# Anthrax Vaccine Immunization Program Process Analysis

**by**

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The military is by definition and necessity a results oriented organization. In order to achieve the myriad results that the President desires of the military, the Secretary of Defense (SECDEF) institutes and oversees programs designed to attain those results. The success of any program is dependent on the results of the various processes used in the attainment of those program goals. Examples include regulatory, logistical, medical, ethical, and policy processes.

To temper the tendency for mission, or results, oriented myopia, the military takes process analysis one-step further through Operational Risk Management (ORM) and Total Quality Management (TQM). These leadership and management tools allow military members to continually evaluate and identify hazards, assess and analyze risks, and review the process to ensure the ORM bottom-line is protected for the safety of the troops: "If it's not worth the risk, don't do it" (Source: USAF Operational Risk Management training materials).

President Clinton desired to protect his military forces against the biological warfare agent aerosolized or inhalation anthrax. President Clinton tasked Secretary of Defense Cohen in 1997 to institute a program that would result in force protection against inhalation anthrax.[1] The success of Secretary Cohen's Anthrax Vaccine Immunization Program (AVIP) was dependent upon the results of the processes used in researching, developing, and implementing a program that would achieve President Clinton's goal. The processes involved in the research and development of the anthrax vaccine, and the implementation of the AVIP, will be reviewed in this paper.

In the case of the AVIP, a process analysis of the vaccine's history should have dictated the ORM bottom-line to kick in: "it's not worth the risk, don't do it." The vaccine was known to be too reactive, of limited effectiveness, and the Food and Drug Administration (FDA) shut down the manufacturer for significant quality control violations. Members of the Joint Staff, soldiers, and even field level commanders expressed this view at various times prior to and during the implementation of the AVIP.[2] Yet, at some level within the Office of the Secretary of Defense or the Executive branch, the analysis was ignored, and the required "knock it off," demanded when the safety of the troops is placed in jeopardy, never occurred.

As a result of this fundamental military objective process breakdown, historic regulatory mistakes were compounded, and laws were circumvented. Processes were not followed, but instead "adulterated" to fit the military objective desired by the Commander in Chief and the SECDEF. The medical AVIP force health protection initiative was taken out of the military

doctor's hands by deeming AVIP a "Commander's Program."[3] Now, a military objective, AVIP became an order to be followed. Any soldier who employed ORM and TQM in evaluating the AVIP was rebuffed or punished in the name of "good order and discipline." The AVIP became widely recognized as a bad order, and by many an illegal one. Honest process evaluation of a legitimate safety and ethics issue was substituted by mandatory blind obedience.

As officers in the Connecticut Air National Guard in the fall of 1998, our commander tasked us to look for answers to questions on the anthrax vaccine that he was being asked by subordinates. Absent any answers, we were tasked to develop those questions concerning the anthrax vaccine, so they could be forwarded up the chain of command. In effect, we were tasked to look at the processes revolving around the AVIP, and how it impacted our unit. Our initial process analysis revealed a stark dichotomy between the facts readily available in medical literature and government documents, when compared to the rhetoric espoused by Defense Department sources. Our subsequent and ongoing analyses of the legal, doctrinal, ethical, policy and medical aspects of this debacle discovered a complex ethical and process breakdown, within the chain of command, and throughout our government, on this particular issue, the AVIP.[4]

## Regulatory Process Breakdown:

In 1970 the regulatory process failed when the license for Anthrax Vaccine Absorbed (AVA), which was patented in 1965 by the US Army, was improperly granted to the Michigan Department of Public Health (MDPH). The regulatory process failed because it allowed a biologic product to be licensed without the required demonstration of efficacy. Efficacy for the vaccine, manufactured by MDPH, was never demonstrated during the Investigational New Drug (IND) trials, so data from a different vaccine, studied in the 1950s, was offered to the Division of Biologic Standards after the fact. This 1950s vaccine differed from the MDPH vaccine in strain, manufacturing process, and formulation (in particular, a four fold difference in levels of protective antigen or "PA"). It was a different vaccine. The issue of improper licensure is academic, and the late 1960's correspondence between the State of Michigan and the Public Health Service documented the lack of proper data submissions.[5] This "false start" in the regulatory process was the first of an assortment of documented "quick fixes" regarding the anthrax vaccine.

At best, the MDPH vaccine might be considered a "copycat" vaccine to the 1950s vaccine. However, the 1962 Drug Industry Act amended the Federal Food, Drug and Cosmetic Act (the Act), abolishing the ability of "copy cat" drug products from gaining a license based on the scientific data from another drug product. Yet, that is precisely what happened with the MDPH vaccine. The 1962 amendment was challenged in the US Supreme Court, and the Court found that the FDA was well within its right to not license "copy cat" drugs; in fact the Act demanded it.[6] Additionally, any discussion of "bridging study" data to validate the MDPH vaccine, after the fact, is similarly absent from the scientific record, contrary to the spirit and rule of the Act. By definition "bridging data" must have data with which to bridge, but no such data existed for the MDPH anthrax vaccine, even if it were relevant.[7]

The regulatory process failed again in 1985, but the reason began in 1972 when the control and oversight of Biologic Products were transferred from the National Institute of Health and the

Public Health Service to the FDA. After this transfer, the FDA Commissioner mandated a review of all previously licensed biologic products to ensure they were properly licensed with respect to safety, effectiveness and labeling. The review of the anthrax vaccine was completed and presented to the FDA Commissioner in 1981. In 1985 the FDA published a proposed rule for the categorization of the anthrax vaccine. The review committee acknowledged the only efficacy data available was from a different vaccine. The review also did not detail any "bridging data," yet recommended that the license be continued. The review also documented the fact that the vaccine dosage was intended to be 3 shots, but was improperly labeled as 6, which means the product is misbranded or mislabeled. This Proposed Rule has yet to be finalized, sixteen years after its publication. This, too, is an improper and continuing failure of the regulatory process. (A Citizen Petition was filed on 15 October 2001 to identify, and rectify, these failures of the regulatory process.)[8]

Over the next ten years additional failures occurred, affecting both the vaccine, and ultimately the AVIP. In 1985 the military sought a new anthrax vaccine from the pharmaceutical industry, as the MDPH vaccine exhibited high adverse reaction rates, and was considered marginal effective. Yet the military, and MDPH, failed to notify FDA, as required by the Code of Federal Regulations, of the vaccine's inability to perform as licensed. The ethical process, or the failure to be guided by it, resulted in MDPH "reinventing" the anthrax vaccine in 1990 (ironically, three former employees of the state of Michigan brought a civil service suit for royalties owed them, because they had "invented" a new anthrax vaccine. The court found, and the defense [the State] did not deny, that the vaccine was new, but a patent was not applied for in a timely manner).[9] At this point, several processes broke down, or were ignored, including legal, ethical, regulatory, and scientific, possibly due to Gulf War requirements.

Coincident with the 1985 Proposed Rule in the Federal Register, a series of methodical and scientifically based evaluations of the anthrax vaccine began. US Army documents, and US Congressional testimony, acknowledged the limitations of the anthrax vaccine in safety, efficacy and legality when used against the inhaled form of the disease. The US Army formally sought a new vaccine that was less reactive, was effective against all strains, and was properly licensed against inhalation anthrax as early as 1985.[10] Ultimately though, unapproved manufacturing changes to the vaccine occurred instead. Many of these changes were not reported to the FDA, some which significantly changed the chemical formulation of the vaccine. It is important to note that the FDA was unaware of some of these changes until Congress was informed in the spring of 2000, and the General Accounting Office (GAO) was ordered to investigate in the fall of 2000. This investigation ultimately resulted in October 2001 testimony to Congress by the GAO, verifying the unapproved changes to the anthrax vaccine.[11]

Any changes, which affect the sterility, potency, stability or purity of a vaccine, must be reported to the FDA for approval prior to implementation. This is the law.[12] Failure to do so is a violation of the Act and renders a vaccine or drug adulterated. Distribution of an adulterated drug is illegal. This is exactly what happened with the MDPH anthrax vaccine. Changes were made without prior approval, adulterating the product. DOD knew of the changes, and the manufacturer had a legal and regulatory obligation to report these changes to the FDA. The adulteration of the vaccine is clear, as is its illegal distribution. The question is: why did the manufacturer violate the required regulatory process, allowing its vaccine to become adulterated?

## Legal Process Breakdown:

A process issue separate from the adulteration of the vaccine is that of its "experimental" use. In 1994 a Congressional report (Senate Staff Report 103-97) confirmed that the Gulf War use of the anthrax vaccine against aerosolized anthrax was a possible cause of Gulf War Illness, and should be considered "investigational" or experimental.[13] Therefore, by 1996, a year prior to the commencement of the mandatory anthrax vaccination program, an investigational new drug (IND) application was prepared by the US Army, and filed with the FDA by the manufacturer, in order to gain approval for the vaccine's specific applied use against "inhalation anthrax" in a biowarfare environment. This IND application is prima fascia evidence that the US Army and MDPH were aware of the regulatory and legal processes required prior to mandatory armed forces immunization against inhalation anthrax. The IND application was updated annually, but the change in the license has never been approved.[14]

In 1997 DOD failed to adhere to the regulatory and legal process, instead moving forward with plans to implement a mandatory anthrax vaccine immunization program without FDA approval for this new use, or at a minimum a Presidential waiver of informed consent. The AVIP commenced after an exchange of "quick fix" personal memos between DOD's Assistant Secretary of Defense for Health Affairs, Dr. Joseph, and acting FDA Commissioner, Dr. Friedman, in March 1997.[15] The long acknowledged inadequacies, and experimental nature, of the anthrax vaccine in a biowarfare environment (inhalation anthrax) were ignored, and a scientifically invalid "quick fix" four-point review, along with a 74 million dollar "Orwellian" education campaign, was crafted in order to market the program to the troops, the US Congress, and the American people. Later, the independent expert required by the SECDEF's four-point review, an OB/GYN who approved the program, renounced himself an anthrax expert, in lieu of testifying before Congress.[16]

These events represent a clear legal process breakdown, documented through premeditated bureaucratic efforts, to obscure that the vaccine was known to be problematic. When an attempt to uncover this process, best described as pounding a "square peg in the round hole," occurred, a convoluted mentality developed where those who questioned the process, or its facades of regulatory and legal compliance, would ultimately become victims of the 'hammer' from the "Commanders Toolbox."[17]

Rhetoric such as: "Soldiers can't refuse to wear their helmets," or "We'd be derelict in our duty," and "It would be unconscionable medical malpractice to not provide this vaccine to our troops," can now be put into perspective. The expensive "education campaign," the online "Commander's Toolbox," the snappy websites, and sound bites all became a requisite replacement for commonsense, ORM, and TQM. In essence, the honest process analysis was suppressed in order to protect and defend the anthrax vaccine policy over the legally prescribed health rights of the troops.[18]

## Ethical Process Breakdown:

By 1999 significant internal resistance from US Servicemembers surfaced as many officers and enlisted personnel discovered the truth and facts beneath the anthrax vaccination program, while

others fell ill. These post Vietnam soldiers had been trained to root out illegalities, and not tolerate false reporting or immoral conduct. Cursory research uncovered the 1994 Senate report documenting the investigational nature of the vaccine; it's possible relationship to Gulf War Illness (GWI), and various medical articles by military researchers detailing the vaccine's questionable safety and effectiveness. The chief military anthrax researcher, Dr. / Col. Arthur Friedlander, wrote one such article describing the anthrax vaccine as "unsatisfactory" in the 1994 medical textbook "Vaccines."[19]

To quell these revelations, or possibly out of ignorance of the facts, the military chain of command resorted to heavy handed tactics; discipline, disparagement, discharge, and even imprisonment of those who questioned the moral imperatives of the anthrax vaccine program. Despite the medical materials that showed the efficacy of antibiotics, the vaccine was touted to the troops as the only thing that stood between survival and certain death. The Air Force Surgeon General actually referred to the vaccine in a Congressional hearing as "body armor."[20] Intimidation, groupthink, and coercion replaced normal critical thought processes, while discipline, harassment, and forced discharges replaced normal personnel processes.

Attempts to follow the proper regulatory and legal processes within the FDA resulted in a series of failed inspections, Warning letters, and a Notice of Intent to Revoke (NOIR) the anthrax vaccine manufacturer's license. From 1993 to 2000, significant violations of current good manufacturing practices (cGMPs) were discovered concerning the anthrax vaccine, which led to the closure of the production facility. For Servicemembers applying ORM and commonsense, a simple conclusion became apparent: you don't take a vaccine from a plant that has been cited and closed by the FDA.

It was later discovered that such noncompliance similarly violated government and FDA procurement policies, which prohibited the contracting of drugs from deviant manufacturers. The 1998 DOD contract, as well as continuous contracts from the early 1990s for anthrax vaccine, ignored this government policy, resulting in a major breakdown of the regulatory and legal process. The government procurement policy is outlined in the FDA Compliance Policy Guide, Section 400.200.[21] In congressional testimony, DOD attempted to paint the plant closure as a 'planned renovation,' avoiding the fact that the FDA would not have allowed continued production by the manufacturer. Congressional testimonies later revealed the truth.[22]

GAO reports and Congressional testimonies, revealing DOD's attempt to obscure the ethical breakdown, show a further compounding of the process violations. Testimonials lacking the requirement for candor and straightforwardness occurred with respect to attrition caused by the anthrax vaccine in the Reserve Components, and also by military officers attempting to obscure the IND application's legal implications. Without question, the breakdown of the ethical process became so extreme that the DOD Inspector General refused to properly investigate the false testimonies of senior military officials, instead referring complaints to obscurity, for investigation by the Defense Department officials running the anthrax vaccine program.[23]

A series of legislative process efforts from 1989 to 2000, including staff reports, Congressional hearings, GAO reports and formal Congressional reports found the anthrax vaccine to be "investigational" or "experimental." The final Congressional report in April 2000 found the

AVIP to be in violation of FDA regulations.[24] Further, absent a Presidential waiver of informed consent, the AVIP violated a new law, 10 U.S.C.§1107, passed in 1999. As a result, US Servicemembers initiated legal actions against their own Defense Department in an effort to compel the institution to obey the law, and correct the policy and process breakdowns.

Some of these efforts by members of the armed forces have utilized the military courts or the Inspector Generals to no avail. Others look outside the military in order to seek a Federal Declaratory Judgment about the proper legal status of the vaccine.[25] At least one attempts to seek compensatory and punitive damages for illnesses and deaths caused by the vaccine.[26] Still others attempt to document the anthrax vaccine's adulterated and illegal status, and the fraud inherent in the US Army contracts for a non-compliant product.[27] These actions are all attempts to correct three decades of compounding process breakdowns.

DOD responses in Court fail to address the issues or facts, and when military judges control the judicial process, they do not allow evidence to be presented. A due process abandonment of Servicemembers, trained in the concepts of ORM and TQM, has become the modus operandi of the chain of command when dealing with the anthrax vaccine program. Serious ethical breakdowns are apparent, reminiscent of previous historical military medical malfeasance and abuse of the troops. The perversion of the process is illustrated by DOD's belated attempt to generate the science in order to convince its troops, the media, and the public that the anthrax vaccine is safe.

There are now 18 studies demonstrating the safety of the vaccine, yet 15 of these studies were conducted after the AVIP began, and are primarily nonscientific attempts to justify the program by any means possible.[28] Of the three pre-AVIP studies; one is an observational analysis of US Army personnel, not specifically related to the anthrax vaccine; one is on the different Merck vaccine, as studied by Dr. Brachman; and one is the Talladega Mill study, which the Public Health Service deemed, "can hardly be accepted as scientific evidence," in a 1969 memo.[29]

Clearly, the process breakdown is so complete and severe that when it comes to the AVIP confusing and irrelevant science is being crafted in order to justify the process and obtain the desired results. Senior military leaders repeat sound bites based on this post-facto science, yet will not engage in an ethical analysis of the issues or facts. No defense is the only defense allowed, and no discussion or ORM analysis is permitted.[30]

## Abuse of Power and Discretion:

Current events are important to help put the anthrax vaccine process debacle in context, and to avoid a further compounding of "quick fix" process breakdowns. As well, a historical perspective of both the Defense Department's and the FDA's conduct is required. Abuse of discretion by the FDA is documented in previous the Supreme Court cases, and should be analyzed in the context of the regulatory history of the anthrax vaccine. The "Griffin" polio vaccine case, the "Dotterweich" drug case, and the "Park" food case are past examples. The anthrax vaccine meets the threshold for analysis at the very least, and may be the next historical example of regulatory abuse of discretion and military medical abuse of power.

The anthrax vaccine manufacturer has applied to receive an expedited approval of their currently non-validated and reconstructed manufacturing plant. The General Accounting Office has simultaneously revealed unapproved manufacturing changes to the vaccine's production filters, which chemically changed key protective antigen (PA) components of the vaccine by an additional factor of 100, perhaps on top of the previous fourfold PA changes documented between the 1950s and 1970 versions of the vaccine. The FDA has admitted to approving the filters as of July of 2001, after GAO brought the changes to their attention in December of 2000, ten years after their adulterating changes to the vaccine. FDA has further admitted it approved the changes without knowledge of the chemical changes, which neither the US Army nor the manufacturer reported. Simply stated, FDA is approving biologic product manufacturing changes ten years after the fact, without knowledge of the impact on the purity, potency, sterility or safety of the product, contrary to their chartered mission to protect the public health.[31] These approvals, after the fact, follow the documented "quick fix" pattern of conduct to create the appearance of a proper process, but are not.[32]

The process breakdowns are clear: flawed original license, based on a different vaccine; no final rule on the 1985 FDA review of the anthrax vaccine; early 1990s unapproved changes to the vaccine; pre-AVIP 1997 FDA and DOD "quick fix" memos; the SECDEF's unsatisfactory four-point review; a preemptive 'education campaign' to fend off criticism; no GWI studies pertaining to the anthrax vaccine; the rebuilding of the non-validated manufacturing plant; a 'no bad news' denial of high adverse reactions and attrition caused by the vaccine program; and most egregious, the FDA's full decade late approval of major manufacturing changes, without scientific comparisons to the original licensed vaccine.

## Final Process Analysis:

The process analysis will continue, however, the pattern is now well established. The process breakdowns in the licensure, manufacturing, alteration, adulteration, and administration of the anthrax vaccine are well documented. Today, the anthrax vaccine remains a "non-validated" product, and neither the FDA nor the CDC recommends its use by the general population. FDA's revalidation of the manufacturing process should only be considered after adequately addressing the regulatory missteps identified in the Citizen Petition (docket # 01P-0471), partially addressed in this paper.[33]

The anthrax vaccine dilemma has clearly been wrought by process problems since its inception. The process problems include regulatory, legal, policy, medical, and ethical breakdowns. An objective analysis of any one of these broken processes should have been sufficient to halt the current anthrax vaccine program implemented within the Defense Department, while pursuit of comprehensive and coherent force health protections programs, utilizing modern and legal medical treatments, were pursued.

When the AVIP is looked at with ORM and TQM tools, the bottom-line is clear: not only does the risk of the anthrax vaccine outweigh the benefit, but also the processes used to achieve the program results were fatally flawed. Commonsense told DOD officials that we needed to "Do It Right," and historical precedents demanded it. US Servicemembers deserved better.

## Recommendations:

Required FDA actions include re-categorization of the anthrax vaccine only as an Experimental Category IIIb product, since the safety and efficacy of the adulterated and altered product is scientifically undeterminable and unbridgeable to the previous studies or versions of the vaccine, which also never satisfied the FDA's licensing requirements. This action would comply with the requirements of the Federal Food, Drug and Cosmetics Act, and would not preclude the mandatory use of the vaccine under Presidential authority, pending submission of proper scientific data. Consideration should also be given to an official investigation by appropriate federal authorities of the US Army's and the manufacturer's circumvention of the laws that allowed a vaccine, known to be inadequate and adulterated, to be forced upon over 500,000 troops during the current AVIP.

As an institution, the Defense Department must analyze and attempt to fix the myriad process problems relating to the anthrax vaccine. It is appropriate we reevaluate the processes that allowed these breakdowns to occur, while troops were punished and made ill. Next, we should "Do it right," and ensure a resurrection of the AVIP does not further compound previous process errors. Instead perhaps, scientifically valid, doctrinally coherent, and medically comprehensive force health protection initiatives must be pursued in the future with a modern anthrax vaccine and sufficient antibiotic stockpiles. Finally, the DOD leadership must "Do the right thing," and correct the records, and care for the ill, casualties which directly resulted from these complex and compounding process breakdowns.

**Notes:**

1. See initial program announcement press briefing: http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html,& see full scale announcement press briefing: http://www.defenselink.mil/news/May1998/x05281998_x0522mfp.html
2. Email by Dr. Michael Gilbreath, Joint Project Office for Biological Defense (JPOBD), May 5, 1998: *"I'm not prepared to defend going forward with the SECDEF's plan if I can't be reasonably sure there will be vaccine available to continue any force immunization. … I will forward a recommendation through BG Doesburg to the SECDEF to either delay the immunization of the force or recommend that the action be terminated because of confidence that the manufacturer will be able to meet vaccine dose requirements is in question."*
3. House Committee on Government Reform report, "Unproven Force Protection", 17 Feb 2000, p. 3: "*Preposterously low adverse report rates generated by DOD point to a program far more concerned with public relations than effective force protection or the practice of medicine. The AVIP raises an ominous question: Who protects the force from ill-conceived force protection? The anthrax vaccine effort is designated a* ***commander's program*** *not a medical program, The anthrax vaccine effort is designated a commander's program not a medical program, so DOD doctors appear unable to act as advocates for individual patients in the face of command pressure to meet force-wide inoculation levels*." See: http://www.house.gov/reform/ns/reports/anthrax1.pdf

4. See: March 24, 1999, House Subcommittee on National Security testimony: http://www.house.gov/reform/ns/hearings/testimony/written_testimony_of_maj.htm, & see October, 12 1999, House Committee on Government Reform testimony: http://www.house.gov/refor m/hearings/healthcare/99.10.12/rempfer.htm
5. FDA Citizen Petition, in accordance with Title 21 of the US Code, Docket # 01P-0471, See: http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/101501.htm#_Toc527850400
6. Ibid. See also, Supreme Court case Weinberger, CW. v Hynson, Westcott and Dunning, Inc. (No. 72-394 and 72-414).
7. Ibid.
8. Ibid.
9. Lansing State Journal, December 5, 2000, article concerning royalty lawsuit by anthrax vaccine manufacturer scientists.
10. Request for Proposals (RFP), DAMD 17-85-R-0078, US Army Medical Research Acquisition Activity, Fort Detrick, Frederick, MD, 16 May 1985: *"There is an operational requirement to develop a safe and effective product which will protect US troops against exposure from virulent strains of Bacillus anthracis. There is no vaccine in current use which will safely and effectively protect military personnel against exposure to this hazardous bacterial agent. … A licensed vaccine against anthrax, which appears to afford some protection from the disease, is currently available for human use...The vaccine is, however, highly reactogenic, requires multiple boosters to maintain immunity and may not be protective against all strains of the anthrax bacillus."*
11. GAO Report concerning unapproved changes in manufacturing process: http://www.gao.gov/cgi-bin/getrpt?gao-02-181t
12. Arthur Levine. FDA Enforcement Manual. Tab 1600. Pg 7. Thompson Publishing Group: "*Enforcement of current good manufacturing practices (cGMPs), as pursued by the Food and Drug Administration (FDA) over the past nearly forty years, originated with the 1962 amendment to the Federal Food, Drug and Cosmetic Act (FD&C Act). Under these amendments, a drug was deemed to be adulterated if 'the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice' to assure that the drug is safe and has the identity and strength and meets the quality and purity characteristics which it is represented to possess (see: 21 U.S.C. § 351(a)(2)(B))* …" Failure to comply with cGMP renders the drug product adulterated. 21 U.S.C. § 331 states: "*The following acts and the causing thereof are prohibited: (b) the adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce.*"
13. Senate Veterans Affaires Committee staff report 103-97, 414 Russell Senate Office Bldg., Washington, DC, 4 Feb 1994, from Senate Report 103-97, 8 Dec 94, Note 61-63: "*Although anthrax vaccine had been considered approved prior to the Persian Gulf War, it was rarely used. Therefore, its safety, particularly when given to thousands of soldiers in conjunction with other vaccines, is not well established. Anthrax vaccine should continue to be considered as* ***a potential cause for undiagnosed illnesses in Persian Gulf military personnel*** *because many of the support troops received anthrax vaccine, and because the DoD believes that the incidence of undiagnosed illnesses in support troops*

*may be higher than that in combat troops. … Records of anthrax vaccinations are not suitable to evaluate safety...However, the vaccine's effectiveness against inhaled anthrax is unknown. Unfortunately, when anthrax is used as a biological weapon, it is likely to be aerosolized and thus inhaled. Therefore, the efficacy of the vaccine against biological warfare is unknown. … The* ***vaccine should therefore be considered investigational when used as a protection against biological warfare***."

14. See: IND Application, dated September 20, 1996, and "Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements", held on 20 Oct 1995, memorandum dated 13 Nov 1995. This IND application sought an approval for a specific licensed use against "***inhalation anthrax***," and subsequent updates listed this purpose exclusively.
15. Dr. Stephen C. Joseph, DoD ASD/Health Affairs, letter to FDA Lead Deputy Commissioner Michael Friedman, 4 Mar 1997.
16. See Dr. Burrows approval: http://www.defenselink.mil/other_info/burrows.html, and see Congressional admissions in a 26 April 1999 letter to Representative Christopher Shays (R-CT) where Burrow stated: "*The Defense Department was looking for some [sic] to review the program in general and make suggestions, and I accepted out of patriotism.* ***I was very clear that I had no expertise in Anthrax and they were very clear they were looking for a general oversight of the vaccination program***."
17. www.anthrax.osd.mil
18. Rhetoric Examples: SecDef Cohen: "*I would be derelict in my duty not to vaccinate the troops*." General Officer helmet analogy – "*this is no different than an order to wear a helmet*." General officer morale imperative example: "*It would be unconscionable not to vaccinate the troops.*"
19. A.M Friedlander and P.S. Brachman, "Vaccines", ed. Plotkin and Mortimer, 1994 edition chapter 26, pg. 737: "***The current vaccine against anthrax is unsatisfactory for several reasons. The vaccine is composed of an undefined crude culture*** *of supernatant adsorbed to aluminum hydroxide. There has been no quantification of the protective antigen content of the vaccine or of any of the other constituents, so the degree of purity is unknown. Standardization is determined by an animal potency test. The undefined nature of the vaccine and the presence of constituents that may be undesirable may account for the level of reactogenicity observed. The vaccine is also less than optimal in that six doses are required over 18 months, followed by annual boosters. There is also evidence in experimental animals that the vaccine may be less effective against some strains of anthrax.* ***Clearly a vaccine that is completely defined, that is less reactogenic****, and that requires on or two doses to produce long-lasting immunity* ***would be highly desirable***.
20. House Subcommittee on National Security testimony on March 24, 1999 by Air Force Surgeon General Roadman.
21. The FDA issued a Warning Letter to the anthrax vaccine manufacturer on August 31, 1995, and a Notice of Intent to Revoke (NOIR) their license on March 11, 1997. See: http://www.fda.gov/cber/infosheets/mich-inf.htm. Additional violative inspections occurred in October 1998, November 1999 and October 2000. The inspection conducted between February 4th and 19th of 1998, found that the previous deficiencies had not been corrected; all three inspections documented egregious violations of current good

manufacturing practices (CGMPs) required under federal law. These regulatory actions, until corrected, made the manufacturer subject to the restrictions contained in the FDA Compliance Policy Guides Manual, Sec. 400.200, titled "Consistent Application of CGMP Determinations (CPG 7132.12)," which states: "*CGMP deficiencies supporting a regulatory action also support decisions regarding non-approval of drug marketing applications, government purchasing contracts, candidates for MAC, etc. Therefore, the issuance of a warning letter or initiation of other regulatory action based upon CGMP deficiencies must be accompanied by disapproval of any pending drug marketing application, or government contract for a product produced under the same deficiencies."* See: http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-200.html

22. 13 Jul 2000 House Armed Services Committee (Military Personnel Subcommittee) transcript, discussion between Representative Christopher Shays (R-CT), DepSecDef Rudy DeLeon, and Anna Johnson-Winegar Ph.D., Deputy Assistant Secretary of Defense for Chemical and Biological Defense. Quoted excerpt: Mr. SHAYS. "**Didn't the FDA make it clear that they would not approve any more from this old plant and that they needed to upgrade it?**" Dr. JOHNSON-WINEGAR. "**Yes**." Mr. SHAYS. "**And that is a matter of public record, correct?**" Dr. JOHNSON-WINEGAR. "**Yes**." Secretary DE LEON. "**Correct**." See also: http://commdocs.house.gov/committees/security/has195020.000/has195020_0f.htm
23. FOIA documents revealed investigations about the illegalities of the AVIP were referred to the AVIP agency in question.
24. http://www.house.gov/reform/ns/reports/anthrax1.pdf
25. http://www.nlj.com/cases/1029anth-bates.pdf
26. http://www.nlj.com/cases/1029anth-milstein.pdf
27. http://www.nlj.com/cases/1029anth-dingle.pdf
28. www.anthrax.osd.mil
29. Ad Hoc Committee letter to Dr. Margaret Pittman, 6 February 1969: "*The lack of cases of anthrax in an uncontrolled population of approximately 600 persons in the Talladega mill can hardly be accepted as scientific evidence …"*
30. http://www.law.duke.edu/shell/cite.pl?50+Duke+L.+J.+1835
31. FDA's mission is to "*protect the public health as it may be impaired by drugs*" by ensuring that these drugs are safe and effective. The gravity of FDA's mission is stated in the announcement of procedures for review of safety, effectiveness, and labeling published on 18 August 1972 (37 FR 16679): "*The importance to the American Public of safe and effective vaccines…cannot be understated.*"
32. GAO Report concerning unapproved changes in manufacturing process: http://www.gao.gov/cgi-bin/getrpt?gao-02-181t
33. FDA Citizen Petition, in accordance with Title 21 of the US Code, Docket # 01P-0471, See: http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/101501.htm#_Toc527850400