February 1, 2001, on DOD acquisition programs for biological warfare defense vaccines.
- An annual detailed report on the program costs.

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[21] Zoon Testimony, July 17, 2000.

[22] "Pentagon Will Consider Building a GO-CO Vaccine Production Facility", *Inside the Pentagon*, November 2, 2000, p.7.

- Tracking of separations from the armed services attributable to the mandatory anthrax vaccination program
- A General Accounting Office report on the impact of the anthrax vaccination program on personnel recruitment and retention
- Uniform procedures for medical exemptions from the vaccination program.
- An expanded medical monitoring system for those vaccinated.
- A detailed vaccine modernization plan

In the 106th Congress, two additional bills regarding the anthrax vaccination program were introduced: H.R. 2543 and H.R. 2548. The former, introduced by Rep. Walter Jones, directs the Secretary of Defense to make the anthrax vaccination immunization program voluntary for all members of the armed forces until the Food and Drug Administration has approved a new anthrax vaccine for humans or a new, reduced course of shots for such vaccine. It has been referred to the House Armed Services Subcommittee on Personnel. H.R. 2548, introduced by Rep. Gilman, would direct DOD to suspend the immunization program pending an independent study on the safety and effectiveness of the vaccine, and an evaluation of that study by the National Institutes of Health. It would also require expedited review of the disciplinary actions taken against those who have refused the vaccination. H.R. 2548 has been referred to the House Committees on Armed Services and Commerce.

The Department of Defense has established a WWW site to provide information on the anthrax vaccination program [http://www.defenselink.mil/other_info/burrows.html]. A moderated Internet discussion by healthcare professionals of anthrax immunization in general is also available [http://www.healthnet.org/programs/promed.hma.html].

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