

Operational Risk Management (ORM) And the Anthrax Vaccine Immunization Program (AVIP)

By Lieutenant Colonel Russell E. Dingle and Major Thomas L. Rempfer

EXECUTIVE SUMMARY:

Several events have occurred since our previous Process Analysis of the Department of Defense (DoD) Anthrax Vaccine Immunization Program (AVIP) that suggests a renewed scrutiny of the risks of both the vaccine and of weaponized anthrax. We will perform the review utilizing the US Air Force's Operational Risk Management (ORM) Program.

Air Force regulations define ORM as the systematic process of identifying hazards, assessing risk, analyzing risk control options and measures, making control decisions, implementing control decisions, accepting residual risks, and supervising / reviewing the activity for effectiveness.

The facts presented in the following paper reveal five major areas of risk concern to the Department of Defense (DoD) and the Department of Veteran's Affairs (DVA):

- A vaccine originally licensed with incomplete scientific data;
- A vaccine whose license the FDA has yet to be finalized;
- A vaccine produced with unapproved, adulterating manufacturing changes;
- A vaccine known by DoD officials to be experimental for inhalation anthrax;
- And a vaccine that could burden DoD and DVA with significant liability.

Based on these documented risks and this review, the DoD should implement the following recommendations:

- Conduct their own legal, medical and ORM analysis of the AVIP;
- Procure antibiotics, external protective garments, and biodetectors;
- Comply with the law and obtain a Presidential waiver or an "animal efficacy rule" approval for inhalation anthrax if continued use of the anthrax vaccine is desired;
- Expunge the records of any servicemember punished for refusing the anthrax vaccine;
- Minimize use of the anthrax vaccine, pending the deployment of the new anthrax vaccine as directed by the President of the United States in 2002;
- And develop a doctrinally sound, institutionally coherent, legal and ethical process for dealing with biological, chemical and other asymmetric threats in the future.

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INTRODUCTION

Several events directly related the threat of weaponized anthrax, to the Anthrax Vaccine Immunization Program (AVIP) and the anthrax vaccine have occurred in the last eighteen months. These events require a renewed look at the Defense Department's risk mitigation program – the AVIP. We previously reviewed the Department of Defense (DoD) AVIP in 2002.¹ The analysis that follows is predicated upon the application of Operational Risk Management (ORM) to the AVIP and the anthrax vaccine. This analysis reviews these new events and the risks they pose for the DoD.

First, there have been developments directly related to anthrax and the anthrax vaccine. Weaponized anthrax, delivered via the U.S. Postal Service caused the deaths of 5 people in 2001. Having failed FDA validation for four years, distribution of the BioPort anthrax vaccine was approved on 31 January 2002.² The National Academy of Sciences Institute of Medicine issued a report on its review of the anthrax vaccine in March 2002, concluding it was either “*acceptably safe*”,³ or “*reasonably safe*”.⁴ Secretary of Defense Paul Wolfowitz directed the resumption of the AVIP on 28 June 2002.⁵ The USAF restarted its vaccination program on 26 July 2002.⁶

Second, in June 2002 Air Force Chief of Staff John P. Jumper issued a memorandum directing the Air Force's senior leaders and commanders to ensure the complete integration of Operational Risk Management in their areas of responsibility.⁷ The Secretary of the Air Force previously codified ORM in policy directives.⁸ However, a DoD Inspector General review called “Eagle Look” had critiqued the internalization of ORM as lacking leadership and adequate training.⁹ This finding reinforces the importance of a more detailed ORM analysis of USAF and related DoD programs, including AVIP.

The ORM Process.

The origins of the USAF ORM program evolved from the US Army's 5-Step risk management program.¹⁰ The Army Chief of Staff in 1995 envisioned that, “*Risk Management is the Army's principle risk-reduction process to protect the force. Our goal is to make risk management a routine part of planning and executing operational missions.*”¹¹ The Army risk management process is depicted below.



Notably, the Air Force modified ORM to reflect its distinct corporate culture. This conscious choice by the USAF leadership provides a window on cultural differences between the US Air Force and the US Army, which go back to the origins of the USAF. Air Force ORM includes one additional step, splitting the Army's step 3 into the Air Force ORM steps 3 and 4. The Air Force specifically includes subordinate inputs as an integral part of the process in step 3, i.e., to analyze risk control measures. The USAF's ORM Step 4 is the commander's risk control decision. The division of this step separates the analysis of risk control measures from the commander's risk control decision. A Presidential Commission adopted the USAF 6-Step version of ORM.¹²

With this distinction in mind, General Jumper's ORM implementation memorandum emphasizes that:

*"ORM provides airmen at every level with a sound, mission-enabling tool to expand our expeditionary capabilities ... the natural way for our people to conduct their professional and personal activities."*¹³

Based on this mandate, and the recent events concerning the anthrax vaccine, this paper applies Operational Risk Management to the Anthrax Vaccine Immunization Program as authorized by Air Force Policy Directives.¹⁴

The following is a brief review of specific tenets of USAF Operational Risk Management.¹⁵

ORM has four guiding principles:

1. Accept no unnecessary risk;
2. Make risk decisions at the appropriate level;
3. Accept risk when benefits outweigh the costs;
4. And integrate ORM into operations and planning at all levels.

ORM also has four fundamental goals:

1. Enhance mission effectiveness at all levels, while preserving assets and safeguarding health and welfare;
2. Integrate ORM into mission processes; ensuring decisions are based upon assessments of risk integral to the activity and mission;

3. Create an Air Force in which every leader, airman, and employee is trained and motivated to manage risk in all their on- and off-duty activities;
4. And identify opportunities to increase Air Force warfighting effectiveness on the battlefield and in the operational aerospace environment, helping to ensure decisive victory in any future conflict at the least possible cost.

ORM enhances traditional USAF risk management through a specific six-step process, utilizing analytical tools to optimize risks and mission outcomes. Air Force regulations define ORM as the systematic process of identifying hazards, assessing risk, analyzing risk control options and measures, making control decisions, implementing control decisions, accepting residual risks, and supervising/reviewing the activity for effectiveness.¹⁶

Six-Step Process:

1. Identify the hazards;
2. Assess the risk;
3. Analyze risk control measures;
4. Make control decisions;
5. Implement risk controls;
6. And supervise and review.



The application and integration of ORM is predicated upon the "risk management continuum", or the requirement to continually assess our evolving knowledge of risks. The risk management continuum requires that the ORM tools be applied not only in the planning phase of any risk-based endeavor, but also during the "operations" and "after-action" phases. Air Force regulations also maintain that the risk management process exists on three levels.¹⁷

ORM levels

1. Time-critical;
2. Deliberate;
3. And strategic.

“Time-critical” management is a real-time mental or verbal review using the basic risk management process. In contrast, the “deliberate” risk management process is the application of the complete process relying primarily on experience and brainstorming to identify hazards and develop controls. The “strategic” risk management process is a more in-depth version of the deliberate process involving research of available data and long-term tracking of the hazards associated with the risk.¹⁸

The use of the strategic risk management process is most appropriate for a review of the AVIP for several reasons. AVIP utilizes the anthrax vaccine, which has a long and complex scientific, medical and regulatory history. AVIP is also a force-wide program affecting virtually every member of the Air Force and therefore the outcome of every mission. A review of AVIP is not constrained by time and therefore deserves the most rigorous risk management process available. Finally, both the hazard and the current risk control measure (AVIP) are complicated by the stark dichotomy between the military and civilian opinions on the threat of weaponized anthrax. In contrast to DoD’s emphasis on the threat, the General Accounting Office (GAO), in both 1999 and 2002, has concluded otherwise:¹⁹

GAO, 1999: “The nature and magnitude of the military threat of biological warfare (BW) has not changed since 1990, both in terms of the number of countries suspected of developing BW capability, the types of BW agents they possess, and their ability to weaponize and deliver those BW agents.”

GAO, 2002: “...the nature and magnitude of the anthrax threat has been stable since 1990 and has not changed materially in terms of the number of countries suspected of developing a BW capability, the types of biological agents they possess, or their ability to weaponize and deliver such agents.”

The same dichotomy exists with respect to the safety and effectiveness of the risk control measure, in this case the anthrax vaccine. Therefore, we must analyze the anthrax vaccine as a risk control measure, specifically:

1. The safety risks based on the vaccine’s scientific and regulatory history;

2. The ethical risks since the anthrax vaccine program was not based on a candid scientific foundation;
3. The doctrinal risks of AVIP as the prototype of more ambitious, vaccine-based force health protection programs;
4. The legal risks to the DoD for mandating a vaccine with an arguably illegal order;
5. And the medical and financial risks to the Department of Veteran's Affairs (DVA), which will inherit the consequences of the AVIP.

APPLYING ORM TO THE AVIP

Weaponized anthrax has been a potential hazard to the U.S. military since World War II. The Chairman of the Joint Chiefs of Staff prioritizes biological warfare agent threats, and anthrax is at the top of that list.²⁰ The AVIP is a risk control measure designed to mitigate the hazard of weaponized anthrax. Widespread use of the vaccine occurred during the 1991 Gulf War on about one-quarter of deployed troops, reoccurred during the 1998-2001 force-wide vaccination program (AVIP) and then continued in 2002. Since the program is ongoing, the ORM analysis begins at Step-6 of the ORM process. Step-6 is used to determine the effectiveness of risk controls throughout the operation. The risk management continuum and the 6 step ORM process is a cyclical one that requires not only a review of the genesis of the AVIP, but also an analysis of all newly available information about the risk and the risk control measure.²¹

Step 6 -- Supervise and Review.



Step 6 is actually comprised of three actions: supervise, review and feedback. Every operation should be supervised to ensure the risk controls measures are effective, that changes which require further risk management are identified, that action is taken when necessary to correct ineffective risk controls, and that the risk management steps be reinitiated in response to new hazards anytime the personnel, equipment or mission tasking changes.²²

The Supervisor action should begin by questioning basic assumptions: what is the extent of the risk and is the selected risk control measure effective? In other words, what is the extent of the threat of weaponized anthrax to US servicemembers and is the AVIP the appropriate response to mitigate the hazard of inhalation anthrax? While US military servicemembers have been vulnerable to weaponized anthrax since World War II, and a licensed vaccine has been available since 1970, the DoD did not implement anthrax-specific risk control measures until the Gulf War, and then only temporarily.

No US servicemember has ever been exposed to weaponized anthrax; therefore, from the standpoint of military effectiveness there is no conclusive answer to this question. Without an answer to this fundamental question, this aspect of Step-6 – the questioning

of basic assumptions about the threat -- cannot be adequately conducted. Since the origins of the actual, as opposed to the postulated "threat" are most likely domestic, and are under investigation, we simply note the two times in US history Americans have died in inhalation anthrax events.

The first event, which researchers characterized as an epidemic, occurred in 1957 during a U.S. Army sponsored anthrax vaccine trial in a textile mill in Manchester, New Hampshire.²³ The second event occurred in 2001 when anthrax spores, genetically linked to a US source or stockpile, were distributed via the US postal system.²⁴ When a White House spokesperson was asked if scientists from the US Army laboratories at Fort Detrick were the source, the response was indefinite:

*"MR. FLEISCHER: All indications are that the source of the anthrax is domestic. And I can't give you any more specific information than that. That's part of what the FBI is actively reviewing. And I just can't go beyond that."*²⁵

An ORM review includes determining whether the actual cost of the risk control measure is in line with expectations.²⁶ There has been no complete public disclosure of the monetary cost of implementing the AVIP, but the total military allocation for AVIP includes a basic contract in 1998 of \$112 million, a DoD-funded manufacturer renovation of at least \$16 million, a contract price renegotiation in 1999 of \$24 million and a DoD funded "Education" Campaign of \$74 million for pens, coffee cups, mouse pads, websites, etc., budgeted over six years.²⁷

This leads to the second part of the review process; determining what effect or cost the risk control measure has had on mission performance.²⁸ This naturally follows the above review action. The cost of the AVIP can be measured in punishments, retirements and resignations, illnesses, deaths, bad publicity, professional dissent and erosion of trust between the ranks.

The DoD has acknowledged 300 pilot resignations from the Air Reserve Components directly related to the anthrax vaccine refusals.²⁹ These losses have been further confirmed through extensive Government Accounting Office investigation, which detailed 16% of aircrew transferring to non-flying positions or leaving the military due to the AVIP, another 20% intending to do so and over 60% not supporting the program. DoD admitted that 441 soldiers have refused the vaccine as of the summer of 2002, before the program was relaunched.³⁰

Additionally, 85% of those surveyed by GAO experienced adverse reactions to the vaccine. The GAO concluded, *"The systemic reaction rate reported through the survey represents a level more than a hundred times higher than the 0.2 percent published in the product insert."*³¹ The Air Force and military are understandably reluctant to enumerate exact figures with respect to punishments, illnesses, deaths, retirements, discharges and resignations, but an operationally oriented ORM analysis requires us to do so.

The final action in Step 6 is Feedback. Supervising and reviewing an operation is not enough. An effective feedback system is required to ensure that the risk control measure is effective and that any newly discovered hazards are identified and appropriate action

taken.³² However, DoD's denial of both attrition and injuries caused by the vaccine has effectively shutdown the feedback step essential to ORM.

Since Air Force and other military servicemembers have not been exposed to the hazard, there is no data to analyze and there is no feedback to determine the effectiveness of the operation. Yet, new hazards from the risk control measure itself have caused servicemembers to leave a military that consistently rejected feedback from its own troops. Until Congress passed a law requiring them to do so, the Defense Department leadership would not publicly disclose refusals, resignations or retirements resulting from the AVIP because it might "*undermine Commander authority*".³³

The military is similarly on record minimizing the health risks associated with the vaccine, but their assertions stand in direct contrast to the extensively revised FDA-approved product insert or label. It now indicates 6 deaths, birth defects based on a US Navy study (the product insert now reads "Category D" – meaning "*positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans*" according to the FDA). The product label also now indicates adverse reaction rates up to 175 times greater than first acknowledged by the manufacturer and the Army.³⁴ By reviewing the budgetary and personnel costs associated with the risk control measure itself and the available feedback, an appropriate Supervisor action would be to initiate the ORM process in response to the new hazard -- the anthrax vaccine. This should have been the case with AVIP, but it has not yet occurred.

According to internal Army documents, weaponized anthrax, the hazard against which AVIP is directed, is effectively mitigated with antibiotics. In contrast, our Step 6 analysis identifies AVIP as a hazard with no quantifiable benefit to-date except for its possible, but indeterminate, deterrence effect. Additionally, There is a quantifiable risk associated with the AVIP. This leads us to an ORM process predicated on the risk management continuum, which requires continual execution of the ORM process to minimize risk and maximize mission effectiveness. Therefore, the analysis cycles back to Step 1.

Step 1 -- Identify the Hazards



Hazard identification is the foundation of the entire ORM process. If a hazard cannot be identified it cannot be controlled.³⁵ Step 1 requires us to analyze: "*any real or potential condition that can cause mission degradation, injury, illness, or death to personnel, or damage to or loss of equipment or property.*" Therefore, the analysis of the AVIP and its primary component, anthrax vaccine adsorbed (AVA), is required. A variety of hazard analysis tools are available,³⁶ and this analysis utilizes several of these tools. Hazard analysis tools allow us to analyze critical components of the mission such as equipment, lost experience, operator issues and the timeline of events. The strategic risk management process requires review of all existing databases or available historical and hazard information regarding the operation.

The first tool used to analyze the AVIP is the Operations Analysis tool, which dictates a review of the historic sequence of events regarding the anthrax vaccine and the AVIP. As the operations analysis or timeline of events demonstrates, the U.S. Army has been intimately involved throughout the history and development of AVA and the AVIP. Whether or not the Army conducted a formal ORM in developing the AVIP, they were aware of the risks involved in implementing such a program. Secretary of the Army indicated he was prepared to execute the program but wanted the responsibility to lie with the Secretary of Defense.³⁷ Army's knowledge of the vaccine's history indicates that either a risk management review did not occur, or that the risks of employing a questionably effective, improperly approved, and highly reactive vaccine were glossed over.

The original decision to implement the AVIP may have omitted this analysis because an understanding of the pre-1998 timeline of events would have revealed unacceptably high risks associated with the anthrax vaccine, the "*unsatisfactory*" nature of the vaccine, as well as the recognition that the anthrax vaccine was known to be "*experimental*." The other Services, having adopted the AVIP in total,³⁸ have by default adopted these now well-chronicled risks. The application of ORM to an on-going program requires a review of the program's genesis as well as a review of any scientific, regulatory, legal and medical factors introduced after the initiation of the program.

The Operations Analysis tool is used to accomplish this review of historic events.³⁹ It is through this timeline that a thorough understanding on the risk of anthrax and the risk-mitigating tool, the anthrax vaccine, can be obtained.

Operations Analysis Tool – 'The Time Line'

1. **January 1955.** An anthrax vaccine supplied by the U.S. Army Chemical Corps was used in the first human field trial. During this clinical trial five workers contracted inhalation anthrax and four died in the first anthrax epidemic of the 20th Century.⁴⁰
2. **September 1965.** A human anthrax vaccine patent was awarded to Milton Puziss and George Wright, representing the U.S. Army.⁴¹ (The vaccine described in this patent was materially different from the vaccine used in the 1955 to 1959 New Hampshire field trial.)
3. **July 1967.** An application is made with the Health Education and Welfare's Division of Biologic Standards to license an anthrax vaccine based on the patented vaccine production method.⁴²
4. **July 1967.** First required annual progress report submitted to the Division of Biologic Standards.⁴³
5. **February 1969.** The Division of Biologic Standards recommended license approval, but noted that clinical data establishing efficacy had not been submitted and requested data be gathered to establish efficacy.⁴⁴
6. **November 1970.** The Division of Biologic Standards approved the anthrax vaccine.⁴⁵

7. **February 1972.** Final Progress Report on the anthrax vaccine was submitted to the Division of Biologic Standards.⁴⁶ (Data establishing efficacy of this vaccine as requested in February 1969 had yet to be generated, collected, submitted or reviewed by the Division of Biologic Standards.)
8. **June 1972.** The responsibility of regulating biologic products, including vaccines, is transferred from the Division of Biologic Standards to the Food and Drug Administration.⁴⁷
9. **August 1972.** The Food and Drug Administration announced a review of all products transferred from the Division of Biologic Standards for safety, effectiveness and labeling.⁴⁸ AVA was one such product.
10. **May 1985.** The DoD (through the Department of the Army) issued a Request for Proposals (DAMD17-85-R-0078) to the pharmaceutical industry soliciting the development of a new anthrax vaccine. The reasons stated in the Request for Proposals was that there was no vaccine in current use that safely and effectively protects military personnel against exposure to anthrax and that the current anthrax vaccine was highly reactogenic, required multiple boosters to maintain immunity, and may not protect against all strains of anthrax.⁴⁹
11. **December 1985.** The review required by the Food and Drug Administration in 1972 was published in the Federal Register as a Proposed Rule. The review panel recommended that AVA be placed in Category I as safe, effective and not mislabeled. The review panel did note the lack of efficacy data: “*the vaccine...has not been employed in a controlled field trial.*” The panel also noted the inability to determine the vaccine’s use in preventing inhalation anthrax: “*efficacy against inhalation anthrax is not well documented . . . no meaningful assessment of its value against inhalation anthrax is possible due to its low incidence.*” Finally, based on the extremely limited use of the vaccine the panel felt the possible benefit outweighed the risk: “*In general, safety of this product is not a concern especially considering its very limited distribution and the benefit-to-risk aspects of occupational exposure in those individuals for whom it is indicated.*”⁵⁰ This panel also found the dosage of the anthrax vaccine to be incorrect, and recommended a correction to the labeling to only 3 shots. The FDA has not finalized the anthrax vaccine license proposed rule.
12. **February 1986.** Dr. Gregory B. Knudsen published an article in Military Medicine on anthrax in man. Knudsen concluded that by extrapolating animal studies, which demonstrate that vaccination is not protective against all anthrax strains or concentrations to humans, we can expect that the vaccine will not protect humans against all strains or concentrations as well.⁵¹
13. **March 1988.** USAMRIID researcher Bruce Ivins wrote in the European Journal of Epidemiology of the inability of the anthrax vaccine to adequately protect against certain strains of anthrax.⁵²
14. **May 1989.** When asked by the U.S. Senate Committee on Governmental Affairs to explain the DoD’s assessment that the U.S. cannot adequately defend its

service personnel against anthrax, Assistant Secretary of Defense Robert B. Barker answered,

*“The assessment in the 1986 report is accurate. Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunization for a variety of reasons: ...a higher than desirable rate of reactogenicity, and, in some cases, lack of strong enough efficacy against the aerosol route of exposure.”*⁵³

15. **March 1990.** Army Colonels E.T. Takafuji and P. K. Russell published an article describing the human anthrax vaccine as a *"limited use vaccine"* and an *"unlicensed experimental vaccine"*.⁵⁴
16. **September 1990.** The anthrax vaccine producer, then the Michigan Department of Public Health (MDPH), increased its production capacity and modified its production process to accommodate DoD needs. These production changes included changing the filtration system, using different fermentation equipment, different sterilization procedures, chill tanks, etc. FDA was eventually notified of some of these changes after the fact. FDA was unaware of others until Congressional and GAO inquiries were made in 2000. DoD involvement to some unknown degree is apparent from a review of declassified documents.⁵⁵
17. **October 1990.** US Army medical research personnel from Fort Detrick, Maryland determined that the changes in the anthrax vaccine manufacturing process produced a 100-fold increase in protective antigen levels of the vaccine.⁵⁶
18. **May 1993.** First in a series of FDA inspections of the anthrax vaccine manufacturing facilities began noting serious deviations from regulations and that the vaccine manufacturer was in violation of current Good Manufacturing Practices (cGMP).⁵⁷
19. **1994.** U.S. Army officer and researcher Col. Arthur M. Friedlander co-authored a chapter on the anthrax vaccine for the medical reference textbook “Vaccines”. Friedlander wrote that:

*“No assessment of the effectiveness of the vaccine against inhalation anthrax could be made because there were too few cases. ... There have been no controlled clinical trials in humans of the efficacy of the currently licensed U.S. vaccine. ... The current vaccine against anthrax is unsatisfactory for several reasons. The vaccine is composed of an undefined crude culture supernatant absorbed 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. ... 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.”*⁵⁸
20. **June 1994.** FDA inspection of manufacturer noted non-compliance with regulations and cGMPs.⁵⁹

21. **December 1994.** Senate Veterans Affairs Committee determined that the use of the anthrax vaccine during the Gulf War was investigational. Future Army Surgeon General Ronald Blanck testified that the anthrax vaccine should be considered a possible cause of Gulf War Illness.⁶⁰
22. **April 1995.** FDA inspection of manufacturer noted continued non-compliance with regulations and cGMPs.⁶¹
23. **August 1995.** FDA issued a warning letter to the anthrax vaccine manufacturer for their continuing failure to comply with the regulations and remedy the deficiencies noted in the various inspections. The manufacturer was warned that failure to promptly correct those deviations could result in regulatory action to include seizure, injunction, and license suspension.⁶²
24. **October 1995.** The U.S. Army contracts with Science Applications International Corporation (SAIC) to develop a plan to obtain FDA approval for a license amendment for the anthrax vaccine. The license amendment would enable the manufacturer of the vaccine to indicate that the anthrax vaccine was effective against "*inhalation anthrax*." The SAIC license amendment plan stated that the anthrax vaccine was not licensed as protection for aerosol anthrax exposure (inhalation anthrax) as expected in a biological warfare environment.⁶³
25. **October 1995.** The Army's newly formed Joint Program Office for Biological Defense (JPOBD) met to discuss the proposed anthrax vaccine license amendment. The participants noted that studies showed the vaccine to be effective for tannery workers, but that there was insufficient data to demonstrate protection against inhalation anthrax.⁶⁴
26. **February 1996.** A U.S Army representative was presented with a report on the anthrax vaccine manufacturer, which indicated equipment in use had not been approved by FDA and could result in severe consequences if FDA found out.⁶⁵
27. **September 1996.** The anthrax vaccine manufacturer submitted an investigational new drug application for the anthrax vaccine to the FDA (IND #6847). At this point the anthrax vaccine was now considered an investigational new drug when used for the purpose described in the application, i.e. "*inhalation anthrax*".⁶⁶
28. **November 1996.** FDA inspected the anthrax vaccine manufacturer and noted continued non-compliance with regulations and cGMPs.⁶⁷
29. **March 1997.** FDA issued a Notice of Intent to Revoke letter to vaccine manufacturer for failure to remedy regulatory deficiencies and non-compliance.⁶⁸
30. **March 1997.** DoD Joint Program Manager for Biological Defense briefed the Deputy Secretary of Defense concerning the anthrax vaccine production problems. A worst-case scenario was laid out, which threatened the as yet to be announced anthrax vaccination program. The AVIP was revealed as the launch program for a larger initiative called the Joint Vaccine Acquisition Program (JVAP), which would field up to 18 more biowarfare vaccines⁶⁹
31. **March 1997.** Acting FDA Commissioner Dr. Friedman wrote a personal memo to DoD Assistant Secretary of Defense (ASD) for Health Affairs, Dr. Joseph, which

- accepted DoD's new position that the anthrax vaccine could be used for inhalation anthrax. The IND application, which requested that the new use be added to the product label, was not addressed. Friedman's memo or opinion had no legal authority. The Code of Federal Regulations at 21 C.F.R. § 10.85 -- Advisory Opinions -- explained why the March 1997 letter by FDA Lead Deputy Commissioner was legally irrelevant -- yet the DoD used this memo to justify product approval for an experimental use.⁷⁰ In his memo to the DoD, Dr. Friedman wrote that, "*Results from animal challenge studies have also indicated that pre-exposure administration of anthrax vaccine protects against inhalation anthrax.*"⁷¹
32. **December 1997.** A Joint Program Office for Biological Defense report continued to note that "*Anthrax and Smallpox are the only licensed vaccines that are useful for the biological defense program, but they are not licensed for a biological defense indication.*"⁷²
 33. **December 1997.** FDA interoffice memorandum indicated that the vaccine manufacturer routinely redated vaccine without proper authority or approval.⁷³
 34. **December 1997.** DoD announced a multi-service vaccination program for all active duty, Reserve and National Guard service members using the anthrax vaccine as a preventative measure for inhalation anthrax.⁷⁴
 35. **February 1998.** FDA inspected the anthrax vaccine manufacturer, found multiple deviations from cGMPs and determined that the manufacturing process was no longer validated.⁷⁵ Manufacturer "voluntarily" quarantined 11 of 19 Lots of the anthrax vaccine.
 36. **February 1998.** Within one day of the FDA inspection, which revoked the validation of the anthrax vaccine manufacturing process, an independent expert completed a four-point review of the AVIP, mandated by Defense Secretary Cohen.⁷⁶ Later this expert admitted in a letter to Congressional investigators he had no expertise in anthrax. One aspect of the four-point review included supplemental testing of the vaccine, which DoD officials later admitted to Congressional investigators was suspended due to "*inconsistencies.*"⁷⁷ Internal documents later revealed that testing results were "*all over the board,*" and were terminated to preclude having to report the problems to FDA.
 37. **September 1998.** Army Secretary Louis Caldera authorized indemnification of the manufacturer stating:

*"the obligation assumed by MBPI under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients. ...[T]he size of the proposed vaccination program may reveal unforewarned idiosyncratic adverse reactions. Moreover, there is no way to be certain that the pathogen used in tests measuring vaccine efficacy will be sufficiently similar to the pathogen that US forces might encounter to confer immunity."*⁷⁸

38. **1999.** New Edition of the civilian medical textbook “Vaccines” printed with minor changes to the anthrax vaccine chapter.⁷⁹ 1994 chronology, verbiage and assessments of the unsatisfactory nature of the vaccine by Friedlander and Brachman remain unchanged.
39. **1999.** 10 U.S.C. § 1107 became law. 10 U.S.C. § 1107 provided that investigational new drugs or drugs unapproved for their intended uses may not be given to members of the Armed Forces without their prior consent except in the case of a waiver by the President of the United States. 10 U.S.C. § 1107 reiterated and codified language already established in federal and military regulations.⁸⁰
40. **January 1999.** A British journal, The Lancet, published a study establishing a link between Gulf War vaccinations and Gulf War Illness.⁸¹
41. **January 1999.** Investigational New Drug application #6847 is updated with the FDA’s Center for Biologics Evaluation and Research. The primary reason, and the only one listed on the application update, was for a clinical indication for “*inhalation anthrax*” on the anthrax vaccine product label.⁸²
42. **March 1999.** Hearings on AVIP began in House Government Reform Committee, the Government Reform Committee Subcommittee on National Security, International Relations and Veterans Affairs, the House Armed Services Committee and the Senate Armed Services Committee. Nine hearings were conducted in 1999.⁸³
43. **March 1999.** The General Accounting Office (GAO) testified and issued the first of many critical reports on the anthrax vaccine and the AVIP.⁸⁴
44. **March 1999.** Dr. Meryl Nass reviewed the anthrax vaccine in a biologic warfare context in Infectious Disease Clinics of North America concluding that when the DoD controls all steps in the vaccine development and production process, along with being the employer of both physicians and the servicemember recipients, there will be problems, including ethical conflicts, insufficient testing of products, inadequate quality control, inadequate record keeping, and lack of proper surveillance for side effects.⁸⁵
45. **April 1999.** DoD admitted the use of the anthrax vaccine was only routine in military research laboratories and that they did not intend to mislead or confuse the public with their previous pronouncements of routine civilian veterinarian use. DoD modified tri-fold brochure replacing “*civilian*” with “*at risk*”.⁸⁶
46. **May 1999.** Internal DoD correspondence by Brigadier General Cain, following Congressional testimony, revealed:

*“... two key areas we came up flat were the GAO’s assertion that #1, the anthrax vaccine licensed was NOT the one tested and #2, how can DoD say that reported desert storm illnesses were not cause (sic) by the anthrax vaccine when we have no record of who received the shots. If we cannot answer these questions we (DoD & the Administration) are in big time trouble.”*⁸⁷

47. **September 1999.** President Clinton issued Executive Order (EO) 13139. EO 13139 stated that before administering an investigational drug, or a drug unapproved for its intended use, to members of the Armed Forces, the DoD must obtain informed consent from each individual unless the President of the United States signs a waiver of this requirement. This EO reiterated the requirements already codified in US law.⁸⁸
48. **October 1999.** The FDA and the DoD proposed to amend the law in a proposed rule, “*New Drug and Biological Drug Products; Evidence needed to Demonstrate Efficacy of New Drugs for Use Against Lethal or Permanently Disabling Toxic Substances When Efficacy Studies in Human Ethically Cannot be Conducted*”.⁸⁹ This amendment would allow evidence of effectiveness derived from appropriate studies in animals, without adequate and well-controlled efficacy studies in humans, to be used to earn full approval for vaccines or drugs for soldiers.⁹⁰
49. **2000.** The House Government Reform Committee, the Government Reform Committee Subcommittee on National Security, International Relations and Veterans Affairs, the House Armed Services Committee and the Senate Armed Services Committee held a total of ten hearings.⁹¹
50. **2000.** GAO testified and issued seven more critical reports on the AVIP and the threat of weaponized anthrax.⁹²
51. **February 2000.** After eight hearings the Committee on Government Reform issued its findings in a report – Unproven Force Protection. They found the use of the anthrax vaccine by the military was experimental, that the AVIP lacked a consistent standard of care, and was designed to reach far beyond those at risk.⁹³ The DoD refused to modify the AVIP in order to comply with FDA regulations and US law as recommended by the Government Reform Committee.
52. **March 2000.** The Institute of Medicine issued a Letter Report assessing the safety of the anthrax vaccine and concluded there was a paucity of data on both the safety and efficacy of the anthrax vaccine.⁹⁴
53. **March 2000.** FDA admitted to Representative Metcalf of WA in a written response that trace amounts of an unapproved adjuvant, squalene, was found in all anthrax vaccine Lots tested. Previously, DoD had categorically denied that the anthrax vaccine has ever contained squalene.⁹⁵
54. **April 2000.** An article reviewing the anthrax vaccine in the journal “*Infectious Diseases*” acknowledged that “*The pre-clinical, clinical, pharmacological and safety data that would be required for a new product to be licensed today [was] never generated.*”⁹⁶
55. **May 2000.** A Canadian Judge, Col. Guy Brais, dismissed a case against a Canadian soldier, Michael Kipling, who refused the anthrax vaccine. The Judge deemed the anthrax vaccine was “*unsafe.*”⁹⁷
56. **July 2000.** DoD slowed AVIP due to a lack of vaccine supply.⁹⁸
57. **October 2000.** GAO issued a report titled: Preliminary Survey of Guard and Reserve Pilots and Aircrew, 01-92T. The report's abstract states:

“Many questions have been raised about the program since DoD began vaccinating its 2.4 million active duty and reserve members in 1998. A major concern has been the program's effect on the National Guard and Air Force Reserve's retention of trained and experienced personnel. A questionnaire sent to 1,253 randomly selected Guard and Reserve pilots and others revealed that the anthrax immunization was a key reason these individuals left or otherwise changed their military status. Since September 1998, an estimated 25 percent of the pilots and aircrew members of the Guard and Reserve in this population transferred to another unit, left the military, or moved to inactive status.”

58. **November 2000.** The American Journal of Epidemiology published a study of Kansas's veterans, which described the Gulf War Illness symptoms of servicemembers who didn't deploy to South West Asia but received the anthrax vaccine.⁹⁹
59. **December 2000.** The Center for Disease Control's Advisory Committee on Immunization Practices issued a report on the use of the anthrax vaccine. They did not recommend the vaccine for emergency first responders, federal responders, medical practitioners or private citizens. Further, the Committee determined that the target population could not be predetermined and that the risk of exposure to anthrax could not be calculated.¹⁰⁰
60. **2001.** GAO testified and issued six critical reports on the AVIP and the threat of weaponized anthrax.¹⁰¹
61. **June 2001.** Senator Daschle, the Senate Majority Leader, and Representative Gephardt, the House Minority Leader, wrote a joint letter to Secretary of Defense Rumsfeld questioning the anthrax vaccine program and the punishments of soldiers.¹⁰²
62. **June 2001.** DoD suspended the AVIP due to a lack of vaccine.¹⁰³
63. **August 2001.** DoD Undersecretaries submitted recommendations to Secretary of Defense Rumsfeld to minimize use of the current anthrax vaccine, develop a new vaccine, procure biodetection systems, and institute a coherent process for dealing with biological warfare threats in the future.¹⁰⁴
64. **September 2001.** Gen. Shelton, Chairman of the Joint Chiefs of Staff, responded to the Undersecretaries' recommendations, adamantly insisted that the AVIP was supported by his subordinate commanders and was the “centerpiece” for biological defense.¹⁰⁵
65. **October 2001.** Anthrax, delivered through the US postal service, arrived in Senator Daschle's office on the 15th of October. One business day earlier BioPort applied for an expedited approval of its anthrax manufacturing line. Senator Daschle ultimately recommended his staff take the anthrax vaccine. It is unknown if Senator Daschle ever followed up on the anthrax vaccine questions presented to the DoD several months earlier.

66. **October 2001.** A Citizen Petition was filed with the FDA requesting they declare the anthrax vaccine adulterated based on the unapproved and illegal manufacturing alterations, and revoke the anthrax vaccine manufacturer's license based on meeting the threshold of license revocation on both the scientific and regulatory grounds.¹⁰⁶ The petition also covered the fact that the DoD's contracts for the anthrax vaccine were in conflict with FDA policy guidance, since the manufacturer had received warning letters and other adverse regulatory actions, and the fact that the FDA proposed rule noted that the vaccine regimen was intended to be only 3 shots, not 6.¹⁰⁷
67. **October 2001.** DoD reported to Congress on their co-sponsorship of the proposed rule to change the law to allow licensure of biological warfare defensive protection measures based on animal data. The proposed rule was attached to the 2001 Bioterrorism bill that passed without dissent.¹⁰⁸
68. **November 2001.** An article in *The Lancet* reviewed how early and aggressive post exposure treatment with antibiotics saved the lives of several anthrax letter victims.¹⁰⁹
69. **November 2001.** A trade journal article, *Nursing Times*, published an article expressing reservations on recommending the vaccine to their members based on published reports of adverse reactions.¹¹⁰
70. **December 2001.** An article published by members of the US Army expressed the belief that the vaccine was effective, in contrast to previous DoD admissions that the vaccine was not effective against all known strains. The article purported to review the adverse reaction data, and minimized the deleterious effects of the vaccine on the military population. These findings were refuted several months later by a civilian review of the same data.¹¹¹
71. **January 2002.** The anthrax vaccine manufacturer's license to manufacture and distribute vaccine (under a new trademark, BioThrax) was approved after the FDA accepted the expedited application. A review of FDA's newly approved anthrax vaccine product label revealed systemic adverse reaction rates now published at 5 to 35% based on post-surveillance studies, which was up to 175 times or 17,500% higher than the original 0.2% on the old product label when the AVIP was announced in 1997. The new anthrax vaccine product label also listed six reported deaths including cardiac arrest, myocardial infarction, aplastic anemia, central nervous system (CNS) lymphoma. Birth defects were also listed based on a US Navy retrospective study. The FDA revised the product labeling, confirming positive risk of birth defects based on human data, and downgraded the vaccine to Category D. Approximately 40 serious adverse events were now on the product label including: cysts, sepsis, angioedema, asthma, aplastic anemia, lymphoma, leukemia, vascular disease, systemic lupus, multiple sclerosis, arthritis, Guillain-Barré syndrome, immune deficiency, seizures, tremors, facial palsy, hearing and visual disorders, meningitis, encephalitis, atrial fibrillation, spontaneous abortion, liver abscess, fatigue, mood-cognition, musculoskeletal disorder.¹¹²

72. **January 2002.** A paper establishing the existence of squalene in the anthrax vaccine was published. Squalene was a substance known to be present in virtually every person with Gulf War Illness.¹¹³
73. **January 2002.** 24 January 2002 Congressional testimonial exchange with GAO investigators revealed that the DVA had data linking anthrax vaccine to GWI, but data was not released to the public:
- Mr. Shays. *“OK. In your testimony, you said according to studies in both the U.K. and the U.S. veterans of the Gulf war who reported receiving biological warfare inoculations for anthrax or other threats were more likely to report a number of symptoms than non-Gulf war veterans who did not report receiving such inoculations. This pattern was observed in data collected in the United Kingdom in an unpublished data collected by the U.S. Department of Veterans Affairs. Why do you think the VA has not published its finding regarding the link between advance symptoms and the anthrax vaccination?”*
- Ms. Kingsbury. *“I don't know why they didn't publish it. We are aware of it. We have asked them. They said to us what they said to you this morning, things about the analysis not being completed and that sort of thing. I'm not in a position to second-guess it. We consider it to be valid, useful information that ought to be in the public domain.”*¹¹⁴
74. **March 2002.** The Institute of Medicine issued a Congressionally mandated, DoD funded, report on the anthrax vaccine. The report recommended the vaccine for soldiers, and was authored by the same experts that had been involved with the DoD's anthrax vaccine program and other experts that were involved with the DoD's original anthrax vaccine trial in 1957¹¹⁵ The report was used to justify the subsequent relaunch of the AVIP, but held no regulatory relevance.
75. **March 2002.** A civilian review of adverse reactions was published showing a significant increase in joint symptoms following vaccination with AVA when compared to joint symptoms following vaccination with hepatitis A and Td.¹¹⁶
76. **April 2002.** A study of over 900 Reserve members showed that Gulf War veterans were more likely to report poor health than non-Gulf War veterans, including veterans who received the anthrax vaccine who reported more reactions to vaccines than those who did not receive the anthrax vaccine.¹¹⁷
77. **April 2002.** A published article demonstrated that the anthrax vaccine caused statistically significant adverse reactions ranging from arthralgia, to vasculitis, to joint disease, to gastrointestinal disease and weight loss.¹¹⁸
78. **June 2002.** DoD formally restarted the AVIP.¹¹⁹
79. **July 2002.** DoD Inspector General (IG) referred an amended complaint (#84142) to the Defense Criminal Investigative Service (DCIS) concerning the anthrax vaccine program. MG Randall West, the Office of the Secretary of Defense officer responsible for the AVIP, was tasked with investigating a previous, similar complaint. Following his investigation, he dismissed the complaint. The original complaint included concerns about questionable testimony to the US Senate, and

- a Canadian Judge concerning the IND application by military officers. The amended complaint added additional questionable testimony to the House of Representatives, and broader concerns about the adulteration of the vaccine, the failure to properly study the vaccine as a possible cause of Gulf War Illness (GWI), and concerns about the willfully blind nature of the DoD's conduct despite soldiers documenting the risks of the vaccine.¹²⁰ The new complaint's investigation is pending.
80. **July 2002.** Article by Kansas State University scientists critiqued the National Academies of Sciences Institute of Medicine Report, which found the anthrax vaccine safe and effective, based on its "*omissions and limitations.*" The critique explained that the report "*ignored evidence of several recent research studies from three different nations that have implicated vaccines, often including anthrax vaccine, in the epidemiology of Gulf War illnesses.*"¹²¹
81. **August 2002.** FDA responded to a Citizen Petition filed under Title 21 of the US Code. The response confirmed the fact that FDA never finalized the anthrax vaccine license as required by law, and that none of the old anthrax vaccine would be released.¹²²
82. **October 2002.** Air Force Chief of Staff General Jumper promulgated AVIP policy and guidance for all active duty and reserve units. The policy stated that, "*The vaccine must be given in accordance with the ... dosing schedule, as approved by the Food and Drug Administration.*" Notwithstanding the CSAF's guidance to follow the licensed vaccination schedule, Paragraph 4c of Annex B of the plan stated: "*Personnel whose vaccination series was interrupted during the previous AVIP slowdown will not need to repeat any doses already received in the vaccine series or receive extra doses. Once these individuals are identified as requiring the vaccine, they will just continue with the next dose in the series.*"¹²³
83. **October 2002.** GAO's final report¹²⁴, Survey of Guard and Reserve Pilots and Aircrew, report #02-445, revealed on page 5 that:
- "The systemic reaction rate reported through the survey represents a level more than a hundred times higher than the 0.2 percent published in the product insert. We were unable to determine why the AVIP reaction rates so exceeded the product insert rates for the vaccine as approved in 1970. However, we found two studies conducted by DoD that looked at the short-term safety of the vaccine -- one in Korea and one in Hawaii. Both reported reaction rates similar to those reported in our survey and disclosed a markedly higher rate of reaction for female shot recipients. Since we first reported these results from our survey in September 2000, the manufacturer's product insert has been revised to include the adverse reaction rates reported in post licensure survey studies."*
84. **October 2002 Continued.** GAO report #02-445 also revealed on pg. 23 that:
- "In addition, although DoD has maintained from AVIP's outset that the anthrax vaccine is very safe and causes minimally adverse effects,*

our survey disclosed that a significantly large number of vaccine recipients reported experiencing adverse events. Further, the results of two DoD studies on anthrax vaccine reactions, both of which used active monitoring systems, as opposed to a passive system such as VAERS, for gathering information on adverse events, are consistent with and support the results of our survey. The rates disclosed in the survey and the DoD studies are each significantly higher than those stated in the vaccine product insert until recently. Such marked variances from the product insert data suggest the possibility of change in the composition of the vaccine from the vaccine originally approved in 1970."

85. **October 2002 Continued.** The GAO report #02-445 abstract summarized the readiness implications of the AVIP:

"GAO reviewed the views of pilots and aircrew members of the Air National Guard and Air Force Reserve regarding the Anthrax Vaccine Immunization Program (AVIP) of the Department of Defense (DoD). ...Between September 1998 and September 2000, 16 percent of the pilots and aircrew members of the guard and reserve had (1) transferred to another unit (primarily to nonflying positions to avoid or delay receiving the anthrax shots), (2) moved to inactive status, or (3) left the military. Additionally, one in five of those still participating in or assigned to a unit in 2000 indicated their intention to leave in the near future. At the time of the survey, two-thirds of the guard and reserve pilots and aircrew members did not support DoD's mandatory AVIP or any future immunization programs planned for other BW agents. However, these negative views did not appear to indicate a general anti-vaccine bias. On the basis of the survey, GAO estimated that 37 percent of the guard and reserve pilots and aircrew members had received one or more anthrax shots as of September 2000. Of these recipients, 85 percent reported experiencing some type of reaction. ..."

86. **February 2003.** FDA approved pyridostigmine bromide (PB) for use to protect soldiers from chemical weapons. The approval marked the first application of the "animal efficacy rule" proposed by the DoD in October 1999, reported to Congress in October 2001 and passed in to law in the summer of 2002 following passage of the Bioterrorism bill. Opponents of the use of PB referenced a 1999 study by the RAND Corporation and a 2000 report by the Institute of Medicine that concluded PB could not be ruled out as cause of Gulf War Illness. Evidence of efficacy inferred from animal data and the unresolved issues pertaining to Gulf War Illness were identical to that of the anthrax vaccine.
87. **February 2003.** United States District Court ruling, for a US Army soldier's discharge upgrade case, cautioned that:

" ... It is important for the parties and the public to understand exactly what the Court is ruling. The Court is not passing on the merits of the

*anthrax program. The plaintiff has raised significant questions about that program. If the Court were reviewing the program, the Court would be very concerned about the question that the plaintiff has raised. Title 10 United States Code Section 1107 provides that whenever the Secretary of Defense requests a member of the armed forces to receive an investigational new drug, the Secretary must provide a member with notice about the investigational nature of the drug and require the member's consent prior to administration ... There have been no tests showing that the vaccine is effective at protecting human beings from exposure to inhalation anthrax, although animal studies by the Army exist. The Court will not substitute its opinion for that of the Army, but it will not review the matter. And its ruling today should not be understood as an approval of what the military is doing in this case. The military will be held accountable to the public if it is using its own soldiers as guinea pigs to determine whether the anthrax vaccine has long-term health consequences and whether it protects against airborne anthrax. Those decisions, are, as I said, decisions that are committed to the Executive Branch of the Government. The Court neither approves nor disapproves of those decisions, because it is not the function of the Court to do that. Those decisions will be debated, and ultimately the Executive Branch will be held accountable to the public for those decisions. And that is the way the system of government works. ..."*¹²⁵

88. **March 2003.** Case 1:03-cv-00707-EGS JOHN DOE et al v. RUMSFELD et al filed in the United States District Court for the District of Columbia requesting that a federal judge declare that the anthrax vaccine an experimental drug and illegal. A separate motion was also filed seeking a Temporary Restraining Order or Preliminary Injunction against the defendants to prevent further anthrax inoculations without informed consent or a presidential waiver according to law and Executive Order. Specific aspects of the suit include:
- a. FDA Failure to properly finalize the anthrax vaccine license;
 - b. Anthrax vaccine experimental use for inhalation anthrax;
 - c. And DoD deviation from anthrax vaccine license requirements.
89. **March 2003.** Additional multiple Federal lawsuits were filed against the manufacturer for wrongful injury, with specific counts including:
- a. Negligence
 - b. Breach of Warranties
 - c. Breach of the right to be treated with essential human dignity
 - d. Strict products liability
 - e. Fraud
 - f. Deprivation of civil rights and

- g. Spouse's loss of assistance, companionship and consortium.

The facts presented in the Operations Analysis tool identify five major areas of risk concern. These risks are listed below and are further analyzed with the subsequent hazard identification tools:

1. A vaccine originally licensed with incomplete scientific data;
2. A vaccine whose license the FDA has yet to be finalized;
3. A vaccine produced with unapproved, adulterating manufacturing changes;
4. A vaccine known by DoD officials to be experimental for inhalation anthrax;
5. And a vaccine that could burden DoD and DVA with significant liability.

Preliminary Hazard Analysis

The Preliminary Hazard Analysis (PHA) tool allows a quick initial assessment of hazards.¹²⁶ Based on the Operations Analysis it is evident that the risk control measures related to anthrax and the anthrax vaccine warrant a more critical review. Several key factors, which can be considered hazards that may or may not have been known when the program was launched but are now well established, justify this re-evaluation. These facts include:

1. The organization responsible for the AVIP (U.S Army) knew the vaccine was not licensed for use in a biowarfare environment as early as 1995.¹²⁷
2. The organization responsible for the AVIP (U.S Army) knew the vaccine might not be protective against all known strains of anthrax or of weaponized anthrax and their expectation for protection was based on studies of laboratory animals.^{128, 129}
3. The organization responsible for the AVIP (U.S Army) is the principal investigator of an Investigational New Drug (IND) application for the anthrax vaccine. The IND regulations require informed consent when an IND drug is used for the purposes stated in the application. In this case, the IND application is for use in preventing disease from inhalation anthrax.^{130, 131}
4. Unapproved major manufacturing process changes were made to the anthrax vaccine casting the legal status of the vaccine and the AVIP in doubt.^{132, 133}
5. The anthrax vaccine has not been definitively ruled out as a cause or contributor to Gulf War Illness, nor has it been specifically studied.^{134, 135}
6. Resistance to the vaccination program negatively impacted the readiness of the Air Force and the integrity of the military institution as reported by the GAO.¹³⁶
7. A statistically significant number of systemic adverse reactions to the anthrax vaccine have been documented; up to 175 times, or 17,500% higher than

- previously experienced. When the AVIP was announced, the FDA published adverse reaction rate was 0.2% versus the current rate of 5 to 35 %.¹³⁷
8. Documented deaths for the anthrax vaccine exceed smallpox by a factor of ten. Six deaths are listed on the anthrax vaccine product label based on slightly over ½ million anthrax vaccine recipients. This compares to 1 death per million for the smallpox vaccine. Adverse reaction rates are comparable.¹³⁸
 9. Birth defects are attributable to the anthrax vaccine according to a US Navy study. Recently, the vaccine's pregnancy use risk has been upgraded from a Category C (risk cannot be ruled out) to Category D (positive evidence of risk based on human data).¹³⁹
 10. Several lawsuits have been entered in federal court contending injury, failure to provide informed consent, and non-compliance with federal law and executive order designed specifically for programs such as the AVIP¹⁴⁰, as well as challenging the manufacturer's compliance with the Federal Food Drug and Cosmetic Act.¹⁴¹
 11. FDA admits they have never finalized the anthrax vaccine license review as required by law and their 1985 proposed rule recommends 3 shots versus DoD's and FDA's current 6 shot regimen. The FDA is conducting clinical trials to obtain a clinical indication for as few as three shots. This seems unnecessary considering this is what the FDA's reviewing committee recommended. Again, these facts cast doubt on the validity of the anthrax vaccine license.¹⁴²
 12. FDA applies the "animal efficacy rule" to license pyridostigmine bromide for use by soldiers in a chemical warfare environment.¹⁴³ Identical circumstances exist for the anthrax vaccine based on FDA and DoD admissions that efficacy against inhalation anthrax is similarly based on animal studies and no proven correlate of immunity between animals and humans currently exists for anthrax infection.¹⁴⁴
 13. A final hazard is the problematic fact that almost everything listed in the Operations Analysis is absent from the DoD "education" website for Commanders and soldiers – www.anthrax.mil. As a result, the degradation of and significant trust, unity of command and good order and discipline are obvious.

"What If" tool

The "What If" tool is a powerful brainstorming hazard ID tool. It is designed to add the intuitive and experiential expertise of operational personnel.^{145, 146} This tool is most often used immediately following the operations analysis and the Preliminary Hazards Analysis, particularly if they reveal hazards that warrant further investigation.¹⁴⁷ Applying "What If" frequently requires developing worst-case scenarios around the hazards. In the case of the AVIP the ongoing analysis requires us to ask:

1. What if the anthrax vaccine is a contributing cause of Gulf War Illness? Is the benefit of the AVIP greater than the risk of maladies similar to Gulf War Illness?

- If it is, then how do we mitigate or minimize the risk, in this instance providing medical care for those injured?
2. What if the anthrax vaccine is not effective against all strains or genetically engineered strains of anthrax? Are our troops in more danger because we think they are protected when they are not? Are we relying too much on the AVIP instead of other risk control measures such as protective Chemical and Biological Defense Ensembles (CBDE gear)?
 3. What if the FDA never approves the manufacturer's IND application to obtain an indication for inhalation anthrax on the product label? Will the President waive servicemember's rights in accordance with 10 U.S.C. § 1107, EO 13139, and DoDD 6200.2?
 4. What if the AVIP causes a continued exodus of personnel? Can we operate with a significantly smaller force? What impact will the AVIP have on morale and trust issues as DoD recruits and finds replacements?
 5. What if no correlation can be found between effectiveness of the vaccine in laboratory animals and humans? What if the DoD's mandatory use of the vaccine is deemed illegal for inhalation anthrax absent application of the "animal efficacy rule" or a Presidential waiver of informed consent?
 6. What if the federal courts decide in favor of the plaintiffs, and not the military, in the various pending legal actions? How will this affect the future credibility of the military to implement force health protection initiatives with vaccines and drugs?
 7. What if the FDA never finalizes the anthrax vaccine license rule as required by law, or what if a federal court directs FDA to finalize the vaccine license properly?
 8. What if the DoD as an institution has not properly investigated the anthrax vaccine as a possible cause of GWI? What if the DoD has not studied the possible deleterious affects of the manufacturing changes of the anthrax vaccine and the dramatic increases in protective antigen?
 9. What if the Legislative, Executive and Judicial branches, the media, subordinate commanders and soldiers at all levels determine the US Army entities responsible for the anthrax vaccine program have not followed the law or have feigned a willful ignorance of the law?
 10. What if, instead of deterring the use of Weapons of mass destruction (WMD), the AVIP escalates the risk of WMD by implying they are a legitimate form of warfare, or causes rogue nations to develop more virulent weapons?
 11. What if groupthink existed within the DoD, and the high level initiative was made to work, despite the documented risks and regulatory problems, because it was the launch program for a more ambitious JVAP effort? What if this same groupthink became infectious as more servicemembers were inoculated, or punished by commanders?
 12. What if the officer that testified to the House of Representatives had admitted in his verbal testimony, instead of waiting to email his colleagues back at the office

a few days later, about the fact that “*the anthrax vaccine licensed was NOT the one tested and #2, how can DoD say that reported desert storm illnesses were not cause (sic) by the anthrax vaccine when we have no record of who received the shots*”?¹⁴⁸

13. What if the officers that testified to both Houses of Congress and a Canadian Court-martial had been candid when specifically asked about the facts behind the core issue of the IND application for inhalation anthrax? Would admitting these facts have stopped the mandatory program, and precluded the punishment, imprisonment and discharge of hundreds of soldiers?

The “What if” tool is without a doubt a powerful tool that assists leaders in taking “self” out of ORM, as well as serving as a “license to think for servicemembers providing inputs to the chain of command.”

Risk-Event Logic tool

The Logic Diagram tool identifies individual operational events, often failures identified in the “What If” tool, and examines the possible consequences.¹⁴⁹

To accomplish the risk-event logic tool, our analysis continues by offering two categorical propositions as premises, followed by one categorical proposition as a conclusion in each of the following categorical syllogisms.¹⁵⁰ These logic examples may help senior leaders understand the ethical issues underlying the professional dissent regarding the AVIP:

1. If a clinical trial of a specific vaccine is required for a proper licensure-- And if according to federal records the anthrax vaccine has not been the subject of a clinical trial -- Then the anthrax vaccine is not properly licensed.
2. If a drug or vaccine that was altered by a major unapproved change to the manufacturing process is “adulterated” under the law – And if the anthrax vaccine was the subject of major unapproved changes according to the FDA – Then the anthrax vaccine was adulterated.
3. If, according to US law, an investigational or experimental drug or vaccine cannot be mandated without a Presidential waiver of informed consent– And if the DoD has previously acknowledged the investigational and experimental nature of the anthrax vaccine – Then a mandatory anthrax vaccine program requires a Presidential waiver of informed consent.
4. If it is illegal to mandate adulterated and experimental drugs to our servicemembers without a Presidential waiver of informed consent – And if the mandated anthrax vaccine is known to be adulterated, experimental and lacks a Presidential waiver – Then the anthrax vaccine order is illegal.
5. If pyridostigmine bromide (PB) was a licensed drug, but not licensed for how the DoD was using it in a biological warfare arena – And if the new “animal efficacy

- rule” has been applied to PB – Then PB is now fully approved for DoD’s use as a force health protection countermeasure in a biological warfare arena.
6. If the anthrax vaccine efficacy is based on animal data, and specifically acknowledged by the DoD as not approved for the biological warfare arena – And if the animal efficacy rule has not been applied – Then the anthrax vaccine is not fully licensed for use by the DoD as a force health protection countermeasure.
 7. If 10 U.S.C. § 1107 specifically dictates that the US armed forces cannot mandate investigational drugs or drugs unapproved for their applied use¹⁵¹ -- And if the DoD’s use of the anthrax vaccine is unapproved for it’s applied use – Then the AVIP is in violation of the law.
 8. If a drug requires specific application of the animal efficacy rule or FDA to follow federal rule making procedures to approve specific indications and approved use to drugs – And if neither of these proper processes have occurred with the anthrax vaccine – Then the anthrax vaccine is not fully approved for such specific applications or uses, i.e., inhalation anthrax.
 9. If DoD and FDA have attempted to obtain permission to use the anthrax vaccine for biological warfare by exchanging memos approving of the other agencies conduct – And if these memos have no legal bearing because they are personal opinions that did not comport with legal rule making procedures – Then such attempts to make the AVIP appear legal are not legally relevant.
 10. If the civilian and military leaders responsible for the AVIP are aware of the above-mentioned categorical syllogisms – And if such willful violations of the law equate to illegal conduct – Then at some level within the Defense Department, officials responsible for the AVIP may be guilty of criminal conduct.

By objectively analyzing these categorical syllogisms, the leadership of the military can better understand the origins of the logic-based concerns by their soldiers over the AVIP and similarly reconsider their risk control measure options.

Change Analysis tool

The Change Analysis tool is intended to analyze hazard implications of either planned or unplanned changes.¹⁵² This tool assists in analyzing the primary issues that have changed since the original AVIP was launched:

1. FDA acknowledges 17,500% increase (0.2% to up to 35%) in adverse reaction rates.
2. According to the product label, expected deaths are now a reality and are ten times higher than those expected for smallpox (6 in slightly over 1/2 million humans inoculated for the anthrax vaccine, versus 1 per million for smallpox).
3. Birth Defect risk category is now D (defined as a positive risk based on data from human studies).
4. As indicated on the product label, a variety of diseases similar to GWI are now attributable to the anthrax vaccine.

5. Based on GAO studies there is significant attrition and dissatisfaction with leadership.
6. FDA admits the anthrax vaccine license review is not complete; yet they have a legal obligation to do so.
7. DoD admits claims of widespread civilian use were inaccurate and that civilian veterinarians were not routinely inoculated.
8. Illegal, unstudied changes occurred to the manufacturing process of the vaccine.
9. GAO uncovers DoD study establishing that the potency, protective antigen, levels increased up to 100-fold.
10. Multiple independent, peer-reviewed and published studies by civilians find a causal connection between the anthrax vaccine and Gulf War Illness.

But the Change Analysis tool also assists in pointing out that the opinions of those objectively providing professional dissent regarding the anthrax vaccine program are actually reiterating the pre-1998 official position of the DoD. DoD's or its expert's official position on the anthrax vaccine prior to 1998 included concerns about:

1. Its "*higher than desirable rate of reactogenicity*";
2. A "*lack of strong enough efficacy against the aerosol route of exposure*";
3. Its being "*unsatisfactory for several reasons*";
4. It possessing "*unusually hazardous risks associated with the potential for adverse reactions*";
5. The "*evidence in experimental animals that the vaccine may be less effective against some strains of anthrax*";
6. And that the vaccine was "*not licensed for a biological defense indication*".

The Change Analysis tool not only demonstrates that these truth and facts were changed for the AVIP "*education campaign*" in 1998, but also points out the revelations of an illegally altered manufacturing process, causal links to Gulf War Illness, a license never finalized by the FDA, as well as hundred fold plus increases in adverse reaction rates, birth defects and deaths listed on the new product label. Failing to address the apparent misrepresentations and revelations is not health for the long-term integrity of the military institution.

Scenario Process tool

The Scenario Process tool is a time-tested procedure to identify hazards by visualizing them, using intuitive and experiential expertise of personnel.¹⁵³

Through the Scenario Process tool our analysis envisions three higher-level problems not directly related to the primary risk of the safety of the anthrax vaccine. One is the ethical risk to the military institution due to the DoD distribution of incomplete information to all levels of the chain of command, Congress and the media regarding the vaccine. The second is a risk created by the doctrinal shift of utilizing vaccines, which singularly target

threats amongst a genre of weaponry with literally infinite iterations based on varying or genetically altering diseases. The third is the risk of legal liability to the DoD, which will be inherited by the DVA if the AVIP is determined to be illegal.

1. Ethical risk. If senior leaders utilized the scenario process tools and academic approach that servicemembers did, they would better understand the professional dissent occurring throughout the ranks and services. Servicemembers, the Congress and the public now know that what the DoD said and still says about the anthrax vaccine is less than complete and accurate. In other words, assume everything DoD presents with respect to the anthrax vaccine equals “X”. This includes their website and educational materials, their testimonies and media reports, etc. Servicemembers, the Congress and the public would reasonably assume that ethically “X” is complete and accurate. What they have found, however is that “X” is not complete or accurate. A complete and accurate value can be represented as “Y”. An ethical representation of the value of “X” should equal “Y”. This is not the case in the present instance with the AVIP. The Operations Analysis shows multiple examples that directly contradict DoD’s expressed knowledge of the safety, efficacy and legality of the vaccine. It is particularly problematic if the science used to support the AVIP has been generated after the fact (it has), if the DoD has omitted independent civilian medical findings (they have), or if DoD knowledge has been “forgotten” during testimony, interviews and other presentations to the public. Obviously, anytime “X” does not equal “Y”, trust in and the ethical appearance of DoD leaders will be diminished. Extrapolated over time, the ethical danger is that blind loyalty or obedience to “X” becomes a condition of employment in the US armed forces. Clearly, this is a dangerous trend and contrary to the oaths, codes, values and principles the military institution represents, namely “Y.”
2. Doctrinal risk. One can envision soldiers being potentially more vulnerable if US enemies target our soldiers with diseases other than those they are vaccinated against. These concepts are memorialized in the editorial work of Brigadier General Malham Wakin, professor emeritus from the USAF Academy, articulating the traditional Chemical and Biological Warfare Taboo (CB Taboo).¹⁵⁴ This previously accepted resolute US doctrinal stance, which does not legitimize biological warfare by falsely implying we can defend against its dynamic nature, is important to remember. Brainstorming about the current doctrinal departure or the shift from the previous ‘CB Taboo’ may cause the senior leadership to realize the dangers of defensively posturing against bioweaponry through vaccines versus more comprehensive, non-escalatory use of external protective garments, detection systems and non-invasive medicine. Throughout the evolution of the AVIP, the vaccine that was initially termed as a “*centerpiece*” of biological defense. It is now defined as merely an “*additional layer*” of protection. The required question is whether or not the anthrax vaccine is a necessary layer based on the documented risks. The change in the rhetoric from “*centerpiece*” to “*additional layer*” may reflect the DoD’s internal awareness that “X” does not equal “Y”. Though it was convenient to expeditiously or defensively term the anthrax vaccine as “*body armor*” and maintain leaders would be “*derelict in their duty*” to not mandate it, this position

may lack the visionary doctrinal implications many years down the road following an escalation of biological warfare.

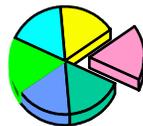
3. Legal liability. Finally, by envisioning the legal implications to the DoD or the DVA, which will inherit the risks or costs of the anthrax vaccine, the cost benefit analysis of the AVIP could be dramatically different. If extensive litigation against these agencies occurs because “X” did not equal “Y”, federal courts could in time find that because “X” \neq “Y” the AVIP is illegal. If the equation produces an illegal policy than an entirely different aspect of severity of risk, potentially more hazardous than the vaccine itself occurs. If such a cost-benefit analysis had occurred with nuclear testing, Agent Orange, or other documented examples of costly military medical malfeasance, extensive litigation against the DoD and DVA could have been avoided. The subsequent burden of legal and health liabilities for treatment of personnel also could have been avoided.

The Scenario Process tool is considered a “vision” tool. If it is reasonable to envision that the tenets behind the AVIP (“X”) were not well founded, and are in conflict with the Operations Analysis (“Y”), then it is also reasonable to assume that the genesis of the AVIP lacked consideration of these ethical, doctrinal, and legal implications. If the resulting program, AVIP, was the product (Z), and if it was not based on a foundation of truth, or a full disclosure of facts, then a reassessment of the program is warranted. The “Strategic” or visionary level of ORM, through the Scenario Process tool, can be pivotal in assuring that such ethical, doctrinal and legal risks are avoided.

Opportunity Assessment tool

Finally, the Opportunity Assessment tool is an advanced hazard identification tool used when in-depth hazard identification is required, and to identify opportunities, reduce operational cost and expand mission capabilities.¹⁵⁵

The opportunity assessment tool claims to “break the next barrier.” This is exactly what President Bush did, by announcing the development of a new anthrax vaccine initiative.¹⁵⁶ This occurred prior to the DoD announcing the resumption of the anthrax vaccine program with the old vaccine.



Step 2 -- Assess the Risk

Step 2 requires us to assess the Risks and Hazards and analyze the probability versus severity of exposure. This step requires us to question impact on the mission, impact on the people, as well as the impact on materials, facilities and the environment. Severity categories range from catastrophic, i.e., mission paralysis or death; to critical, i.e., major mission degradation, severe injury or occupational illness; to moderate, i.e., minor mission degradation, injury or illness; to Negligible, i.e., less than minor mission

degradation, injury, or illness. This subjective analysis of probability versus severity is known as the Risk Assessment Matrix, and is depicted in the diagram below:¹⁵⁷

			MISSION DEGRADATION/MISHAP PROBABILITY				
			FREQUENT	LIKELY	OCCASIONAL	SELDOM	UNLIKELY
			A	B	C	D	E
S E V E R I T Y	CATASTROPHIC	I	EXTREMELY				
	CRITICAL	II	HIGH		HIGH		
	MODERATE	III		MEDIUM			
	NEGLIGIBLE	IV				LOW	
			RISK LEVELS				

As the tools implemented in Step-1 demonstrate, this analysis finds competing risks. If the DoD cancels the AVIP because of court action, or the unwillingness of the President to waive informed consent for soldiers, or the lack of application of the “animal efficacy rule” by FDA, then the mandatory program will have failed. Alternatively, there will be no more injuries from the vaccine, no more resignations, no more professional dissent, no more loss of trust, and no more degradation of morale. Similarly, if the vaccine gets approved for inhalation anthrax by FDA finalizing the licensing rule or approving the IND application, the operation will continue, having a negligible impact on the mission, but the exodus of personnel and the injuries could rise to catastrophic levels.

Based on the cyclical nature of the ORM continuum, and our assessment of the facts listed in Step-1, the anthrax vaccine can reasonably be labeled as "Extremely High Risk". This determination is based on the "catastrophic" risks of death as well as the "critical" risks of severe injury and the likelihood or frequency of these occurrences as published on the new FDA product label. Both the severity and frequency are corroborated by GAO reports, surveys and a myriad of additional government documents. The severity issue is objective, and not refutable, based on documented deaths, the severe illnesses and the potential for birth defects indicated on the product label. The subjective determination of frequency or probability is debatable, but cannot be dismissed based on the fact that both the GAO and FDA document the dramatic differences between the previously published and currently observed adverse reaction rates. The disparity between the acknowledged "*unusually hazardous risks*"¹⁵⁸ of the anthrax vaccine and the fact that readily available antibiotics were effective against inhalation anthrax infection following onset of symptoms in the anthrax attacks of 2001 require this ORM analysis to continue.

Step 3 -- Analyze Risk Control Measures



Step 3 requires leaders and their subordinates to analyze the Risk Control Measures available to mitigate risk. They range from rejecting the risk altogether, to avoiding the risk, to delaying the risk, to accepting the risk if the benefits outweigh the costs.¹⁵⁹

Specific "Macro Options" are available to military leaders through ORM at anytime:

Senior leadership could "Avoid" the ethical dilemmas associated with mandating an experimental vaccine on their soldiers by utilizing antibiotics, which have proven to be fully effective in treating inhalation anthrax. It is possible that the DoD considered this for the first AVIP, but that the costs were excessive and that pre-deployment inoculation proved a more attractive public relations and cost effective option.

DoD leaders could also "Avoid" these ethical risks by requesting the Presidential waiver of informed consent in accordance with 10 U.S.C. § 1107, EO 13139 and DoDD 6200.2. It is possible that senior leaders attempted to mitigate this risk and accountability for the President and Commander in Chief during the first AVIP by creating an impression the vaccine was properly licensed, despite internal acknowledgments to the contrary.

Leaders could "Delay" utilizing the current anthrax vaccine until the "next generation" vaccine is available as ordered by the President in his 2002 State of the Union Address, a priority reiterated in his 2003 State of the Union Address. Col. Grieder, the former Dover AFB Wing Commander, attempted this step of ORM in his temporary suspension of the anthrax vaccine program based on the ORM expressed by multiple members of the unit. The USAF leadership, however, promptly replaced him.

If use of the vaccine is determined to be necessary, a "Transfer" or elevating of responsibility for this directive should be presented to the President as required by federal law. The accountability for ordering the use of experimental drugs and vaccines has been legislated through 10 U.S.C. § 1107 to the Commander in Chief. The President is the sole authority under the law for directing use of experimental inoculations or drugs.

Simultaneously, an effort to "Spread" and also "Reduce" the risk could be accomplished by ensuring our soldiers have modern and effective Chemical and Biological Defense Ensembles.

Such macro options avail many possibilities to the senior leaders of the military short of the reinstatement of a known problematic and expensive program, utilizing a known experimental vaccine of questionable effectiveness with pending serious legal problems, which are yet to be adjudicated. By thoroughly understanding the variety of risk control options, senior leaders can then make educated Control Decisions.

Step 4 -- Make Control Decisions

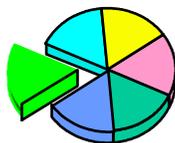


Beginning with Step 4, senior military leaders must take control of this ORM analysis. This step requires our leaders to assess the right time and the right level to implement control decisions. More time allows ORM to improve the process. The bottom-line in making the control decision continues to require leaders to accept risks when total benefits outweigh the costs, and reject risks when total costs outweigh the benefits. This can be a subjective process, but ORM requires us to question the difference between decisive risks and gambles. The answer, according to ORM, is that *“it is not the result, it is the process used to manage the risk.”*¹⁶⁰ Therefore, if the process is not an objective one, or utilizes incomplete information, current leaders must evaluate the validity of previous and future control decisions. The Operations Analysis and additional tools in Step-1 reflect this condition where inaccurate, incorrect, or incomplete information was utilized in the initial risk control decisions with the AVIP.

If leaders are unable to sort fact from misinformation, leaders have the ability and the responsibility to “Elevate” their concerns to higher levels of the chain of command. The Operations Analysis reveals that the AVIP originated from high levels within the chain of command, perhaps lacking the proper staffing and ORM expertise. The re-launch of the AVIP similarly originated from the highest levels. A thorough Operations Analysis documents the unusually high and unnecessary risks associated with the anthrax vaccine. Recent events demonstrate the efficacy of timely antibiotics against weaponized anthrax and the lack of any investigation into the vaccine’s relationship with Gulf War Illness. Based on the risk and involvement continuum, this new information necessitates that senior leaders be informed of the facts listed in Step-1 in case their subordinate staffers were unaware of or have failed to do so.

Without a doubt, the "Control Decisions" at this juncture must remain at the highest office of the executive branch. If the SECDEF, Joint Chiefs of Staff and their subordinate leaders have failed to follow the laws put in place by the legislative and executive civilian authority (10 U.S.C. § 1107) or fail to do so in the near future, the Executive Branch and the President, as Commander in Chief of the Armed Forces, should intervene in this ORM analysis and make the control decision.

Step 5 -- Implement Risk Controls



Step 5 requires leaders to initiate three specific actions: 1) make the implementation plan clear, 2) establish accountability, and 3) provide support.¹⁶¹

Initial attempts to "make the implementation plan clear" encompassed a "4-Point Review" by SECDEF Cohen in 1998. It is clear from reading the original approval letter by the independent expert that the DoD anticipated the risks of implementing their program.¹⁶² The reviewer, Dr. Gerard Burrow of Yale University, acknowledged that, *“There have been no controlled clinical trials of the currently licensed US vaccine in humans,”* which are required by law. He also acknowledged that, *“The decision to perform supplemental tests was based on a March 11, 1997 letter to MBPI from FDA,*

outlining a number of systemic issues. The FDA directed MBPI to do a comprehensive review to demonstrate that deviations in biologic product lines did not impact anthrax vaccine quality and integrity.” This meant procuring the vaccine violated government policy based on the FDA documented deviations. Burrow’s review also showed the DoD was aware of the risk of soldiers being concerned about Gulf War Illness:

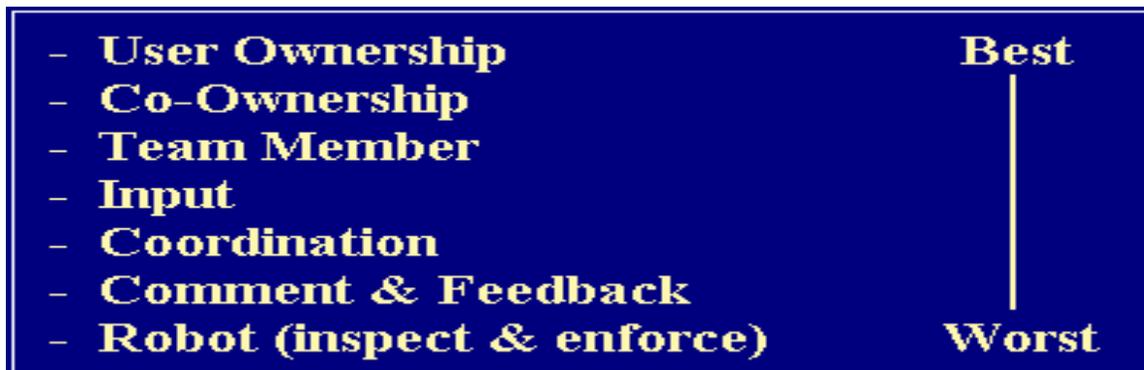
“The Communication Program Including Risk Communications for our Troops and the Public ... The communication problem will be compounded by the fact that anthrax vaccine has been mentioned as possibly playing a role in the health effects experienced by some Gulf War veterans.”

Unfortunately, the 4-point review proved to be problematic when the testing of the vaccine was terminated before the AVIP was launched due to "inconsistencies." Later the independent expert review authority that approved the AVIP for the SECDEF turned out to be an OB/GYN, with "no expertise in anthrax," and he retracted his expert status to Congressional investigators. Ultimately, the logistical and communications plan requirements of the 4-Point Review failed as well, causing suspension of the AVIP by 2001. Most recently, multiple independent, peer reviewed and published medical studies show a definitive link between the anthrax vaccine and GWI. Also, the pregnancy risk rating of Category C (given to a pregnant woman only if clearly needed) documented in the initial review has now been elevated to Category D (positive evidence of risk). Ultimately, the implementation plan of the 1st AVIP was a failure, based on an incomplete ORM analysis of the vaccine.

From 1998 to the present, the "accountability" allowed by the "risk control implementation" process has been directed at soldiers at the lowest level of the chain of command using the drumbeat of good order and discipline versus senior leaders holding themselves accountable for their program. Soldiers have been punished, imprisoned, fined and discharged for raising the above questions; in other words, for utilizing the analysis tools given them by their superiors. Approximately 500 soldiers have been punished and discharged, with approximately a dozen serving time in prison, in addition to at least 300 Guard and Reserve aircrew being lost. As this risk continuum is further analyzed, accountability should be directed towards the past and present members of the Anthrax Vaccine Agency and the US Army Medical Corps if it is determined that they misled the military and civilian leadership with respect to the legal, regulatory and scientific status of the anthrax vaccine. If this analysis’ “what ifs” are correct, the soldiers punished are not the ones who have broken the law.

As the "involvement continuum" required in this step of ORM proceeds, and as the DoD holds itself accountable for the problems associated with the AVIP, our leaders should consider exonerating the punished soldiers, provide care for the ill and terminate any ongoing judicial or non-judicial punishments of US armed forces personnel. DoD officials should consider immediately pursuing their alternative risk control options by obtaining a Presidential Waiver of Informed Consent if they continue to accept the risks of the anthrax vaccine, "Rejecting" the current AVIP or making it voluntary. It is very important to mitigate the risk to the integrity, credibility and trust in the military institution. Therefore, it is imperative the DoD follows the rule of law and does the honorable thing in correcting the records of those wrongly punished.

DoD leaders have a choice to allow ORM to work and be applied to the AVIP yielding the strongest level "ownership" in the involvement continuum. Such user level ownership is an inherent requirement in the decentralized execution of this "*commander's program*," as the AVIP has been termed. Such user ownership is the "best" level on the involvement continuum, and it will restore faith and trust in the process and leadership. To do otherwise means the AVIP stands at the weakest level of the involvement continuum, where soldiers are intended to be "Robots" according to the ORM paradigm and as the diagram below depicts.



If the DoD continues to implement its AVIP risk controls as has traditionally been witnessed with a heavy handed, one-sided approach lacking intellectual objectivity, it will erode trust in the DoD leadership. This lowest level of the "involvement continuum" is also contrary to the express guidance of ORM, where utilizing our personnel "expertise" is a fundamental requirement of the hazard identification tools. This characteristic and requirement for soldiers to have expertise is also ingrained in the earliest levels of professional military education. Samuel Huntington's classic study of military professionalism, The Soldier and the State, identified "expertise" as one of the three criteria for a military profession. Clearly, DoD leaders have a responsibility to "Support" their soldiers and utilize their expertise, such as that presented by this ORM analysis.

The bottom-line posed by ORM is to accept risks if outweighed by the benefits, but to ALWAYS reject them if the costs outweigh the benefits. ORM also requires our armed forces and our leaders at every level to "*adapt and reapply ORM as the mission unfolds.*" Efficacy of antibiotics, greater than one hundred fold increases in adverse reaction rates, the revelations of the illegal 1990 manufacturing changes and the known experimental status of the anthrax vaccine all dictate the reapplication of these tools.

In the ongoing ORM analysis within the risk continuum of the AVIP, even if the DoD and the Commander in Chief (CINC) decide to accept the risk of the anthrax vaccine protection, there is a legal way to do so by following 10 U.S.C. § 1107, EO 13139 and DoD Directive 6200.2.

Step 6 -- Supervise and Review



The DoD leadership must once again “Supervise and Review” their policy decisions based on the risk-continuum and the facts provided in this ORM analysis.

Ethically, the credibility and integrity of the institution is at risk if the DoD clings to flawed or illegal policies of “unusually” and unnecessarily hazardous risks in lieu of admitting where errors have occurred. This “feedback” stage of ORM is fundamental to the process if servicemembers become aware that our leaders are knowingly or unknowingly breaking the law. Servicemembers are duty bound to provide this feedback by all means available. And, if servicemembers have discovered an institutional incapability to admit such criminal conduct, or a willful ignorance of the law, they have a duty to attempt to correct this as well.

Had the “What if” tool been utilized in Step 1, senior DoD officials would have had the ability to game out the possibility of "what if" the truth came out about the “adulterated”, "unsatisfactory" and "experimental" nature of the vaccine, and its possible connection to GWI? It is questionable if the US Army’s 5-step process was utilized in the development of the original AVIP, or whether the USAF utilized ORM in their review of AVIP before accepting the program in 1997 and again in 2002. Further, it is doubtful the senior leadership or medical professionals even realize that the never finalized 1985 FDA review of the vaccine also recommends only 3 shots, versus the current 6 shots. This would assist in minimizing documented health risks, i.e., systemic adverse reactions. Reducing adverse reactions also reinforces the need for the FDA to complete their long ago mandated review of AVA.

Regardless of the ultimate control decisions that are made in the future, it is vital to note that the declaration that the anthrax vaccine is an IND does not preclude its use by the DoD, as long as the appropriate consent or waiver is obtained. The DoD has adopted the requirements of 10 U.S.C. § 1107 and Executive Order 13139 and set up procedures to follow these requirements in DoD Directive 6200.2 dated August 1, 2000.¹⁶³

Finally, summarizing the above feedback in the form of recommendations is appropriate while senior military leaders continue to reevaluate their control measures and decisions:

1. Reinitiate legal, medical and ORM analysis of the AVIP.
2. Stockpile antibiotics as a medical layer of force health protection and ensure troops have modern effective external protective garments and biodetectors.
3. If the anthrax vaccine continues to be mandated, the DoD must comply with the law - 10 U.S.C. § 1107, which is specifically written to protect soldier’s health rights in this scenario -- *"In the case of the administration of an investigational new drug, or a drug unapproved for its applied use, ... the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under the Federal Food, Drug, and Cosmetic Act may be waived only by the President."*

- a. DoD must obtain a Presidential waiver if the program remains mandatory, or
 - b. Obtain animal efficacy rule approval for inhalation anthrax for the vaccine.¹⁶⁴
4. Until recommendation #3 above is accomplished, Service Chiefs or the SECDEF should direct the cessation of non-judicial and judicial punishment of soldiers being prosecuted or punished for vaccine refusal.
 5. Service Chiefs or the SECDEF should request the Board for the Correction of Military Records (BCMR) to review and expunge the records of any servicemember previously punished over vaccine refusal.
 6. Similar to Under Secretaries of Defense Aldridge and Chu's recommendations to the SECDEF concerning the vaccine on 10 AUG 2001, the DoD should:
 - a. Minimize use of the anthrax vaccine, pending the deployment of the new vaccine as directed by the President.
 - b. Develop a doctrinally sound, institutionally coherent, process for dealing with biological, chemical and other asymmetric threats in the future.

CONCLUSION

Available risk management tools and their application to the AVIP are incomplete. The five-step Army risk management process, if employed, may have omitted crucial information, apparent from the Operations Analysis, due to the command level orientation of Army ORM. The information presented in this analysis is absent from the Army managed DoD website, casting into question the completeness of the anthrax vaccine education campaign. Regardless, the information documented in this analysis is publicly available and warrants reinitiating an objective and formal ORM analysis.

Historical perspectives are relevant in this ongoing analysis. In September 1925 Brigadier General William "Billy" Mitchell voiced his belief that the Army Air Service should become an independent arm of the military following the crash of the airship Shenandoah. Mitchell effectively voiced his professional dissent, an early example of Operational Risk Management. Mitchell was court-martialed at the request of President Coolidge for his accusations that the leadership was guilty of, "*incompetency, criminal negligence, and almost treasonable administration of the national defense.*"¹⁶⁵ But in September 1947, 22 years after General Mitchell was court-martialed for conduct unbecoming an officer, the US Air Force did become a separate service due to President Truman's signing of Executive Order 9877. This followed Congress' passage of the National Security Act, which established the DoD. The vision of General Mitchell became a reality.¹⁶⁶

Even today the US Army's West Point Cadet Handbook warns, "*Within our school of military thought, higher authority does not consider itself infallible. Either in combat or out, in any situation where a majority of military trained Americans become undutiful, that is sufficient reason for higher authority to resurvey its own judgments, disciplines, and line of action.*"¹⁶⁷ The US Army, which is responsible for the anthrax vaccine program, would be well served by applying this adage in their ORM of the AVIP. These historical perspectives and encouragement by modern military training for the senior leadership to resurvey its judgments are crucial in the ongoing anthrax vaccine dilemma that threatens the integrity of the military. But absent senior military leaders doing their duty in this instance, servicemembers have an obligation to complete the task in accordance with the Air Force Policy Directives.

As Brigadier General Eddie Cain, the former director of the Pentagon agency responsible for the AVIP, cautioned following his 29 April 1999 testimony to Congress concerning the risk issues highlighted in this paper; the Pentagon was "*digging ourselves a hole that will be difficult to crawl out of.*"¹⁶⁸ This ORM analysis attempts to describe to senior leaders the "*hole that will be difficult to crawl out of,*" and to help visualize the risks associated with continuing the digging.

This analysis demonstrates that the US Army entities responsible for the anthrax vaccine were aware of the risks. It is still unclear if the other services were aware as well. But considering Air Force ORM is predicated upon the objective analysis of adverse safety scenarios, these tools clearly apply to the dilemma of the mandatory anthrax vaccine immunization program as new information surfaces. ORM concepts are partially based upon the Pareto law, which says, "*The art and science of mishap analysis can be approached in many ways.*"¹⁶⁹ Therefore, Pareto's law supports the consideration of the dissenting opinions and conclusions found in this analysis. Hopefully senior military leaders will agree, in the spirit of this Pareto law and the principles of ORM, that the AVIP analysis can similarly "*be approached in many ways.*" Many of their soldiers have already come to this conclusion, and though it is disconcerting to highlight the potential misconduct of senior leaders, it does not obviate this responsibility.

Just as the "risk management continuum" and the "involvement continuum" enable this subordinate level analysis of the anthrax vaccine program, they also empower senior leaders to correct the mistakes identified. Additionally, a new concept called the "time continuum" is a synergistic extension for the ORM toolbox. By analyzing risks, hazards or deceptive information changes over a continuum of time historical facts and lessons learned can be applied to future similar programs and policies. The time continuum application can also further expand to benefit different concepts, organizations, policies or programs not implicated in the original analysis. Understanding the time continuum, and the fact that future generations will critique what DoD has done, or has failed to do, will aid senior leaders to correct errors real-time, versus many decades later as with previous examples of military medical malfeasance.

The ORM time continuum also adds perspective to DoD's goal of "transformation." The call for transformation, in concert with the ORM time continuum vision, provides a means for current senior leaders to review the anthrax vaccine program's risks to the integrity and credibility of the DoD highlighted with the Operations Analysis tool, the evident revision of the truth and facts identified with the Change Analysis tool, and the

compounding ethical, doctrinal and legal risks articulated through the Scenario Process tool. If DoD has the vision and courage “*to resurvey its own judgments, disciplines, and line of action*” it will mitigate long-term risks of lost trust and increased liability for future generations that will otherwise be forced to deal with the consequences.

In the end, senior leaders of the Air Force, Navy, Coast Guard and Marines must insist that a proper legal, medical, regulatory, and scientific analysis be conducted. Further, they must insist the Defense Department hold the responsible entities accountable for accepting and transferring the “*unusually hazardous risks*” and altered facts presented in this paper.

Ignorantly violating the law is not a right of the senior leadership of the military; especially when other viable and legal risk control options, or proper processes, exist. Failure to properly implement these processes is an overt failure to follow our own Operational Risk Management directives, as well as the legal processes all servicemembers swear an oath to defend.

Disclaimer

The conclusions and opinions expressed in this document are those of the authors, cultivated through freedom of expression in an academic environment. The views do not reflect the official position of the U.S. Government, the DoD, or the USAF.

¹ Anthrax Vaccine Immunization Program Process Analysis. Rempfer TL, Dingle RE. Airpower Chronicles, Jan 2002 available at <http://www.airpower.maxwell.af.mil/airchronicles/cc/remper.html>

² FDA News Release. Available at <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00792.html>

³ The Anthrax Vaccine. Is it Safe? Does It Work? Institute of Medicine Report available at <http://www.nap.edu/books/0309083095/html/>

⁴ <http://www.nap.edu/catalog/10310.html>

⁵ Wolfowitz announcement available at <http://www.anthrax.mil/media/pdf/resumptionpolicy.pdf>

⁶ Air Force announcement available at <http://www.anthrax.mil/media/pdf/AFPlan.pdf>.

⁷ General Jumper memorandum available at http://safety.kirtland.af.mil/AFSC/CSAF_ORM_memo.pdf.

⁸ Air Force Policy Directive 90-9 available at: <http://www.e-publishing.af.mil/pubfiles/af/90/afpd90-9/afpd90-9.pdf>.

⁹ See supra note 7.

¹⁰ Class notes, 4 March 2003, ORM Application and Integration Course, Kirtland AFB, NM.

¹¹ <http://safety.army.mil/home.html>. Click on risk management.

¹² Class notes, USAF Safety Center, ORM Application and Integration Course Manual, pg. 2-5.

¹³ See supra note 7.

¹⁴ See supra note 8, AFD 90-9 § 5.7.

- ¹⁵ Air Force Instruction 90-901 available at <http://www.e-publishing.af.mil/pubfiles/af/90/afi90-901/afi90-901.pdf>.
- ¹⁶ Ibid.
- ¹⁷ Air Force Pamphlet 90-902 available at <http://www.e-publishing.af.mil/pubfiles/af/90/afpam90-902/afpam90-902.pdf>.
- ¹⁸ Ibid.
- ¹⁹ GAO, "Medical Readiness: Safety and Efficacy of the Anthrax Vaccine." [T-NSIAD-99-148](#), April 29, 1999; and, GAO, "Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew." [GAO-02-445](#), September 20, 2002: [Abstract](#), <http://www.gao.gov/new.items/d02445.pdf>.
- ²⁰ AVIP announcement: http://www.defenselink.mil/news/Dec1997/x12181997_x1215mfp.html.
- ²¹ See supra note 17 at page 27.
- ²² See supra note 17 at page 26.
- ²³ Brachman PS et al, Field Evaluation of a Human Anthrax Vaccine, American Journal of Public Health 1962, Vol. 52 pp 632-645 available at http://www.anthrax.mil/media/pdf/field_eval.pdf.
- ²⁴ Details of the anthrax letter attacks available at: <http://www.fas.org/bwc/news/anthraxreport.htm>
- ²⁵ White House Press Briefing, 25 February 2002 available at: <http://www.whitehouse.gov/news/releases/2002/02/20020225-16.html>
- ²⁶ See supra note 17 at page 27.
- ²⁷ Congressional testimony, www.house.gov, or www.gpo.gov
- ²⁸ See supra note 17 at page 27.
- ²⁹ Per Telecon with Pentagon official, ASD/RA, November 3, 2001
- ³⁰ http://www.dod.mil/news/Jun2002/n06282002_200206283.html.
- ³¹ Anthrax Vaccine: GAO's Survey of Guard and Reserve Pilots and Aircrew, available at: [GAO-02-445](#)
- ³² See supra note 17 at page 27.
- ³³ Deputy Secretary of Defense John Hamre testimony before the House Armed Services Committee testimony, 30 Sep 99.
- ³⁴ 2002 Anthrax vaccine product insert / new label: <http://www.fda.gov/cber/label/biopava0131022LB.pdf>.
- ³⁵ See supra note 17 at page 13.
- ³⁶ See supra note 17 at page 14.
- ³⁷ SecArmy memo for SecDef, dated 11 December 1997.
- ³⁸ See supra note 20.
- ³⁹ See supra note 17 at page 33.
- ⁴⁰ See supra note 23.
- ⁴¹ U.S. Patent No. 3,208,909; 28 September 1965.
- ⁴² Michigan Department of Public Health application to the Public Health Service Division of Biologic Standards, 11 July 1967.
- ⁴³ Ibid.

- ⁴⁴ Pittman M, Division of Biologic Standards Memorandum dated 10 February 1969.
- ⁴⁵ Health, Education and Welfare letter to Michigan Department of Public Health, dated 10 November 1970.
- ⁴⁶ Michigan Department of Public Health Final Report, dated 3 February 1972.
- ⁴⁷ Federal Register at 37 FR 12865, 29 June 1972.
- ⁴⁸ Federal Register at 37 FR 16679, 18 August 1972.
- ⁴⁹ DoD Request for Proposals (RFP) -- DAMD17-85-R-0078. 16 May 1985.
- ⁵⁰ Federal Register at 50 FR 51058, 13 December 1985
- ⁵¹ Knudsen GB. Treatment of Anthrax in Man: History and Current Concepts. Military Medicine, Vol. 151, No. 2 pp 71-77.
- ⁵² Ivins BE, Welkos SL. Recent Advances in the Development of an Improved Human Anthrax Vaccine. European Journal of Epidemiology. Vol. 4 pp 12-19.
- ⁵³ Global Spread of Chemical and Biological Weapons. Hearings before the Committee on Governmental Affairs and its Permanent Subcommittee on Investigations. Senate Hearing 101-744.
- ⁵⁴ Takafuji ET, Russell PK, Military Immunizations: Past, Present, and Future Prospects. Infectious Disease Clinics of North America. Vol. 4, No. 1 pp 143-58 1990
- ⁵⁵ Excerpts from DoD declassified chronology: "14 SEP 90 -- ... task from DJS to form a special group to develop proposed PA guidance for the BW Vaccination Program ... under the auspices of J-5 (Deputy Director for Political Military Affairs -- BG Jumper)..."

21 SEP 90 -- 'Special Topic' briefed in the TANK to the Operations Deputies by J-4 (RADM Smyth) and J-5 (BG Jumper) ... Bottomline: decision necessary were no longer "medical" in origin; rather were political, social, and military / operational. Also, no matter what decision made, insufficient vaccines (both AX and BT) to cover all US forces at risk existed.

25 Sep 90 -- AX Production Charts provided DJS with explanation regarding commencement of production ... 25 Oct 90 -- Memo from DDMR (ADM Smyth) on status of AX production ... 2 Nov 90 -- Third TANK informational briefing held with OPSDEPS and Joint Chiefs ... No change in threat; AX vaccine production has been maximized ...

9 Nov 90 -- Trip to Michigan Department of Public Health Lab (Lansing, MI) by J5 (BG Jumper, COL Fleming) and J4 (ADM Smyth, COL Fry). Purpose: Determine problems and prospects affecting production of BW vaccines. Visited Director of the Lab (Dr. George Anderson) and the Chief of Biologic Products Division (Dr. Robert Myers). -- Increases in AX vaccine production favorable. ... here is need for an additional fermentor however. -- MDPH has suspended production of BT vaccine in favor of AX vaccine.

9 Nov 90 -- J5 / DDPMA (BG Jumper) formed a working group consisting of DIA, J3, J4, J5 to assure accurate tracking of vaccine production. 16 Nov 90 -- BG Jumper provided summary of BW threat and general overview of US defensive capabilities (to include vaccines). Briefing showed existing inventories fell short of requirements in the near term.

16 Nov 90 -- COL Lewis furnished latest information on MDPH fermentor. New fermentor installed and pre-production testing is beginning. Provided to BG Jumper and DJS by DDMR. 19 Nov 90 -- ASD (HA) memorandum to SECARMY, "Expansion of Industrial Base for Biological Vaccine Production." ... on short term production of AX and BT. -- Requested steps be taken on a priority basis to monitor ongoing efforts at MDPH (increased production by 20 Feb 91)...

19 Nov 90 -- Initial information on quantities of antibiotics (doxycycline, ciprofloxacin) ... furnished by COL Lewis to DDMR and BG Jumper.

21 Nov 90 -- DA OTSG sent tasking from SECARMY to form Task Force to evaluate ways to increase production of AX and BT vaccines. Implementation Working Group, chaired by BG Blanck, would provide weekly production reports to DASD (MR).

3 Dec 90 -- J5/BG Jumper outlined course of action needed prior to next TANK session. Need to push toward total integration of all planning efforts associated with BW defensive measures. ... VCSA has tasked Surgeon General to get plan together (public affairs, psyops, POLMIL, medical, doctrine). Draft memorandum to SECDEF prepared by J5 / COL Fleming requesting SECDEF direct accelerated procurement actions to improve the US biological defensive posture. Memorandum was not finalized.

10 Dec 90 -- Paper submitted to ADM Smyth and BG Jumper on "Rationale for Antibiotics in Prophylaxis Against Inhalation Anthrax" (Rhesus Monkey Paper). Research effort has been used in considering the use of antibiotics following exposure to AX and before initiation of symptoms. Only one monkey died following treatment with 30 days of Ciprofloxacin antibiotic.

14 Dec 90 -- Armed Forces Epidemiological Board met to consider the use of antibiotics as an adjunct in countering the threat of inhalation AX. 8 Mar 91 -- CENTCOM Surgeon msg (081808ZMar91), ... Also indicated vaccination programs for AX and Bot T discontinued due to diminished threat."

⁵⁶ Ezell JW, Abshire T. In Vitro Analysis of Michigan Department of Public Health Human Anthrax Vaccine, U.S. Army Medical Research Institute of Infectious Diseases, 25 Oct 1990, (unpublished)

⁵⁷ Form FDA 483 dated 4 May 1993.

⁵⁸ Friedlander AM, Brachman PS, "Vaccines", ed. Plotkin and Mortimer, 1994 edition chapter 26.

⁵⁹ Form FDA 483 dated 3 June 1994.

⁶⁰ Is Military Research Hazardous to Veterans' Health? Lessons Spanning Half a Century. S. Prt. 103-97, 8 December 1994.

⁶¹ Form FDA 483 dated 23 April 1995.

⁶² FDA letter to Michigan Department of Public Health, dated 31 August 1995.

⁶³ SAIC Corporation plan, 29 Sep 1995, enclosure to memorandum from Dr. Anna Johnson-Winegar (US Army) to Dr. Robert Myers (MDPH), US Army Medical Research and Material Command, Fort Detrick, Frederick, MD

⁶⁴ LTC David Danley, "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 meeting; Joint Program Office for Biological Defense memorandum, 13 Nov 1995.

⁶⁵ Kenimer Associates report to SAIC on trip to MDPH dated 6 February 1996.

⁶⁶ Michigan Biologic Products Institute application to Dr. K. Zoon, Director, Center For Biologics Evaluation and Research, dated 20 September 1996.

⁶⁷ Form FDA 483 dated 18 November 1996.

⁶⁸ NOIR letter from FDA to Michigan Biologic Products Institute dated 11 March 1997, available at <http://www.fda.gov/cber/infosheets/mich-inf.htm>

⁶⁹ <http://www.defenselink.mil/pubs/prolif97/secii.html>.

⁷⁰ 21 CFR 10.85, "Advisory Opinions" -- See: <http://frwebgate.access.gpo.gov/cgi-bin/get-cfr.cgi?TITLE=21&PART=10&SECTION=85&YEAR=1999&TYPE=TEXT> -- "A statement made or

advice provided by an FDA employee constitutes an advisory opinion only if it is issued in writing under this section. A statement or advice given by an FDA employee orally, or given in writing but not under this section or Sec. 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."

- ⁷¹ 13 March 1997 memo from FDA's Dr. Friedman to DoD's ASD/HA Dr. Joseph.
- ⁷² Industrial Capabilities Assessment, Summary Report for the Production of Anthrax Vaccine, Preliminary report prepared by the Joint Program Office for Biological Defense, Falls Church, VA, December 1997.
- ⁷³ Memorandum from Jeanne Novak (DVRPA) to M. Carolyn Hardegree (CBER) dated 10 December 1997.
- ⁷⁴ See supra note 20.
- ⁷⁵ Form FDA 483 dated 4 February 1998.
- ⁷⁶ http://www.defenselink.mil/other_info/burrows.html,
http://www.anthrax.osd.mil/resource/qna/ind_rev.asp#11,
http://www.af.mil/news/Apr1998/n19980416_980507.html,
http://www.defenselink.mil/news/Aug1998/t08171998_t814ntrx.html,
- ⁷⁷ <http://www.house.gov/reform/ns/hearings/testimony/cain4-30.htm>
- ⁷⁸ SecArmy Memorandum of Decision, dated 3 September 1998.
- ⁷⁹ Friedlander AM, Brachman PS, "Vaccines", ed. Plotkin and Mortimer, 1999 edition chapter 24.
- ⁸⁰ 10 U.S.C § 1107, [TITLE 10, Subtitle A, PART II, CHAPTER 55, Sec. 1107](#)
- ⁸¹ Unwin C, et al. Health of UK Servicemen Who Served in Persian Gulf War. The Lancet. Vol. 353 pp 169-178.
- ⁸² IND 6847 update to FDA dated January 29, 1999 -- block 7 specifically and exclusively reads:
"Indication(s) (covered by this submission) Inhalation Anthrax"
- ⁸³ 1999 hearings:
1. 24 March – Subcommittee on National Security, Veterans Affairs and International Relations; Oversight of the AVIP.
 2. 22 April – Subcommittee on National Security, Veterans Affairs and International Relations; Implementation of the Persian Gulf War Veterans' Act of 1998.
 3. 29 April - Subcommittee on National Security, Veterans Affairs and International Relations; Anthrax II – Efficacy of the Mandatory Vaccine
 4. 30 June - Subcommittee on National Security, Veterans Affairs and International Relations; Oversight of the DOD Sole Source Procurement.
 5. 21 July - Subcommittee on National Security, Veterans Affairs and International Relations; Anthrax Vaccine Adverse Reactions
 6. 29 September - Subcommittee on National Security, Veterans Affairs and International Relations; Impact of the AVIP on Reserve and Guard Units
 7. 30 September – House Armed Services Committee; DOD and the AVIP
 8. 12 October – Government Reform Committee; Defense Vaccines: Force Protection or False Security?

9. 9 November - Subcommittee on National Security, Veterans Affairs and International Relations; Force Protection – Improving Safeguards of IND Drugs.

⁸⁴ GAO Reports from 1999 are available at www.gao.gov or [NSIAD-99-5](#), [NSIAD-99-148](#), [NSIAD-99-214](#), [NSIAD-99-226](#), [NSIAD-00-48](#), [NSIAD-00-36](#)

⁸⁵ Nass M. Anthrax Vaccine-Model of a Response to the Biologic Warfare Threat. Infectious Disease Clinics of North America. Vol 13. No. 1 pp 187-208

⁸⁶ Army Times, April 5, 1999.

⁸⁷ May 3, 1999 – email exchange between JPOBD BG Eddie Cain and Col John Wade, reference 29 APR 99 Congressional testimonies and an ongoing Congressional investigation of the AVIP.

⁸⁸ <https://www.denix.osd.mil/denix/Public/Legislation/EO/note54.html>

⁸⁹ <http://www.fda.gov/cber/rules/lethtox.pdf>;

⁹⁰ [21 CFR 314.126](#)

⁹¹ 1. 2 February - Subcommittee on National Security, Veterans Affairs and International Relations; Gulf War Veterans Illnesses – The Current Research Agenda

2. 13 April – Senate Armed Services Committee; Review of the DOD AVIP

3. 14 April - Senate Armed Services Committee; DOD’s anti-biowarfare vaccine acquisition program

4. 24 May – Subcommittee on National Security, Veterans Affairs and International Relations; DOD Chemical and Biological Defense Program . Management and Oversight.

5. 21 June - Subcommittee on National Security, Veterans Affairs and International Relations; Force Protection –Current individual protective equipment.

6. 12 July - Senate Armed Services Committee; AVIP- The Threat, Effectiveness, Safety and Supply

7. 13 July – House Armed Services Committee; DOD and the AVIP

8. 27 September - Subcommittee on National Security, Veterans Affairs and International Relations; Gulf War Veterans-Linking Exposure to Illnesses

9. 3 October – Committee on Government Reform; AVIP-What Have We Learned

10. 11 October – Committee on Government Reform; AVIP-What Have We Learned

⁹² GAO Reports available at www.gao.gov or [NSIAD-00-157](#), [NSAID-00-140](#), [NSIAD-00-138](#), [NSIAD-00-97](#), [GAO-01-92T](#), [GAO-01-21](#),

⁹³ The Department of Defense Anthrax Vaccine Immunization Program - Unproven Force Protection. House Report 106-556. Available at [House Report 105-556](#)

⁹⁴ Institute of Medicine Letter Report to MGen West on 30 March 2000 available at: http://www.nap.edu/html/anthrax_vaccine/

⁹⁵ HHS letter from Melinda K. Plaisier to Representative Metcalf, 20 March 2000.

⁹⁶ Turnbull PCB. Current status on immunization against anthrax: old vaccines may be here to stay for a while. Current Opinion in Infectious Diseases, Vol. 13, No. 2 pp 113-120.

⁹⁷ May 5, 2000; Canada News Briefs By The Associated Press -- Judge Agrees Anthrax Vaccine Unsafe; Halts Court Martial, WINNIPEG, Manitoba.

⁹⁸ SecDef Cohen announcement available at http://www.defenselink.mil/news/Jul2000/n07112000_20007114.html

- ⁹⁹ Steele L. Prevalence and Patterns of Gulf War Illness in Kansas Veterans: Association of Symptoms with Characteristics of Person, Place, and Time of Military Service. *American Journal of Epidemiology*, Vol. 152, No. 10 pp 992-1002.
- ¹⁰⁰ Hughes JM, Cohen ML. Use of the Anthrax Vaccine in the United States-Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2000;49(No. RR-15).
- ¹⁰¹ GAO Reports available at [GAO-01-13](#), [GAO-01-915](#), [GAO-02-38](#), [GAO-02-181T](#), [GAO-02-219T](#), [GAO-02-445](#)
- ¹⁰² Letter provided by Senate Majority Leader's office staffer Mr. Randy DeValk.
- ¹⁰³ DOD announcement available at:
http://www.defenselink.mil/news/Jun2001/n06112001_200106112.html
- ¹⁰⁴ DoD memo to SECDEF Rumsfeld dated 10 August 2001.
<http://www.washingtonpost.com/wp-dyn/articles/A42952-2001Sep28.html>
- ¹⁰⁵ A Citizen Petition on lack of data and unapproved manufacturing changes – docket #01p-0471:
http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/101501.htm#_Toc527850400;
This Citizen Petition PDF can be reviewed at the following link:
<http://www.fda.gov/ohrms/dockets/dailys/01/Oct01/101501/cp00001.pdf>
- ¹⁰⁷ Compliance Policy Guides Manual, Sec. 400.200, titled -- “Consistent Application of CGMP Determinations (CPG 7132.12), http://www.fda.gov/ora/compliance_ref/cpg/cpgdrg/cpg400-200.html” 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.*”
Note: 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. A subsequent FDA inspection, conducted between February 4th and 19th of 1998, found that the previous deficiencies had not been corrected; all three inspections documented 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 this government policy. On September 3, 1998, the FDA informed the new owner of the anthrax vaccine manufacturing facility, BioPort Corporation, that “the Notice of Intent to Revoke issued to MBPI on March 11, 1997 would effectively transfer with the issuance of the license to BioPort and would remain in effect until all compliance issues had been satisfactorily resolved.” These deficiencies have still not officially been resolved, and most certainly were not when the DoD contracted for Anthrax Vaccine in 1998. These discrepancies are available at the following link:
FDA Warns Michigan Biologic Products Institute of Intention to Revoke License:
<http://www.fda.gov/cber/infosheets/mich-inf.htm>
- ¹⁰⁸ http://www.defenselink.mil/pubs/chem_bio_def_program/2001_CBDP_Annual_Report.pdf -- “**ISSUE: DoD does not have a current approved mechanism for licensure of chemical and biological defense medical products (i.e., drugs and vaccines) because legal and ethical constraints prevent adequate full testing in humans. SOLUTION: The FDA and DoD are working together to amend the Code of Federal Regulations to allow animal efficacy data to be used in lieu of large-scale human clinical efficacy trials.** This mechanism of licensure is vital to provide military service personnel with licensed products. This rule will also establish requirements for licensure and allow the DoD to plan and conduct the appropriate studies to obtain approval for the products planned for production and licensing. Requests for approval of each medical product will be reviewed on an individual basis.”

- ¹⁰⁹ McCarthy M. Early and aggressive treatment saves US anthrax victims. *The Lancet*, Vol. 358 pp 1703
- ¹¹⁰ Munro R. When Immunity may not be safe. *Nursing Times*, Vol. 97, No. 44 pp 10-11
- ¹¹¹ Pittman PR et al. Anthrax vaccine: short-term safety experience in humans. *Vaccine*, Vol. 20 pp 972-978.
- ¹¹² See supra note 34.
- ¹¹³ Asa PB et al. Antibodies to Squalene in Recipients of Anthrax Vaccine. *Experimental and Molecular Pathology*, Vol. 73 pp 19-27.
- ¹¹⁴ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_house_hearings&docid=f:82953.wais
- ¹¹⁵ See supra note 3.
- ¹¹⁶ Geier DA et al. Anthrax vaccination and joint related adverse reactions in light of biological warfare scenarios. *Clinical and Experimental Rheumatology*, Vol. 20, No. 2 pp 217-220
- ¹¹⁷ Schumm WR et al. Self-Reported Changes in Subjective Health and Anthrax Vaccination as Reported by over 900 Persian Gulf War Era Veterans. *Psychological Reports*, Vol. 90 pp 639-653.
- ¹¹⁸ Geier DA et al. Smallpox and Anthrax in the United States. *Mealey's Emerging Drugs & Devices*, Vol. 7, No. 8 pp 26-30
- ¹¹⁹ See supra note 5.
- ¹²⁰ DoD IG complaint #84142, POC -- Mr. Trahan, 800-424-9098.
- ¹²¹ Schumm, Webb, Jurich, Bollman, Kansas State University. *Psychological Reports*, Volume 91, 2002, 187-191, "Comments on the Institute of Medicine's 2002 Report on the Safety of the Anthrax Vaccine."
- ¹²² <http://www.fda.gov/ohrms/dockets/dailys/02/Sep02/091102/80027a9f.pdf>
- ¹²³ <http://www.anthrax.mil/media/pdf/AFPlan.pdf>.
- ¹²⁴ GAO-02-445, Report to Congressional Requesters, United States General Accounting Office, September 2002 ANTHRAX VACCINE GAO*s Survey of Guard and Reserve Pilots, and Aircrew - <http://frwebgate.access.gpo.gov/cgi-bin/useftp.cgi?IPaddress=162.140.64.21&filename=d02445.txt&directory=/diskb/wais/data/gao>.
- ¹²⁵ United States District Court for the District of Colorado Civil Action No. 00-N-1022, 2 FEB 2003; *Jemekiah Barber vs. the United States Army, et al.* The Court: "... *the issues in this case are beyond the purview of the federal judiciary and that the Court must decline review because the Department of Defense has wide latitude over military personnel decisions. ... The courts have little competence in the complex decisions as to the control of a military force, and such professional military judgments are more properly subject to civilian control of the Legislative and Executive Branches, which are directly responsible for the people ... the defendants concede that the plaintiff has sufficiently alleged that she suffered the deprivation of a constitutional right or that the military violated federal statutes for its own regulations...*"
- ¹²⁶ See supra note 17 at page 37.
- ¹²⁷ See supra note 64.
- ¹²⁸ DAMD17-85-R-0078, 16 May 1985 at paragraph C.1.3.
- ¹²⁹ See supra note 63.
- ¹³⁰ See supra note 66.
- ¹³¹ 10 U.S.C § 1107 and Executive Order 13139, [TITLE 10, Subtitle A, PART II, CHAPTER 55, Sec. 1107](#)

- ¹³² See GAO report GAO-01-181T: Anthrax Vaccine-Changes to the Manufacturing Process available at: [GAO-02-181T](#)
- ¹³³ See supra note 55, DoD Declassified Chronology.
- ¹³⁴ This is established in public law public law in the 105th Congress [P.L. 105-277, Title XVI, sec. 1603(d)], Congressional Reports and DoD admissions. See House Report 106-556, footnote #1: <http://www.house.gov/reform/ns/reports/anthraxreport.pdf>.
- ¹³⁵ See supra notes 3, 81, 85 and 112.
- ¹³⁶ See supra note 124.
- ¹³⁷ See supra note 34.
- ¹³⁸ <http://www.fda.gov/cber/label/smalwye102502LB.pdf>.
- ¹³⁹ See supra note 34.
- ¹⁴⁰ <http://www.sskrplaw.com/publications/newguinea.html>; <http://www.sskrplaw.com/vaccine/lahiff.pdf>; <http://www.sskrplaw.com/vaccine/allairepleadings.html>; <http://www.sskrplaw.com/vaccine/bonassepleadings.html>; <http://www.sskrplaw.com/vaccine/nancycleadings.html>;
- ¹⁴¹ <http://www.miwd.uscourts.gov/profile/dingle~v~bioport.pdf>
- ¹⁴² See supra note 102.
- ¹⁴³ http://www.fda.gov/cder/drug/infopage/Pyridostigmine_Bromide/default.htm.
- ¹⁴⁴ 23 Apr 2002. FDA CBER meeting: <http://www.fda.gov/cber/minutes/anthrax0402.htm>.
- ¹⁴⁵ Class notes, USAF ORM Supervisor's Course, Essentials for Leaders, by the USAF Safety Center.
- ¹⁴⁶ See supra note 17 at page 38.
- ¹⁴⁷ Ibid.
- ¹⁴⁸ See supra note 87.
- ¹⁴⁹ See supra note 17 at page 43.
- ¹⁵⁰ Encyclopedia Britannica, Categorical syllogisms: "The next more complex form of argument is one with two categorical propositions as premises and one categorical proposition as conclusion. When arguments of this type have exactly three terms occurring throughout the argument and when the predicate term of the conclusion occurs in the first premise and the subject term of the conclusion occurs in the second premise, the argument is called a categorical syllogism."
- ¹⁵¹ 10 USC § 1107 -- *"In the case of the administration of an investigational new drug, or a drug unapproved for its applied use, ... the requirement that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under the Federal Food, Drug, and Cosmetic Act may be waived only by the President."*
- ¹⁵² See supra note 17 at page 47.
- ¹⁵³ See supra note 17 at page 41.
- ¹⁵⁴ War, Morality, and the Military Profession. 2d ed. Boulder: Westview Press. 1986, Biological Warfare Chapter, Edited by BG Malham M. Wakin, Professor Emeritus, USAF Academy
- ¹⁵⁵ See supra note 17 at page 76.
- ¹⁵⁶ President Bush's State of the Union Address, 2002.

¹⁵⁷ See supra note 17 at page 17.

¹⁵⁸ See supra note 78.

¹⁵⁹ See supra note 17 at page 21.

¹⁶⁰ See supra note 17 at page 23.

¹⁶¹ See supra note 17 at page 25.

¹⁶² http://www.defenselink.mil/other_info/burrows.html

¹⁶³ <http://mrmc-www.army.mil/docs/rcq/62002.pdf>

¹⁶⁴ FDA Press release: <http://www.fda.gov/bbs/topics/NEWS/2002/NEW00811.html>
Final Rule: <http://www.fda.gov/OHRMS/DOCKETS/98fr/98n-0237-nfr0001-voll.pdf>

¹⁶⁵ Air Force Academy Cadet Handbook, “Contrails,” Volume 32, pg. 50.

¹⁶⁶ See supra note 165 at page 144.

¹⁶⁷ West Point Graduate testimony, Louis Font, Esq., Federal Court hearing, Pittsburgh, PA, 4 DEC 1999.

¹⁶⁸ See supra note 87.

¹⁶⁹ See supra note 17 at page 63.