

The Anthrax Debate

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The following paper closely examines the anthrax vaccine, and the decision of the Department of Defense (DOD) to make that vaccine mandatory for all military members. A case is built in opposition to that decision, by demonstrating the significant lack of both short and long-term testing, the unethical contract negotiated between our government and the vaccine's manufacturer, the large volume of documented adverse effects, and the moral value of choice. The paper is supported by government documents and reports condemning the vaccination and the DOD's decision to make it mandatory. In order to condense the material and decrease bias content, I have removed my own personal experiences associated with the military and its decision to mandate inoculation. Instead, I have tried to prove my thesis by using the large volume of evidence provided by our own government. The paper is then concluded with an appeal to reason, demonstrating to the reader the dangerous results that have occurred from rushing into an untested program.

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Although threats of terrorism are a serious concern and have raised the Department of Defense's (DOD) awareness about biological warfare, the insufficient anthrax vaccine only adds danger to an already dangerous situation; the possibility for complications occurring in the latter has shown itself to be greater than that of the former because there are hundreds of documented cases of *extreme* adverse effects, the House of Representatives deemed the vaccine "too scientifically experimental," and the Food & Drug Administration (FDA) have even closed the manufacturing plant for "sanitary reasons."

Prior to Operation Iraqi Freedom, it had been reported that Iraq had a known compilation of what have been dubbed "Drones of Death." These "kamikaze" designed planes were allegedly filled with the toxic spores known as anthrax, and then sent on suicide missions with the intention of the opposing side shooting them down, there-by spreading the deadly virus throughout large quantities of air where it can be inhaled and inflict serious damage or even death. These planes are said to be auto-piloted, and could be sacrificed in flight without the loss of personnel to the Iraqi military. However, Iraq was currently following strict charters set forth and enforced by the UN (United Nations), and has been quarantined in a "No-Fly Zone." Surprise inspections were conducted on all Iraqi property without a moments notice, and there has been no evidence either pre or post-war to suggest that Iraq ever had chemical or biological weapons, or weapons of mass destruction. These planes *have never* and hopefully *will never* leave the ground, and so the threat that they create is one of thought rather than action. It disturbs peace of mind, but little else will fall the victim of these "Drones of Death." It is true; we cannot deny the disturbance that arises from this primitive technology, or the possibilities that it creates. The threat is an immediate one that deserves immediate attention, but to what extent does this immediate threat inflict itself upon us?

Most people are somewhat familiar with the term "anthrax," but have only a vague knowledge of what the anthrax virus and vaccine are, and where they come from. Anthrax is an acute infectious disease caused by the spore-forming bacterium *Bacillus Anthracis*. Anthrax spores can be produced in a dry form for biological warfare, which may be stored and ground into particles. When inhaled by humans, these particles cause respiratory failure and will reveal symptoms that resemble those of the common cold. After several days those symptoms may progress to severe breathing problems that cause respiratory failure and shock. The disease can be fatal in *untreated* cases. Deaths are rare with appropriate antimicrobial therapy. Usually penicillin is preferred, but erythromycin, tetracycline, or chloramphenicol can also be used. The anthrax vaccine is a cell-free filtrate vaccine, which means it uses dead bacteria as opposed to live bacteria. The DOD has contracted sole production of the anthrax vaccine to the company Bioport Corporation. Multiple shareholders own Bioport, whose headquarters is located in Lansing, Michigan. The two main companies that make up Bioport are Intervac, headed by William Crowe and Faud El-Hibri, and Michigan Biologic Products Incorporated.

First of all, we will assess the vaccine and the measures used to test the vaccine (including the actual time-frame of that testing), all of which I call into question. You will hear people defend the vaccine with the statement "how can you say it hasn't been long-term tested... it's been around for 30 years!" What these people fail to realize is there are 36 different strains of the anthrax virus, and the vaccination provides protection against only *one* of these strains. And which one shall we guard against with so many to choose from? How can we possibly know? Research would seem to be the answer, but thus far the scientific process seems to have been traded in for guesses and lady luck. An anthrax vaccine *has* been around for 30 years, but *that* particular vaccine is designed to protect farmers from livestock (as goats are the largest transporters of the anthrax virus). The airborne agent that the military must be guarded against is an entirely different strain, and the vaccine that has been created to protect us from *this* strain has only been around for 3 years. Not exactly what you could call viable time for long-term testing, as recognized by the FDA, the National Institute of Health, and the House of Representatives.

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The vaccine has been tested for short-term effects on Rhesus monkeys (whose biological make-up is said to be the closest to that of humans). There was a control group, who was not administered the vaccine, and the experiment group, which *had* been inoculated. They were then all infected with the anthrax virus, and the test results documented that the monkeys in the control group perished while none of the monkeys that were inoculated “died.” It does not say whether or not the monkeys became ill or suffered long-term effects, they simply did not “*die*.” It is also important to note that clinical studies were never tested on humans, as required by the Food and Drug Administration, yet the order for mandatory inoculation was given.

The FDA had come in contact with numerous problems concerning the anthrax vaccine. They released a report of “Adverse Effects Concerning the Anthrax Vaccine” which at that time had documented 14 cases of extreme reactions. During one inspection, the FDA found Michigan Biologic Products Inc. (the only plant that made the vaccine at that time) to be excessively dirty and therefore not within health standards. Consequently the plant was shutdown, and was not allowed to re-open until a new plant was built that met the FDA’s standards. The FDA refused to allow Phase II to be implemented. Phase I was the inoculation of military personnel who were stationed in “high risk areas” whereas Phase II calls for the inoculation of all 2.4 million members of the armed forces. The DOD has released various statements concerning this matter with inclinations intoned close to threats, such as “the FDA *will* approve Phase II, and when they do...” and “failure to identify excess vaccine for redistribution that results in expiration of vaccine *cannot* be permitted.” The DOD employs the Surgeon General, so it is to no surprise that he has approved the vaccine after *first* consulting with the DOD in reference to the conclusions based from his final analysis.

The House of Representatives has passed two bills concerning the anthrax vaccine, the first to make it voluntary, and the second to cease implementation all together. The first bill, cited as the ‘American Military Health Protection Act’ was designed with the intent to “make the anthrax vaccination immunization program voluntary for all members of the armed forces until the Food and Drug Administration has approved a new anthrax vaccine for humans or a new, reduced course of shots for such a vaccine.” The bill was introduced on July 16th, 1999, and it listed the following reasons for approval:

- (1) *All branches of the Armed Forces are faced with severe challenges in recruiting and retaining quality military personnel.*
- (2) *Time and again military personnel are asked to place their lives on the line and to ultimately sacrifice themselves and their families in defense of the United States.*
- (3) *The Department of Defense has initiated an anthrax vaccination program, which a rapidly growing number of military personnel believe may jeopardize their long-term health and safety as well as that of their families.*
- (4) *The lack of a single, conclusive independent study regarding the long-term health effects of the anthrax vaccine on humans has created additional concerns among military personnel.*
- (5) *Despite assurances by the Secretary of Defense of minimal adverse reactions to the anthrax vaccine, the standards, which the Secretary uses to determine adverse reactions, are insufficient to support such claims.*
- (6) *As a result of the lack of conclusive data on the long-term effects of the anthrax vaccine, many military personnel are being forced to make decisions between the safety and security of their families and their dedication and commitment to serving the United States.*

The second bill passed, introduced on July 19, 1999, cited under the short title ‘Department of Defense Anthrax Vaccination Moratorium Act’ had the intention to “suspend further implementation of the Department of Defense anthrax vaccination program until the vaccine is determined to be safe and effective and to provide for a study by the National Institutes of Health of that vaccine.” The House of Representatives transcribed that “an insufficiently proven vaccine should not be advocated as a substitute for research, development, and production

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of truly effective vaccines and antibiotics, adequate protective equipment, and nonproliferation measures.” The House of Representatives then directed the Secretary of Defense to suspend further implementation of the DOD anthrax vaccination program, with the requirements that:

- (1) *An independent study of the effectiveness and safety of the vaccine is conducted.*
- (2) *A report from the Director of the National Institutes of Health to specified congressional committees on study results is sent.*
- (3) *The Comptroller General is to conduct a study and comment to Congress on the vaccine program and the effect of the use of contractor-operated facilities for such a program.*
- (4) *Requires expedited consideration by the respective Boards for Correction of Military Records for current or former military personnel for remedies for adverse personnel actions that were the result of the vaccine program.*
- (5) *States that if the Director determines that the vaccine used in the DOD program meets specified criteria, the Secretary may resume the program. It then also follows that if such a program is resumed, the Secretary may use only newly produced vaccine for vaccinations after such resumption.*
- (6) *The Director of the National Institutes of Health shall require the appropriate national research institute to conduct or oversee an independent study of the effectiveness and safety of the vaccine used in the Department of Defense anthrax vaccination program. The Director shall include in the study under determination of the following with respect to that vaccine:*
 - (A) *Types and severity of adverse reactions.*
 - (B) *Long-term health implications, including interactions with other (existing and planned) vaccines and medications.*
 - (C) *Efficiency of the anthrax vaccine for protecting humans against all the strains of anthrax pathogens members of the Armed Forces are likely to encounter.*
 - (D) *Correlation of animal models to safety and effectiveness in humans.*
 - (E) *Validation of the manufacturing process focusing on, but not limited to, discrepancies identified by the Food and Drug Administration in February 1998 (especially with respect to the filter used in the harvest of anthrax vaccine, storage times, and exposure to room temperature).*
 - (F) *Definition of vaccine components in terms of the protective antigen and other bacterial products and constituents.*
 - (G) *Such other matters as are in the judgment of the Director required in order for the Director to come to a decision and submit that report to the Committee on Government Reform of the House of Representatives, the Committee on Governmental Affairs of the Senate, and to the Secretary of Defense.*

Section 6 of the ‘Department of Defense Anthrax Vaccination Moratorium Act’ outlines the ‘Boards for Correction of Military Records’ requirements. This paragraph talks of “remedies for adverse personnel actions (both voluntary and involuntary) that were a result of the mandatory anthrax vaccination immunization program, including rescission of court-martial convictions, rescission of administrative discharges and separations, rescission of retirements and transfers, restoration of flying status, back pay and allowances, expunging of negative performance appraisal comments or ratings, and granting of physical disability certificates.” In essence, the House of Representatives is saying to re-instate all those personnel who were discharged or taken action against for refusing the anthrax vaccine, wipe every blemish from their record that is concerned with such, and issue them back pay to repent for the hardships caused during that time. The Department of Defense chose not to comply with the standards set forth by the House, whom cannot oversee the “military,” as they are not subject merely to the code of “civilian” law.

A critical report released on February 17, 2000, by the Government Reform Committee’s National Security Subcommittee stated that the military’s program to inoculate all 2.4 million troops against anthrax was based on “dangerously narrow scientific evidence.” The panel recommended the vaccination program be suspended and the vaccine be considered experimental,

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however, Department of Defense officials recently said that they had no intention of ending their program of mandatory anthrax vaccinations for service members. The Pentagon's top Bio-Defense official, Marine Major General Randy L. West, said, "I would champion their proposal that we aggressively seek a better vaccine. In fact," the General continued, "there's currently a funded, aggressive program under the supervision of the Centers for Disease Control (CDC) in Atlanta to do just that. We also believe anything that we can do to improve the shot protocol would be a good thing. If you can give this vaccination in less than six shots, you're probably going to have fewer reactions, and the fewer reactions we have the better it is." West said the DOD budgeted 20 million dollars in 1999 to work with the CDC and determine ways to improve the anthrax vaccination program, concentrating their efforts in four areas:

- (1) *Shot regimen.*
- (2) *Gender differences.*
- (3) *Method of delivering the vaccine.*
- (4) *Determining the amount of immunity gained from the regimen.*

West went on to say, "but those things take time. Those are months or years away, and we've got troops that are in danger of aerosolized, weaponized anthrax today. We can't wait until we've got a new and improved vaccine to give them the protection they need."

Chief of Naval Operations Admiral Jay L. Johnson reiterated, "taking care of sailors is still the Navy's top priority in the short-term." What does he mean, in the *short-term*? The average enlistment is four years, so as long as you're in good health for those four years, what does it matter to the service what your condition becomes after that? Long-term effects apparently are not a Naval concern; the military is more concerned with your health between right now and possibly up to 20 years from now when you retire at age 38 or 39 (as is the case for most). Then, apparently, once your enlistment is over you are of no value to the service, so the service has no value for you.

Aside from the lack of long-term testing, lack of testing on humans, and the complete absence of tests concerned with reproduction, there are several definitive moral issues related to the anthrax vaccine. The first issue has to do with the inception of the vaccine itself, and the decision to make it mandatory. During the trial of Air Force Captain John E. Buck it was revealed that the vaccine used in the mandatory inoculation program was different from that used in the Pentagon's own studies of the anthrax vaccines effectiveness. This means that there had been no official testing done whatsoever on the vaccine that was actually distributed to the armed forces, inadequate or otherwise. To further complicate matters, there are several conspicuous links between then President Bill Clinton and Secretary of Defense William Cohen, and the co-owner of the civilian plant solely contracted to produce the anthrax vaccine, retired Navy Admiral William Crowe of Bioport in Lansing, Michigan. Crowe served as Chairman of the Joint Chiefs of Staff under President's Ronald Reagan and George Bush. Then, according to political insiders, Crowe not only made considerable contributions to Bill Clinton's campaign, but reportedly "stabbed the knife in George Bush's back," and helped get Clinton elected, for which Crowe was awarded with the post of ambassador to Great Britain, and also a multi-million dollar contract that makes Bioport the sole supplier of a vaccine plan intended to inoculate the entire military. The six-shot inoculation process is an 18-month program that requires an annual "booster" shot thereafter. At \$62.50 a shot, that comes to \$375 per person for the initial inoculation process alone; which lends to a total cost for the inoculation of all 2.4 million members of the military at nine hundred million dollars. No contract of this size has ever been awarded in the history of the United States government to a sole supplier.

Which now brings us to the most prevalent ethical issue of this paper: the simple lack of *choice*! The service men and women of the United States have been told there is no choice; that the anthrax vaccine is mandatory, and in order for them to avoid administrative action they must

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follow this “lawful order.” However, how lawful is an order that’s in contrast to civilian law, as voted by the House of Representatives?

Since the original FDA report cited in this text, six deaths have been confirmed in the United States as a direct result of the anthrax vaccine. Great Britain has reported hundreds of deaths or illnesses related to either the anthrax vaccine, or a mixture involving the anthrax vaccine. You see, the vaccine was never tested for adverse reactions when given in conjunction with other shots, and in the military you are likely to receive several shots at one time. This has led to extreme complications, though the United States has only recently begun to admit the fault of this and seek a resolution.

The anthrax vaccine has the potential to save lives, but until that potential is fully realized the vaccine should be made voluntary. How many lives has the vaccine saved thus far? Need a hint... how about *none*. That’s right, absolutely *zero*. And how many lives has the vaccine taken? Do you define death as the end of one’s life, or the end of one’s will to live? Per the FDA report written in 1999, 14 people have been *seriously* injured. Three will *never* recover. One is paralyzed. One is in a coma. One has developed Meningitis. They will never be who they were again... yet still they breathe. The life they once had has passed away, and why, for what reason? The only apparent reason is because the Department of Defense insisted... because the Department of Defense made it mandatory.