Accountability of

DoD, FDA and BioPort Officials

For the Anthrax Vaccine Immunization

Program (AVIP)

Committee on Government Reform Hearings for the

United States House of Representatives

October 3rd and 11th, 2000

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Officials Held Accountable

Mr. Ken Bacon, Assistant Secretary of Defense for Public Affairs
Dr. Sue Bailey, M.D. Former Assistant Secretary of Defense for Health Affairs
LTG (Dr.) Ronald Blanck, D.O. Retired former U.S. Army Surgeon General
Dr. Gerard N. Burrow, M.D., Professor of obstetrics and gynecology, Yale University Medical School and DoD's "independent expert" on anthrax vaccine
Hon. William S. Cohen Secretary of Defense
Mr. Charles Cragin Principal Deputy Assistant Secretary of Defense for Reserve Affairs
Hon. Rudy de Leon Then-Undersecretary of Defense for Personnel and Readiness (now Deputy Secretary of Defense)
COL (Dr.) Arthur Friedlander, M.D. Chief, bacteriology division, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID)
Mr. Fuad El-Hibri President and Chief Executive Officer, BioPort Corporation
Dr. Robert Myers, D.V.M., Chief Operating Officer, BioPort Corporation. and former Executive Director, Michigan Biologic Products Institute
Mr. David Oliver (RADM, USN, ret.) Principal Deputy Under Secretary of Defense For Acquisition And Technology
Maj Guy Strawder, Former Director of the US Army AVIP Agency
MGen Paul Weaver Director of the Air National Guard
Kathryn C. Zoon, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Accountability of DoD, FDA and BioPort Officials
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Issue:	**DoD denials of adverse reactions**.
Question(s):	Why have DoD public affairs officials repeatedly denied adverse reactions caused by the anthrax vaccine, while anthrax vaccine victims were simultaneously being treated at Walter Reed Army Medical Center and being visited by the Army Surgeon General, LTG Blanck?
Who said it:	**Mr. Ken Bacon**, Assistant Secretary of Defense for Public Affairs

Statement	**Fact**
	1.
Comments at a DoD press briefing, 21 Jan 1999:[1] "It's proven itself safe and reliable. It works, and **it does not have side effects**... We have given now I think shots to nearly 170,000 people in the military**... All these people are fine**." *Comments at a DoD press briefing, 30 Jun 1999*:[2] " **I've had three shots**. My hair is growing more robust than ever. (Laughter) **I sleep better. I eat better, run farther**. It's been nothing but a great experience. (Laughter)"	2. Dr. Renate Engler, the chief of immunology at Walter Reed Army Medical Center addressed a conference on the anthrax vaccine policy at Ft Detrick Maryland on 25-27 May 1999. During her address she described "**Chronic Illness Perceived as Linked to Anthrax Vaccine: Dover AFB**". She went on to observe: • **"Potentially more than 25 individuals from same location, having received anthrax vaccinations** around the same time & from same lot, **growing "belief" that anthrax has caused potentially long term, indefinite, untreatable disease**!" • "**Fear of military medical establishment: affected service members fail to report**" 3. The patients described by Dr. Engler in her briefing at Ft Detrick in May 1999 reported having chronic systemic reactions to the anthrax vaccine during the fall of 1998 -- well before Mr. Bacon's comments discrediting the idea of serious adverse reactions to the vaccine.

[1] Ken Bacon, Assistant Secretary of Defense for Public Affairs, DoD press briefing, 21 Jan 1999.
See: http://www.defenselink.mil/news/Jan1999/t01211999_t121asd_.html

[2] Ken Bacon, Assistant Secretary of Defense for Public Affairs, DoD press briefing, 30 Jun 1999
See: http://www.defenselink.mil/news/Jun1999/t06301999_t0629asd.html

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Statement	Fact
Issue:	**Squalene in anthrax vaccine**. Misleading servicemembers, military families, and the American public about the existence of an unapproved substance in the DoD anthrax vaccine.
Question(s):	Why does Mr. Bacon, the Assistant Secretary of Defense for Public Affairs, still issue categorical denials of the existence of squalene in the anthrax vaccine 15 months after FDA experts found it in five lots of anthrax vaccine?
Who said it:	**Mr. Ken Bacon**, Assistant Secretary of Defense for Public Affairs

Statement	Fact
At a DoD press briefing, 28 Sep 2000: Reporter: On the same subject, what can you say about reports that squalene has been found in some of the vaccine lots? Bacon: There have been recurrent reports of squalene. We have never found any confirmation of those reports. These reports go back to the use of anthrax vaccine during the Gulf War period. **Squalene has not been used in vaccines for a long period of time, and we're not aware that there was any squalene in any of the vaccine.**	1. Contrary to Mr. Bacon's assertion, the FDA has found squalene in five of five lots it has tested for the presence of squalene. These tests were performed in Jun 1999, but were not disclosed by FDA until 20 Mar 2000, in a letter to Congressman Jack Metcalf (R-WA).[3] 2. According to the FDA (CBER), the FDA did find squalene in the five lots of anthrax vaccine on 23 and 24 June 1999. The test results follow:[4] AVA 020 — 11 ppb squalene AVA 030 — 10 ppb AVA 038 — 27 ppb AVA 043 — 40 ppb AVA 047 — 83 ppb Diphtheria — 22 ppb Tetanus — 29 ppb 3. While the impact of squalene is under debate, it is clear that **DoD was wrong about the presence of squalene in the vaccine. DOD has not corrected their denials to Servicemembers or to Congress**.

[3] Melinda Plaisier, FDA Associate Commissioner of Legislation, letter to Congressman Jack Metcalf, 20 Mar 2000.
[4] Telephone interview with FDA CBER, 28 Sep 2000.

Accountability of DoD, FDA and BioPort Officials
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Issue:	**SecDef Cohen's 4 preconditions for implementing AVIP**. Misrepresenting to Congress that DoD's "independent expert" contracted to perform a review of the medical aspects of the anthrax vaccine policy was qualified to review the safety of the anthrax vaccine.
Question(s):	Why did Dr. Bailey, a physician herself, infer to Congress that a professor of obstetrics and gynecology who subsequently admitted to "no expertise in anthrax" was qualified to perform DoD's "independent review" of the AVIP?
Who said it:	**Dr. Sue Bailey**, then-Assistant Secretary of Defense for Health Affairs

Statement	**Fact**
In testimony before the House Government Reform Subcommittee chaired by Congressman Shays, 24 March 1999: Dr. Bailey. "The safety of our AVIP was also confirmed by an independent review of the program. Dr. Gerald Burrow, who serves as Special Advisor for Health Affairs for the President of Yale University, conducted the review."[5]	*Dr. Gerard Burrow's letter to Congressman Christopher Shays, 26 April 1999*: "The Defense Department was looking for some [sic] to review the program in general and make suggestions, and I accepted out of patriotism. **I was very clear that I had no expertise in Anthrax** and they were very clear they were looking for a general oversight of the vaccination program."[6]

[5] Dr. Sue Bailey, testimony before the National Security, Veterans Affairs, and International Relations Subcommittee of the House Government Reform Committee, 24 Mar 1999.
See: http://www.house.gov/reform/ns/hearings/subfolder/baileytest324.htm

[6] Gerard N. Burrow, letter to Representative Christopher Shays, 26 Apr 1999.

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Issue:	**Endorsements of anthrax vaccine**. Misrepresenting to Congress the American Academy of Pediatrics position on the anthrax vaccine.
Question(s):	Why did Dr. Bailey, a physician, use an out-of-date policy statement from the American Academy of Pediatrics to infer to Congress that this organization endorsed the anthrax vaccine?
Who said it:	**Dr. Sue Bailey**, then-Assistant Secretary of Defense for Health Affairs

Statement	**Fact**
Before the House Government Reform Subcommittee chaired by Congressman Shays on 24 March 1999: Dr. Bailey. "In addition, the Committee on Infectious Disease, American Academy of Pediatrics (1994), states that "the vaccine is effective in preventing or significantly reducing the occurrence of cutaneous and inhalation anthrax in adults."[7]	1. The 24th edition of the American Academy of Pediatrics Committee on Infectious Disease most recent recommendations, published in 1997 -- two years before Dr. Bailey's testimony -- does mention the anthrax vaccine, but removed the statement that the vaccine was effective for inhalation anthrax:[8] "The vaccine is effective in preventing or significantly reducing the occurrence of cutaneous anthrax in adults, and it causes minimal adverse events. No data on vaccine effectiveness or reactogenicity in children are available, and the vaccine is not currently licensed for use in children or pregnant women." 2. The 25th edition of the Academy of Pediatrics Committee on Infectious Disease most recent recommendations, published in 1997 states:[9] "The vaccine is effective for preventing or significantly reducing the occurrence

[7] Dr. Sue Bailey, testimony before the National Security, Veterans Affairs, and International Relations Subcommittee of the House Government Reform Committee, 24 Mar 1999.
See: http://www.house.gov/reform/ns/hearings/subfolder/baileytest324.htm

[8] Committee on Infectious Diseases, American Academy of Pediatrics, "Immunization of Adolescents: Recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association", 24th edition, 1997.

[9] Committee on Infectious Diseases, American Academy of Pediatrics, "Immunization of Adolescents: Recommendations of the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American Medical Association", 25th edition, 2000.

	of cutaneous anthrax in adults, and it causes minimal adverse events. While **protection against aerosol challenge has not been evaluated in humans**, multiple studies in animals have shown the vaccine to be effective. No data on vaccine effectiveness or safety in children are available, **and the vaccine is not licensed for use in children or pregnant women**." 3. Even if the data on efficacy in animals was conclusive, which it is not, efficacy tests in animals to not meet federal regulatory standards for licensure of a product for a specific purpose. The FDA did not propose new rules to allow animal tests to be substituted for human efficacy tests until 5 Oct 1999, and has not yet implemented such a change into federal law.[10]

[10] "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 Humans Ethically Cannot Be Conducted", FDA Notice of Proposed Rulemaking, 5 Oct 1999.
See: http://www.fda.gov/cber/rules/lethtox.pdf

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Issue:	**Squalene in anthrax vaccine**. Misleading servicemembers, military families, and the American public about the existence of an unapproved substance in the DoD anthrax vaccine.
Question(s):	Why does the Department of Defense still have categorical denials of the existence of squalene in the anthrax vaccine on their AVIP website over 15 months after FDA experts found it in five lots of anthrax vaccine?
Who said it:	**Dr. Sue Bailey**, then-Assistant Secretary of Defense for Health Affairs

Statement	**Fact**
Comments in a DoD News Service article on 24 Jun 1999, which was still on the DoD Defenselink website on 28 Sep 2000:[11] **Bailey countered reports that the vaccine was somehow tainted with a substance called squalene**. Squalene is a substance that appears naturally in everyone's body, she explained. "You also find it in a lot of beauty products and in some health food products," she said. "**But, squalene has never been used in the anthrax immunization vaccine production, and it is not now present**." Following the reports, DoD contracted with a civilian laboratory that tested the vaccine for squalene and "found **there is no squalene in the anthrax vaccine we are using," she said**.	1. Contrary to Dr. Bailey's assertion, the FDA has found squalene in five of five lots it has tested for the presence of squalene. These tests were performed in Jun 1999, but were not disclosed by FDA until 20 Mar 2000, in a letter to Congressman Jack Metcalf (R-WA).[12] 2. According to the FDA CBER) the FDA did find squalene in the five lots of anthrax vaccine on 23 and 24 June 1999. The test results are the following:[13] AVA 020 11 ppb squalene AVA 030 10 ppb AVA 038 27 ppb AVA 043 40 ppb AVA 047 83 ppb Diphtheria 22 ppb Tetanus 29 ppb While the physiological impact of these amounts of squalene is subject to debate, it is clear that **DoD was wrong about the presence of squalene in the vaccine. And it has never issued a statement correcting their denials to either servicemembers or to Congress**.

[11] Jim Garamone, "Anthrax Vaccine Safe, Effective, Health Chief Says", Armed Forces Press Services, 24 Jun 1999

[12] Melinda Plaisier, FDA Associate Commissioner of Legislation, letter to Congressman Jack Metcalf, 20 Mar 2000.

[13] Telephone interview with FDA CBER, 28 Sep 2000.

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Issue:	**Safety and efficacy**. Misrepresenting to Congress that adequate studies of the safety and efficacy of the anthrax vaccine exist.
Question(s):	Why did LTG Blanck, the Army Surgeon General, tell the House Armed Services Committee that "a group reviewed all of the studies on safety and efficacy" of the anthrax vaccine, when, in contrast, the Institute of Medicine later found "a paucity of published peer-reviewed literature on the safety of the anthrax vaccine -- in fact, only one 38 year-old study of a different anthrax vaccine"?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	**Fact**
In testimony before the House Armed Services Subcommittee on Military Personnel, 30 Sep 1999:[14] "The most recent paper in vaccine done by a group reviewed all of the studies on safety and efficacy, and that was published in 1998, and their conclusion was, we see no reason for further studies on safety. This is a safe vaccine. We believe it to be effective based on the studies that we have."	*From the Institute of Medicine preliminary report on the safety of the anthrax vaccine, 30 Mar 2000:*[15] • "**There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine**. The committee located only one randomized peer-reviewed study of the type of anthrax vaccine used in the United States (Brachman et al., 1962). However, the formulation of the vaccine used in that study differs from the vaccine currently in use." • "**There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically** evaluated with active surveillance." • "The committee concludes that in the peer-reviewed literature there is inadequate/ insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. This finding means that the evidence reviewed by the committee is of

[14] LTG Ronald Blanck, testimony before the House Armed Services Subcommittee on Military Personnel, 30 Sep 1999

[15] "An Assessment of the Safety of the Anthrax Vaccine", Committee on Health Effects Associated with Exposures During the Gulf War, Institutes of Medicine, 30 Mar 2000.
See: http://www.nap.edu/html/anthrax_vaccine/

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	insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association between the vaccine and a health outcome in humans."

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Issue:	**Investigational New Drug application**. Misrepresenting to the Senate Armed Services Committee that the Investigational New Drug application prepared by the U.S. Army (USAMRIID) for the anthrax vaccine manufacturer to submit to the FDA on 20 Sep 1996 applied only to the facility, not to the vaccine.
Question:	1. Was the Investigational New Drug application submitted by the anthrax vaccine manufacturer (MBPI) on 20 Sep 1996, a product license amendment for the manufacturing facility or for the anthrax vaccine itself? 2. When LTG Blanck stated to the Senate Armed Services Committee that the IND application was "really for the facility" was that a true statement?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	**Fact**
Before the Senate Armed Services Committee, 13 April 2000: Sen. Roberts: "General Blanck, the annual Congressionally mandated chemical and biological defense program report to Congress submitted on March 15, 2000, states: "The Department submitted data to the FDA last year to license the vaccine to provide protection against aerosol exposure to anthrax." My question is why is the Department seeking a license for the vaccine when the license for the anthrax vaccine has existed since 1970?" Gen. Blanck: **"It is really for the facility, not for the vaccine per se."** Sen. Roberts: "Oh, I see, okay. All right. That clears that up."	1. The Investigational New Drug application was specifically for anthrax vaccine absorbed (AVA) and the modification sought by the manufacturer, at the request of and with DoD assistance, and will apply <u>regardless</u> where the anthrax vaccine is manufactured. 2. **The 20 Sep 1996 IND application** cover letter from the manufacturer, Michigan Biologic Products Institute, **contains no mention of the facility**. **It simply states**: "The purpose for filing this IND is to conduct clinical investigations designed **to investigate changes in the approved labeling for the licensed product**. The potential labeling changes would affect the specific clinical indication, route, and vaccination schedule for AVA [anthrax vaccine absorbed]."[16] 3. The IND application was submitted following an Army, Joint Staff, and OSD staff process in which there was

[16] Robert C. Myers, Executive Director, Michigan Biologic Products Institute (now Chief Operating Officer of Bioport, Inc.), letter to FDA CBER director Dr. Kathryn Zoon,, 20 Sep 1996

Statement	Fact
	concurrence that it was necessary to obtain FDA approval of a new licensed indication for inhalation anthrax before DoD could start mass anthrax vaccinations.[17] That consensus was reversed within a month of Mr. William Cohen being confirmed as SecDef, following DoD pressure on FDA to give permission to begin vaccinations without obtaining a new licensed indication.[18]

[17] 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.
[18] Dr. Stephen C. Joseph, DoD ASD/Health Affairs, letter to FDA Lead Deputy Commissioner Michael Friedman, 4 Mar 1997

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Issue:	**Independence of DoD's "Anthrax Vaccine Expert Committee"(AVEC)**. Misrepresenting the autonomy of the panel of experts commissioned by DoD to review anthrax vaccine adverse reaction reports (VAERS).
Question(s):	1. Do DoD representatives participate in all meetings of the Anthrax Vaccine Expert Committee, and if so, why? 2. Are representatives of those opposed to the anthrax vaccine allowed to participate in meetings of the Anthrax Vaccine Expert Committee? 3. How can a committee of experts commissioned by a DoD Agency be relied upon to issue reports that are unfavorable to a program closely associated with the Secretary of Defense?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

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Statement	Fact
Written testimony submitted by LTG Blanck before the Military Personnel Subcommittee of the House Armed Services Committee, 30 Sep 1999:[19] "**The AVEC represents a special panel of experts commissioned by the AVIP Agency** in early 1998 to review any signaling event that would identify problems stemming from the anthrax vaccine. **These experts come from the Health Resources & Services Administration (HRSA); a component of the Department of Health & Human Services** sponsored Vaccine Injury Compensation Program (VICP). **To date, the AVEC has found no pattern of causality stemming from the use of the anthrax vaccine**."	1. The Army's concern about the Anthrax Vaccine Expert Committee operating too independently was revealed in an internal email sent by COL Frederick Gerber, Director, Health Care Operations, Office of the Army Surgeon General on 22 Oct 1998. COL Gerber was intent on insuring that the Army had a representative at the first AVEC meeting, which occurred on 26 Oct 1998. The text of his email reads: Subject: Re: FW: Vaccine Expert Panel Review of Anthrax Vaccine Author: COL Fred Gerber Date: 10/22/98 11/20 PM "**OK, but you see the problem with us not being there is…NOT being included in the loop** of what's already been done re: fixing the VAERS report form and procedures, etc. Last thing we want is them coming up with an entirely new solution set up after we've already worked one. **Think about this one and be sure we don't let them [AVEC] go down a road we don't need going down**."[20] 2. **In fact, at least three DoD representatives attended the first AVEC meeting** on 26 Oct 1998: Dr. Phillip Pittman of USAMRIID, Ft. Detrick, MD; CAPT David Trump of OSD Health Affairs, and Ms. Cathy Call of the Office of the Army Surgeon General.[21]

[19] LTG Ronald Blanck, U.S. Army Surgeon General, written testimony before the Military Personnel Subcommittee of the House Armed Services Committee, 30 Sep 1999.
See: http://www.house.gov/hasc/testimony/106thcongress/99-09-30hamre.htm
[20] COL Fred Gerber, email to colleagues in the Office of the Army Surgeon General, 22 Oct 1998.
[21] Ms. Cathy Call, email to colleagues in the Office of the Army Surgeon General, 4 Jan 1999.

Accountability of DoD, FDA and BioPort Officials
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Issue:	**Relevance of animal models for human efficacy**. Misrepresenting to the House Armed Services Committee that the FDA has accepted animal models as a legal substitute for efficacy testing
Question(s):	1. Has the FDA amended federal regulations to now accept animal studies as substitutes for human efficacy studies? 2. Are there currently any peer reviewed scientific studies that establish correlates of immunity between humans and animals for the purpose of testing efficacy of vaccines that would allow an amendment of federal regulations as proposed by the FDA in a Notice of Proposed Rulemaking on 5 Oct 1999? 3. If the FDA does not accept animal tests as acceptable alternatives to legally required human efficacy tests required for vaccine licensure, then of what legal relevance are the guinea pig, rabbit, and primate tests which DoD continually uses to assert the safety and efficacy of the vaccine?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	Fact
Before the House Armed Services Committee on 30 September 1999: Gen. BLANCK. "So what we have done **with full FDA concurrence** is develop several animal models, and that is part of how we know that this protects against the strains…the mechanism and all of that kind of thing."	1. The Investigational New Drug (IND) application prepared by the US Army, and submitted by the anthrax vaccine manufacturer (MBPI) to the FDA on 20 Sep 1996 proposed establishing animal models as a "correlate for immunity" in humans. This is an exception to current federal law, which requires human studies to prove efficacy. 2. The FDA did not even propose rules for allowing animal studies to substitute for human studies until it issued a Notice of Proposed Rulemaking on 5 Oct 1999 [22] -- three years after the submission of the IND application, and 19 months after AVIP immunizations began. The FDA still has not amended the regulations, and thus has not accepted as valid any animal models as substitutes for legally

[22] "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 Humans Ethically Cannot Be Conducted", FDA Notice of Proposed Rulemaking, 5 Oct 1999.
See: http://www.fda.gov/cber/rules/lethtox.pdf

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Statement	Fact
	required efficacy tests for vaccine licensure. Therefore, LTG Blanck's mention of animal tests is misleading, because they are irrelevant with respect to meeting the requirements of federal law (Food, Drug, and Cosmetic Act).

Accountability of DoD, FDA and BioPort Officials
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Issue:	**Efficacy against multiple strains**. Misrepresenting to the House Armed Services Committee the efficacy of the anthrax vaccine against all strains of anthrax.
Question(s):	1. Does LTG Blanck's statement that the anthrax vaccine "applies to all of the strains" mean that the anthrax vaccine has demonstrated efficacy in all, or even most, of the strains sufficient to satisfy federal regulatory requirements for licensure for the purpose of inhalation anthrax? 2. Has the anthrax vaccine been tested against all strains of the anthrax vaccine? 3. In which animals and how many strains were used on each animal, and against how many of the strains did the anthrax vaccine prove efficacious? 4. Is there a scientifically valid "correlate of immunity" in any of the animals in which the anthrax vaccine has demonstrated efficacy that is accepted by the FDA as a substitute for human efficacy studies required by federal regulations?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	**Fact**
Before the House Armed Services Committee on 30 Sep 1999: Mr. GILMAN. "General Blanck, let me ask you another serious question. I understand that there are many, many strains of anthrax. Does this vaccine that you are using apply to all of the strains or just to one or two of the strains of anthrax?" General BLANCK. "**No, it applies to all of the strains."**	1. See statements in the medical textbook "Vaccines" by the Army's chief anthrax researcher, Col. (Dr.) Arthur Friedlander, USA, and the author of the only peer-reviewed efficacy study of an anthrax vaccine by Dr. P.S. Brachman (although a different vaccine, it was used for the original approval of the current vaccine used in the AVIP):[23] • "The current vaccine against anthrax is unsatisfactory for several reasons…There is also evidence in rodents that the efficacy of the vaccine may be lower against some strains of anthrax than others." • "There have been no controlled clinical trials in humans of the efficacy of the

[23] "Vaccines", ed. S. Plotkin, chapter on anthrax vaccine, 1999 edition, by P. Brachman and A. Friedlander, pg. 635-636.

Statement	Fact
	currently licensed U.S. vaccine. The vaccine has been extensively tested in animals…" 2. Statements undermine claims of efficacy in animal tests by Col. (Dr.) Arthur Friedlander, the Army's chief anthrax researcher. During internal DoD deliberations leading to the decision to implement the DoD anthrax vaccine program, he acknowledged that there are no scientifically valid "correlates of immunity" between animals used in Army testing, and humans. According to meeting minutes of a 20 Oct 1995 meeting to discuss obtaining FDA approval for an amendment to the FDA license for anthrax vaccine:[24] • "Col Friedlander discussed efforts at USAMRIID to develop in vitro correlates of immunity…The current thinking is that antibodies against "protective antigen (PA)" are important for immunity against anthrax infection. **Yet, sensitive antigen-antibody assays, such as ELISA, fail to demonstrate a correlation between PA antibody levels and immunity**." • The same 20 Oct 1995 DoD meeting minutes go on to state: "**A serious complication in amending the license for anthrax vaccine is the lack of a suitable surrogate animal model**; i.e. a model in which human immunity can be transferred directly and shown to be protective."

[24] 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.

[25] " 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 Humans Ethically Cannot Be Conducted", FDA Notice of Proposed Rulemaking, 5 Oct 1999.
See: http://www.fda.gov/cber/rules/lethtox.pdf

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Statement	Fact
	3. Further, **US law (Food, Drug, and Cosmetic Act) does not allow the use of animal efficacy tests, even if scientifically valid, as a substitute for human efficacy tests required for vaccine licensure**. Recognizing this, the FDA issued a Notice of Proposed Rulemaking on 5 Oct 1999 to allow the use of animal efficacy tests for biowarfare vaccines and drugs.[25] The FDA has taken no further action on this proposal. Therefore, **the repeated testimony by DoD and FDA representatives of the results of efficacy tests on guinea pigs, rabbits, and primates are legally irrelevant**, because these tests cannot be used to fulfill regulatory requirements for amending the anthrax vaccine license to include an indication for inhalation anthrax.

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Issue:	**Genetically altered anthrax**. Misrepresenting as "rumors" publicly reported statements regarding bioengineering of anthrax, which can be genetically altered to cause a degradation of the effectiveness of the anthrax vaccine.
Question(s):	Isn't it true that there have been published reports of bioengineering of anthrax in such a way that the current vaccine's effectiveness is really unknown?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	Fact
Before the Senate Armed Services Committee on 13 Apr 2000: Gen Blanck: "Yes, we worry about the genetically engineered strains of bacteria that have been written about and talked about. We have not seen any, nor do we have access to any, so it is unknown as to whether our vaccine would protect against that..." (later) Sen. Warner: "To your knowledge, has any foreign nation or other group that we might have knowledge of manufactured anything that is beyond the strains that we have? GEN. BLANCK: Nothing that I have knowledge of. **We keep hearing rumors** and we need to look into what the former Soviet Union has."	1. DoD concern about possible bioengineering to defeat the anthrax vaccine was one of the reasons for **Secretary of the Army Louis Caldera** to issue a **letter indemnifying the anthrax vaccine manufacturer** from liability on 3 Sep 1998. He stated in that letter: "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 U.S. forces might encounter to confer immunity**."[26] 2. Dr. Ken Alibek, former deputy director of the Soviet biological warfare directorate (BioPreparat), testified before the Joint Economic Committee of Congress on May 20, 1998: "In the case of most military and all terrorist attacks with biological weapons, **vaccines would be of little use**. "[27] 3. Dr. Alibek's rationale was explained in a New York Times article on 5 Apr 1998, in which he commented on Soviet efforts to genetically alter anthrax: "Moscow mastered the art of rearranging genes to

[26] Louis Caldera, Secretary of the Army, Memorandum of Decision to Indemnify, 3 Sep 1998
See: http://www.dallasnw.quik.com/cyberell/Anthrax/Mem_D_98.html
[27] See: http://www.house.gov/jec/hearings/intell/alibek.htm

Statement	Fact
	make harmful microbes even more potent and harder to counteract. **Anthrax, a top biological warfare agent that causes high fever and death, was genetically altered**, he [Alibek] says, to resist five kinds of antibiotics."[28] [Note: this is not equivalent to resistance to a vaccine.] 4. Contrary to LTG Blanck's assertion of "rumors", Russian scientists published an article about having genetically altered anthrax in the British medical journal "Vaccines" in Dec 1997. This was three months before DoD anthrax vaccinations began and two months before DoD's "independent expert", Dr. Gerard Burrow, submitted his review which endorsed DoD's plans to implement a mass vaccination program with the anthrax vaccine.[29]

[28] "Defector Tells of Soviet and Chinese Germ Weapons", by William J. Broad And Judith Miller, New York Times, 5 Apr 1999

[29] Gerard N. Burrow, MD, letter to Undersecretary of Defense for Personnel and Readiness Rudy DeLeon, 19 Feb 1998. See: http://www.defenselink.mil/other_info/burrows.html

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For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Current anthrax vaccine "state of the art"?** Misrepresenting to the Senate Armed Services Committee that the current anthrax vaccine is a state-of-the-art vaccine.
Question:	1. Is LTG Blanck's concurrence with Senator Warner's questioning as to whether the anthrax vaccine used by DoD is "state of the art" an accurate statement? 2. Is LTG Blanck's assertion that the current anthrax vaccine "will protect against all natural strains" substantiated by efficacy tests using all known strains on animals that the FDA has accepted as demonstrating a "correlate of immunity" in humans? 3. Isn't it true that the current anthrax vaccine's high adverse reaction rate has been known to DoD since before the Gulf War, and was reason for Bush Administration defense officials to characterize it as unsuitable for mass immunizations for this reason? 4. Is LTG Blanck's assertion that the anthrax vaccine being used on US servicemembers "meets all standards" substantiated by the anthrax vaccine manufacturer's record of repeated failed FDA inspections due to significant deviations from federal regulatory manufacturing standards substantiate?
Who said it:	**LTG Ronald Blanck**, then-Army Surgeon General

Statement	**Fact**
Before the Senate Armed Services Committee on 13 Apr 2000: SEN. WARNER: "In my opening statement **I carefully used the phrase, wrote it out myself, "state of the art," so that this vaccine meets state of the art knowledge on all strains**, and it is your professional judgment that it will inoculate against them?" GEN. BLANCK: "**Yes, sir. This is a current vaccine, meets all the standards**, it will protect against all natural strains. We are working, as Mr. Oliver has testified, on a new, even further advanced recombinant vaccine."	1. **"Current" and "State of the art"**. DoD and the Army have long been aware of the anthrax vaccine's significant shortcomings. • In a 24 Aug **1989** letter responding to questions by Senator John Glenn during a hearing, former Assistant Secretary of Defense Robert B. Barker stated the following: "**Current vaccines, particularly the anthrax vaccine, do not readily lend themselves to use in mass troop immunization** for a variety of reasons: the requirement in many cases for multiple immunizations to accomplish protective immunity, **a higher than desirable rate of reactogenicity**, and,

Statement	Fact
	in some cases, lack of strong enough efficacy against infection by the aerosol route of exposure."[30] • Col. (Dr.) Arthur Friedlander, the Army's chief anthrax researcher at Ft Detrick, MD, co-authored the chapter on anthrax vaccine in the medical textbook "Vaccines" in 1994 and again in 1999. In the article he critiqued the current anthrax vaccine as "unsatisfactory" because of high rates of adverse reactions and a multiple shot regimen.[31] • Col. (Dr.) Friedlander also acknowledged the anthrax vaccine's deficiencies during a meeting held by the Joint Program Office for Biological Defense on 20 Oct 1995.[32] 2. "**Meets all standards**". The former and current anthrax vaccine production facility have failed FDA inspections with consistent "significant deviations" from manufacturing practices (CGMP) required by FDA regulations on the following inspection dates: • May 4 - May 7, 1993 • May 31- June 3, 1994 • April 24 - May 5, 1995 • Nov 18 - Nov 27, 1997 • Feb 4 - Feb 20, 1998 • Nov 15 - Nov 23, 1999 (current facility) The seriousness of these deficiencies was emphasized to the manufacturer (MBPI and Bioport) in:

[30] Robert B. Barker, former Assistant Secretary of Defense, letter to Senator John Glenn, 24 Aug 1989, see Senate Hearing 101-744, page 474, 480.
[31] "Vaccines", ed. S. Plotkin, chapter on anthrax vaccine, 1994 edition, by P. Brachman and A. Friedlander, , pg. 737. See also 1999 edition at page 636.
[32] LTC David Danley, memorandum - minutes of 20 Oct 1995 meeting, Joint Program Office for Biological Defense, 13 Nov 1995, page 1.

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	• An FDA letter dated 22 Dec1993. • An FDA Warning Letter dated 31 Aug 1995 • An FDA "Notice of Intent to Revoke" (NOIR) MBPI's license dated 11 Mar 1997 • An FDA inspection report finding "The manufacturing process for Anthrax Vaccine is not validated" dated 20 Feb 1998 • And another FDA letter with the same observation of Bioport's new production facility dated 23 Nov 1999.[33]

[33] FDA inspection report, CBER Office of Compliance and Biologics Quality, Bioport Corporation inspection 15-23 Nov 1999, 23 Nov 1999.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**SecDef Cohen's 4 preconditions for implementing AVIP**. Was the "independent expert" contracted by Undersecretary of Defense Rudy De Leon to review the medical aspects of the anthrax vaccine immunization program qualified to perform this review?
Question(s):	1. Why did the current Deputy Secretary of Defense, Mr. De Leon, select a professor of obstetrics and gynecology who has subsequently admitted in a letter to Congress to "no expertise in anthrax" to perform DoD's "independent review" of the AVIP?[34] 2. Dr. Burrow stated in a 26 Apr 1999 letter to Rep Shays that he performed his "independent" review of the DoD anthrax vaccine program "out of patriotism." Was Dr. Burrow paid for his "independent review"? How much? 3. At the end of his 19 Feb 1998 report to then-Undersecretary of Defense Mr. De Leon, Dr. Burrow expressed gratitude to numerous DoD medical officials for their assistance. How does this reflect on the independence of Dr. Burrow's review? 4. Did Dr. Burrow provide subsequent assistance during implementation of the anthrax vaccine program, as he offered to Mr. De Leon in Feb 1998?
Who said it:	**Dr. Gerard N. Burrow**, M.D., DoD's "independent expert" hired to perform an independent review of the proposed anthrax vaccine immunization program.

Statement	**Fact**
In a letter to Undersecretary of Defense Rudy DeLeon, 19 Feb 1998: "At your request, I have reviewed the Department of Defense plan to immunize the force against the biological warfare threat of anthrax. I have made several visits to the Pentagon, have had a number of telephone conferences and have consulted extensively with experts in allergy, immunology and infectious disease…"	*In a letter to Congressman Christopher Shays, 26 April 1999*: "The Defense Department was looking for some [sic] to review the program in general and make suggestions, and I accepted out of patriotism. I was very clear that I had no expertise in Anthrax and they were very clear they were looking for a general oversight of the vaccination program."[36]

[34] Rudy de Leon, Undersecretary of Defense for Personnel and Readiness, letter to Dr. Gerard Burrow, 17 Dec 1997

[35] Gerard N. Burrow, M.D., letter to Undersecretary of Defense Rudy DeLeon, 19 Feb 1998. See: http://www.defenselink.mil/other_info/burrows.html

[36] Gerard N. Burrow, letter to Representative Christopher Shays, 26 Apr 1999.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
"…The anthrax vaccine appears to be safe and offers the best available protection against wild-type anthrax as a biological warfare agent. Steps have been taken to ensure the safety and quality of the department's vaccine stockpile…." "… I would like to thank Dr. Edward Martin for facilitating my access to information. I am particularly indebted to CAPT John Mateczun, MC, USN for his assistance and to the dedicated men and women in the various services who shared their knowledge with me. I hope this report is helpful to you and would be glad to provide assistance during implementation."[35]	Note: 1. **Dr. Burrow's observation** that "steps have been taken to ensure the safety and quality of the department's vaccine stockpile" is **contradicted by the FDA inspection report on the Michigan Biologic Products Institute that was released the day after Dr. Burrow's 19 Feb 1998 positive review letter was submitted to DoD**. The FDA's 20 Feb 1998 letter to MBPI was the result of a two-week inspection of the anthrax vaccine plant that preceded Dr. Burrow's review letter. The FDA letter stated: "The manufacturing process for Anthrax Vaccine is not validated", and listed dozens of separate deviations from FDA manufacturing standards. 2. Dr. Burrow declined an invitation to testify before Representative Shays' committee on 29 Apr 1999 to explain his "independent review" of the DoD anthrax vaccine program.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**The threat**. Senior DoD officials misrepresenting the threat to Congress, servicemembers, and the American people
Question(s):	1. Why did Secretary of Defense Cohen claim that at least 25 countries had bioweapons in 1999, and then reduce that claim to only 10 nations in 2000? 2. Why does Secretary Cohen assert that "there is not a moment to lose" in preparing for a biowarfare attack when the number of countries he now claims (in 2000) to have these weapons is no different than DoD's position during the Reagan Administration?
Who said it:	**Hon. William S. Cohen**, Secretary of Defense

Statement	**Fact**
In an op-ed titled, "Preparing for a Grave New World", Washington Post, 26 July 1999: • "**At least 25 countries, including Iraq and North Korea, now have -- or are in the process of acquiring and developing -- weapons of mass destruction**. Of particular concern is the possible persistence in some foreign military arsenals of smallpox...This is not hyperbole. It is reality...The race is on between our preparations and those of our adversaries. We are preparing for the possibility of a chemical or biological attack on American soil because we must. There is not a moment to lose." (One year later….) *William S. Cohen, Secretary of Defense, "Force Protection Is My Priority", Army Times, 31 Jul 2000:* "**At least 10 countries have or are developing anthrax as a weapon**."	*Testimony of Thomas J. Welch, Ph.D., Deputy Asst. to the Secretary of Defense for Chemical Matters, hearings before the Subcommittee on Oversight of Government Management, Committee on Government Affairs, US Senate, 28 July **1988***: • "...what has happened is that **we have seen the number of nations possessing biological agents increase from 4 to 10 that we know of -- there are probably more** -- and this drove us to approach the Armed Services Committee asking for increased funding for biological defense." *GAO report (after reviewing DoD's threat data), "Medical Readiness: Safety and Efficacy of the Anthrax Vaccine" (T-NSIAD-99-148), 29 Apr 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..." *Dr. Jonathan Tucker, former UN biological*

Statement	Fact
	weapons inspector in Iraq: • "**U.S. policy-makers** and several outside analysts **have predicted catastrophic consequences** if a terrorist group or an individual-alone or with state sponsorship-ever mounts a major chemical or biological attack... **But these scenarios have not drawn on a careful assessment of terrorist motivations and patterns of behavior**... Contrary to the conventional wisdom about the catastrophic nature of chemical and biological terrorism, **actual attacks were few in number, small in scale, and generally produced fewer casualties than conventional bombs**."[37] *Milton Leitenberg, senior fellow, Center for International and Security Studies at the University of Maryland*: • "**Nothing supports these propositions. They are exaggerated and alarmist**. They are probably even dangerous and counterproductive, since they virtually solicit and induce precisely what they portray as fearing... **The portrayal of this subject by senior government officials is grossly exaggerated, and the government's policy is accordingly based either on faulty assessments or no assessment at all**."[38]

[37] Jonathan B. Tucker and Amy Sands, "An Unlikely Threat", Bulletin of Atomic Scientists, July/Aug 1999, Vol. 55, No. 4, pp. 46-52. See: http://www.bullatomsci.org/issues/1999/ja99/ja99tucker.html
[38] Milton Leitenberg, "False Alarm" , Washington Post, 14 Aug 1999, (page A15)

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Coercion/Punishment for refusing the anthrax vaccine**.
Question(s):	1. If anthrax vaccine is intended for the purpose of force protection, why have Guard commanders attempted to use it as a quid pro quo for training assignments in units which were not required under DoD guidance to be vaccinated? 2. Why has a general officer in the Indiana Air National Guard threatened a junior officer, in writing, with over 300 days in jail as punishment for failure to submit to the anthrax vaccine?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr. Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined to nominate Mr. Cragin for Senate confirmation.)

Statement	**Fact**
Before the House Government Reform Subcommittee chaired by Congressman Shays on 29 September 1999: "If someone is going to resign, Mr. Shays, they are certainly not going to be subject to any penalties. That is one of the points of the Guard and Reserve."	1. **Air Force Reserve**. Guidance to commanders directed them not to allow transfers of USAF Reserve personnel to non-mobility positions in the reserves unless the reservists submitted to being vaccinated, even though their new positions did not require the anthrax vaccine.[39] 2. **Maryland Air National Guard**. An Air National Guard general officer attempted to use the anthrax vaccine as a quid pro quo for training, even when the unit was not an AVIP Phase I unit requiring the vaccine.[40] 3. **Kansas Air National Guard**. Four days after Mr. Cragin's testimony, the commander of the 184th Bomb Wing, Kansas Air National Guard, issued a written warning to a B-1 bomber pilot, **threatening a $500 fine and six months in jail** because the pilot had asked to

[39] Air Force Reserve Command "Interim Anthrax Policy" message, from AFRC/ACV (assistant vice commander) to NAF/CC's (numbered air force commanders), 1 Oct 1999

[40] " Maryland National Guard Head Rescinds Anthrax-Vaccine Letter, by Tom Bowman, Baltimore Sun, 25 Jan 2000

Statement	Fact
	transfer to a non-mobility position in lieu of submitting to the vaccine.[41] 4. **Indiana Air National Guard**. At least one pilot has been threatened in writing, although half (15) of the pilots in the unit left. • On 24 June 2000 a captain in the Ft. Wayne F-16 squadron who had refused the anthrax vaccine was issued a letter from a general officer which stated: "1. You are reprimanded 2. You are fined 2/3 of 1 month's base pay; however, the fine is suspended upon the condition that you submit to Anthrax Vaccination within 30 days of imposition of punishment."[42] • When that officer declined to be vaccinated, he was sent another letter 20 Aug 2000 from a different general officer which stated: "I have determined that you violated... the condition of the suspension of your punishment.... I have determined that you did not take the anthrax vaccine on or before 24 July 2000.... **If you do not pay the fine voluntarily, then you will be committed to the Allen County Jail until such fine is paid or until one day shall be served for each one dollar of the fine**."[43] 5. **Michigan Air National Guard**. An A-10 pilot was removed from flying status in June 2000 for refusing to take the

[41] Col Edward A. McIlhenny, Commander, 184th Bomb Wing, letter to subordinate officer, 4 Oct 1999 (submitted to National Security, Veterans Affairs, and International Relations subcommittee of the House Committee on Government Reform, Oct 1999)
[42] BG Dale K. Snider, Commander IN ANG, letter to Captain Daniel W. Marohn, 24 Jun 2000.
[43] BG James K. Wilson, Chief of Staff, IN ANG, letter to Captain Daniel W. Marohn, 20 Aug 2000.
[44] Major George H. Benefield Jr., 172nd Fighter Squadron Commander, letter to Captain Tuttle, 4 Aug 2000.
[45] LtCol Michael A. Snider (USAFR), personal email, "Anthrax harassment program continues", 25 Sep 2000, forwarded to the House Government Reform Committee.

Statement	Fact
	anthrax vaccine. The unit leadership attempted to separate this officer with an other than honorable discharge -- without ever charging him with an offense. On 4 Aug 2000 this pilot was sent a letter from his unit commander which informed him he would be separated honorably because "apparently, the JAG, Capt Niedergall says that legally we cannot offer you a General / Administrative discharge…" **This officer has been thrown out of the Air National Guard without a single charge ever being proffered against him**.[44] 6. **Air Force Reserve**. When the DoD anthrax vaccine policy changed in July 2000 to a 30-day in-theater requirement, an Air Force Reserve officer who had left his unit in 1999 applied to rejoin his C-5 transport unit at Travis AFB, the 301st Airlift Wing. He informed the On 24 Sep 2000 the Air Force Reserve the lieutenant colonel met a board comprised of the wing commander and two other senior officers to determine whether he would be allowed to rejoin his unit. The board lasted just a few minutes, ending when the wing commander told the officer that he would have to submit to the anthrax vaccine as a quid pro quo for rejoining the unit.[45]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Compliance with shot protocol in FDA license**. Misrepresenting DoD's intention to follow the FDA licensed shot protocol.
Question(s):	1. Last September Mr. Cragin testified that DoD was adhering to the licensed six shot protocol to the "greatest extent possible". Does Mr. Cragin consider DoD to be adhering to that standard by initiating shots when it was clear the AVIP program would run short of vaccine due to the FDA declining to certify the manufacturer? 2. Last summer Army ROTC cadets were given twice the normal dose of anthrax vaccine prior to deploying to South Korea for their summer training.[46] -- Does Mr. Cragin considers this to be an example of adhering to the FDA shot protocol? -- Why was DoD sending untrained ROTC cadets who could serve no useful combat role to a so-called high-threat area? Does this mean South Korea is actually not a high-threat area? Is this why the South Korean military does not vaccinate its troops for anthrax? 3. When DoD ran short of vaccine this past summer they quickly referenced a CDC panel's (Advisory Committee on Immunization Practices) approval of a deviation from the FDA licensed shot protocol. Does seeking an outside endorsement of this deviation represent adhering to the FDA shot protocol "to the greatest extent possible"? 4. The committee has been advised that the Massachusetts Air National Guard F-15 unit at Otis Air Force Base is about to deploy to Southwest Asia, and they received only one anthrax shot last spring -- well before Secretary Cohen's July curtailment announcement. Does this action represent adhering to the FDA shot protocol "to the greatest extent possible"?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined to nominate Mr. Cragin for Senate confirmation.)

Statement	**Fact**

[46] "25 cadets given a vaccine overdose: Mishap with anthrax shots occurs at Ft. Lewis", The Seattle Post-Intelligence and Associated Press, June 20, 2000

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
Before the House Government Reform Subcommittee chaired by Congressman Shays on 29 September 1999: Mr. Shays. "So you are abiding by the FDA's [6 shot] protocol?" Mr. Cragin. "**We are abiding by the FDA protocol to the greatest extent possible** in inoculating this force."	The military has deviated from the protocol by: 1. The non-compliance with the FDA-licensed shot protocol has been egregious. For instance, in Sep 1999 the CT ANG was in 90% non-compliance with FDA-licensed shot protocol. 2. Continuing to start the shots when they knew that six shots could not be administered. Because of a predictable shortage of vaccine that was the result of FDA declining to certify the new anthrax vaccine facility, over 500,000 servicemembers are, or will soon be, in non-compliance with the FDA licensed protocol. 3. Unilaterally establishing a +/- 30-day criteria for compliance with the shot timeline that allows for large deviation from the FDA licensed protocol. (i.e. a 2nd shot scheduled for day 14 could be administered at day 44 and DoD will report it as "on schedule.") 4. Vaccinating ROTC cadets who were unnecessarily deployed to a "high-risk" area for only 2-4 weeks, and then returned to civilian colleges where their vaccination schedule would lapse.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**The biowarfare threat**. Misrepresenting the threat and the historical context of the anthrax vaccine immunization program to Congress.
Question(s):	1. Does the British military find the Boer War example you cited in your 16 May 2000 letter to Congress compelling enough to mandate anthrax vaccinations for their military? 2. Do any U.S. allies in those countries DoD designates as "high-threat" areas -- for instance, South Korea and Israel -- mandate the anthrax vaccine for their military servicemembers? 3. Do any other U.S. allies mandate the anthrax vaccine for their military servicemembers?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined to nominate Mr. Cragin for Senate confirmation.)

Statement	Fact
Responding on behalf of Secretary of Defense William Cohen in a letter to 35 members of Congressmen, 16 May 2000: "…In closing, let me share a true story from an earlier era. In 1898, the British were preparing to fight the Boer War. Their senior leadership considered giving all their troops the recently approved Typhoid Vaccine. Opposition arose, some protests were held, some in their Parliament objected, and that vaccine was made voluntary. Fourteen thousand troops elected to take the shot. The troops went to war and 59,000 came down with typhoid. Nine thousand of them died while a perfectly safe and effective vaccine remained on the shelf. We cannot allow the last chapter of the anthrax story to be a BOER War analogy!"[47]	1. **Apples vs. Oranges**. Mr. Cragin compares vaccination against a common natural health risk (typhoid) with vaccination against a biological warfare agent (weaponized anthrax). Naturally occurring anthrax is not a health risk to U.S. forces. 2. **United Kingdom**. The anthrax vaccination program in the British military is voluntary, and over 70% of British servicemembers choose not to be vaccinated.[48] Clearly, the Boer War example cited by Mr. Cragin is not compelling to the British government or their military leadership. **3. Canada**. In May 2000, the Canadian military suspended court-martial charges against a Canadian Air Force career servicemember who had refused the

[47] Charles Cragin, letter to 35 Members of Congress on behalf of SecDef Cohen, 16 May 2000
See: http://www.house.gov/reform/letters/cohen.5.16.00.pdf
[48] A. Gilligan, "British Troops Mutiny Over Gulf Anthrax Jab", The Sunday Telegraph (London), 7 Jun 1998.

Statement	Fact
	anthrax vaccine. **Canada's chief military judge stated the anthrax vaccine was:** "…**unsafe and hazardous** and could be responsible for the important symptoms reported by so many persons who took that vaccine."[49] 4. **France**. In Sep 2000 the French ministry of defense announced the creation of an independent commission that will look into the health of French military servicemembers who served in the Gulf War attached to US forces. A physician spokesman for the French military reiterated that: "…France's belief that allied troops were victims of their own protective measures were based on a long series of meetings with U.S. medical experts."[50] The French military physician noted that while about 16% of US Gulf War veterans have complained of ailments associated with Gulf War syndrome, less than 1% of French troops had similar symptoms. The French did not use the anthrax vaccine, but will study whether their servicemembers stationed with US forces took the vaccine and other biowarfare drugs. 5. **South Korea**. Does **not** use the anthrax vaccine, despite being labeled by DoD as a so-called "high-threat" area and DoD efforts to convince them to use it.[51] 6. **Israel**. Does **not** use the anthrax vaccine, despite being labeled by DoD as a so-

[49] Ruth Walker, "Last week, a military judge issues a precedent-setting ruling on individual rights", The Christian Science Monitor, 9 May 2000. See: http://www.majorbates.com/news/09may00_csm.htm
[50] "French to Check Liaison Officers for Gulf Syndrome", Reuters, 14 Sep 2000
See: http://www.majorbates.com/news/14sept00_reuters.htm
[51] MGen Randall West, USMC, comments during a DoD press conference, 13 Dec 1999.
See: http://www.defenselink.mil/news/Dec1999/t12141999_t213anth.html

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	called "high-threat" area. 7. **Other U.S. NATO or non-NATO allies**. None uses the anthrax vaccine.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Endorsements of anthrax vaccine**. Misrepresenting to Congress that the American Public Health Association supports the DoD anthrax vaccine policy.
Question(s):	Why did Mr. Cragin use a medical reference book to convince Congress that the American Public Health Association supports DoD's use of the anthrax vaccine instead of confirming the Association's stance by contacting them directly (or referencing their website)?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined to nominate Mr. Cragin for Senate confirmation.)

Statement	Fact
Responding on behalf of Secretary of Defense Cohen in a 16 May 2000 letter to 35 bipartisan Members of Congress: "Comment -- A reading of that association's 17th Edition of the American Public Health Association's Control of Communicable Diseases Manual (James Chin, MD, MPH editor) specifies a preventive measure for exposure to anthrax is to "immunize high risk persons with a cell-free vaccine prepared from a culture filtrate containing protective antigen. Evidence indicates that this vaccine is effective in preventing cutaneous and inhalational anthrax; it is recommended for laboratory workers who routinely work with B anthrax and workers who handle potentially contaminated industrial raw materials. It may also be used to protect military personnel against potential exposure to anthrax as a biological warfare agent. Annual booster injections are recommended if the risk of exposure continues."[52]	1. Policy Statement #9930 adopted by the Governing Council of the American Public Health Association, November 10, 1999:[53] • **Urges the US Department of Defense to delay any further immunization against anthrax using the current vaccine** or at least to make immunization voluntary; and • Urges that a commission of military and non-military public health experts be formed to review the evidence for effectiveness and safety of the current vaccine and the time at which an improved vaccine may be available, and to make recommendations about the continuation of the current immunization program. 2. Mohammed N. Akhter, MD, MPH, Executive Director, American Public Health Association, in a 23 May 2000 letter to Congressman Jack Metcalf

[52] Charles Cragin, letter to 35 Members of Congress, 16 May 2000.
See: http://www.house.gov/reform/letters/cohen.5.16.00.pdf
[53] American Public Health Association, Governing Council Policy Statements, 10 Nov 1999
See: http://www.apha.org/legislative/policy/99policy.pdf

Statement	Fact
	reiterating the APHA's policy statement on the anthrax vaccine: • "**This policy statement is based upon the controversy in the medical literature about the efficacy of the vaccine; the lack of valid monitoring of its potential adverse effects; and the stance taken by the United Kingdom and other allies that the receipt of the vaccine remain voluntary among their troops**."[54]

[54] Mohammed N. Akhter, MD, MPH, Executive Director, American Public Health Association, letter to Congressman Jack Metcalf, 23 May 2000

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Retention and recruiting impact of AVIP**. Misrepresenting to the House Government Reform Committee the retention impact of the anthrax vaccine program on the Guard and Reserve.
Question(s):	1. Just days after Mr. Cragin testified before Rep Shays' subcommittee on September 29, 1999, 60 servicemembers, including 22 pilots left the Tennessee Air National Guard C-141 unit in Memphis over the anthrax vaccine. Does he view this as "no appreciable impact" when it costs $6 million to train a new military aviator and all of the military pilot production pipelines are already operating at full capacity? 2. Fifteen (15) pilots in an Indiana Air National Guard F-16 unit -- one-half of the unit's pilots -- left the Guard over the anthrax vaccine last February. That is $90 million worth of pilots in one fighter squadron, and many years of experience. Does he view this as having "no appreciable impact" on readiness?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined for undisclosed reasons to nominate Mr. Cragin for Senate confirmation.)

Statement	Fact
Mr. Charles Cragin, testimony before National Security Subcommittee of the House Government Reform Committee, 29 Sep 1999: "We should not look to a single-factor explanation, such as concern about anthrax vaccinations, to account for the decline in recruiting and retention that has generally characterized the Total Force in recent years. According to the Chiefs of the Reserve components, recent recruiting and retention trends do not show any substantial increase or decrease attributable to the anthrax vaccination program. And although the military recruiting market has posed significant challenges to all Services, both active and reserve, in the past few years, **we currently see no appreciable impact**	1. Two weeks prior to testifying, Mr. Cragin had direct, personal knowledge of attrition in air reserve component units. He was briefed on 15 Sep 1999 that the NYANG C-5 unit would be only 57% manned with pilots if mandatory vaccinations scheduled for that month took place. Cragin later acknowledged this in an exchange of letters with Rep Christopher Shays.[56] However, in that letter Mr. Cragin repeated an assertion by the unit commander that losing over 40% of its pilots would leave readiness in that unit at "acceptable levels". 2. According to anecdotal reports received by the House Government Reform

Statement	Fact
as a result of implementation of the anthrax vaccination program."[55]	Committee from Reserve officers, over 240 pilots left just the first 5% of Air National Guard and USAF Reserve units that forced their personnel to take the anthrax vaccine**. The cost to taxpayers for replacing these experienced pilots is nearly $1.5 billion**. The rate of attrition has slowed coincident with the delay of mandatory vaccinations at other Reserve Component units caused by the vaccine shortage brought about by the manufacturer's in ability to obtain FDA certification. 3. **Reserve attrition**. As of early 2000, published media reports of pilot attrition in Reserve Component units subsequent to mandatory anthrax vaccinations being imposed was:[57] • 7 of 30 pilots assigned to the 115th Fighter Wing, WI ANG. • 8 pilots, pilots assigned to the 103rd Fighter Wing, CT ANG. • 17 pilots assigned to the 79th Air Refueling Squadron, USAF Reserve, Travis AFB, CA. • 30 of 58 pilots assigned to the 97th Airlift Squadron, USAF Reserve, McChord AFB, WA. • 20 pilots assigned to the 514 Air Mobility Wing (USAF Reserve) or 108th Air Refueling Wing (NJ ANG). McGuire AFB, NJ.

[55] Charles Cragin, testimony before National Security Subcommittee of the House Government Reform Committee, 29 Sep 1999
See: http://www.house.gov/reform/ns/press/cragin.htm
[56] Charles Cragin, letters to Representative Christopher Shays, dated 14 Oct 1999 and 21 Oct 1999; in response to letter from Representative Christopher Shays to Mr. Cragin dated 7 Oct 1999
[57] Andrew J. Bacevich, "Bad Medicine for Biological Terror", Orbis, Foreign Policy Research Institute, Spring 2000

Statement	Fact
	• 22 of 50 pilots, plus 38 additional non-pilot personnel, assigned to the 164th Airlift Wing, TN ANG. • At least 12 of 34 F-16 pilots in the 122nd Fighter Wing, IN ANG.[58] 4. **Active duty attrition**. Losses have also occurred in active duty units, where the personal cost of refusal is much higher, often a court-martial: • In the active duty Marine Corps, there have been two dozen (24) Marines on Okinawa, 30 more at Camp Pendleton, CA, and 10 at Twenty-Nine Palms, CA -- with several being court-martialed, jailed, and given bad conduct discharges.[59] • In the active duty Navy 29 active duty sailors on the aircraft carrier *USS Theodore Roosevelt*, 7 sailors on the carrier *USS John C. Stennis*, and 7 more on the carrier *USS Independence*.[60] • The Air Force has court-martialed or discharged servicemembers at: -- Dover AFB, DE[61] -- Andrews AFB, MD[62] -- Offut AFB, NE[63]

[58] "Pilots Punished for Refusing Vaccine", Associated Press, 11 Feb 2000
[59] Andrew J. Bacevich, "Bad Medicine for Biological Terror", Orbis, Foreign Policy Research Institute, Spring 2000
[60] Bacevich, Orbis op ed.
[61] Tom Eldred, "Pilot discharged over anthrax shots at Dover (Del.) Air Force Base -Sickened by first three, flyer says he refused inoculations", Delaware State News, 26 Sep 2000
[62] Michael Kilian, "Unable To Quit, Air Force Pilot Who Refused Vaccine May Be Dishonorably Discharged:, Chicago Tribune, 19 Apr 2000
[63] Mike Sherry, "Offut in Thick of Anthrax Dispute, by Mike Sherry", Omaha World Herald, 7 Mar 2000
[64] Steven Lee Myers, "Armed Services opt to discharge those who refuse vaccine, New York Times, 11 Mar 1999.
[65] Thomas D. Williams, "Judge Denies Soldier Over Anthrax Shot", Hartford Courant, 2 Jun 2000
[66] Steven Lee Myers , "Military Reserves Are Falling Short in Finding Recruits", New York Times, 28 Aug 2000.
[67] LtCol Craig Manson, CAANG, email to all ANG Judge Advocates General (JAGs), 17 Sep 2000. He explains the childcare study is a: "national initiative directed by [Director of the Air National Guard] Maj Gen Weaver and being headed by Brig Gen Sullivan of Ohio."

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	-- Travis AFB, CA[64] 5. The Army has given less than honorable of general discharges to servicemembers, but usually without court-martial.[65] However, a court-martial of an active duty soldier at Ft. Hood, TX, is scheduled to begin on 11 Oct 2000. 6. The New York Times reported on 28 Aug 2000 that Army, Navy, and Air Force reserve components would fail to meet their recruiting goals (this was <u>not</u> attributed to anthrax in article.)[66] 7. To stem continuing attrition in Air National Guard units, the Director of the Air National Guard has initiated a study of how to provide childcare for Air National Guard personnel while they are on duty.[67]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Retention**. Misrepresenting to the House Government Reform Committee that DoD would make an effort to ascertain the retention impact of the anthrax vaccine immunization program (AVIP).
Question(s):	Why doesn't the current DoD survey of Reserve Component military personnel include any questions about the impact of the anthrax vaccine on the morale and retention of reserve component personnel?
Who said it:	**Mr. Charles Cragin**, Principal Deputy Assistant Secretary of Defense for Reserve Affairs *(Note: Mr Cragin was named as an acting assistant secretary of defense for reserve affairs during the 105th Congress. This title lapsed after the White House declined to nominate Mr. Cragin for Senate confirmation.)

Statement	Fact
In testimony before National Security Subcommittee of the House Government Reform Committee, 29 Sep 1999: Rep. Shays: " First off, I make an assumption that you are intending to measure AVIP impact on readiness or retention. Should I make that assumption?" Mr. Cragin: "...So I think it stands to reason that medical readiness from that perspective would be looked at, yes sir." Rep. Shays: "And also retention." Mr. Cragin: "We would look at retention and a number of issues. Readiness certainly is affected by retention. There is not question about that."	The Reserve Components for which Mr. Cragin is responsible are currently conducting a survey of both federal Reserve and National Guard personnel.[68] • The survey does not address the anthrax vaccination program. • In the survey the anthrax immunization vaccination program (AVIP) is not included as a reason for leaving the reserve components or as a morale issue.

[68] Survey Of Reserve Components Personnel And Spouses, Defense Manpower Data Center, contact Dr. Robert Simmons or Dr. Jacquelyn Scarville, DMDC East, (703) 696-6763 (Survey is online, but limited access).

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**SecDef Cohen's 4 preconditions for implementing AVIP**. Did Undersecretary of Defense Rudy De Leon insure that the "independent expert" he contracted to review the medical aspects of the anthrax vaccine immunization program had access to relevant information regarding the manufacturer's failure of an FDA inspection that occurred concurrent with the "independent expert's" review?
Question(s):	1. Why did Mr. De Leon incorrectly claim to U.S. troops in April 1998 that DoD's "independent expert" contracted to review DoD's planned anthrax vaccination program, Dr. Burrow, was the Dean of the Yale Medical School?[69] 2. DoD's independent expert, Dr. Burrow, submitted his review approving the DoD anthrax vaccine program on 19 Feb 1998. Did Mr. de Leon and his staff insure that their "independent expert", Dr. Burrow, was aware of an FDA inspection of the anthrax vaccine manufacturer that occurred between 4-19 Feb 1998, which concluded in a report "The manufacturing process for Anthrax Vaccine is not validated"? 3. Why did Mr. de Leon and his staff charge Dr. Burrow with insuring "the safety and efficacy of the Department's vaccine stockpile"[70], and then accept a review in which Dr. Burrow had commented favorably about the "integrity of the system" to review the vaccine stockpile, despite having never reviewed the results of the supplemental testing ordered by the Secretary of Defense? 4. Why did Mr. de Leon charge Dr. Burrow with insuring "the safety and efficacy of the Department's vaccine stockpile", and then accept a review in which Dr. Burrow failed to mention, or discuss, the reasons for the FDA-mandated quarantine of 11 of 40 lots of anthrax vaccine which occurred during his review?
Who said it:	**Hon. Rudy de Leon**, then-Undersecretary of Defense for Personnel and Readiness (now Deputy Secretary of Defense)

Statement	**Fact**

[69] Staff Sgt. George Hayward, "DoD Officials Say Anthrax Vaccine is Safe, Effective", 16 Apr 1998
See: http://www.af.mil/news/Apr1998/n19980416_980507.html

[70] Rudy de Leon, Undersecretary of Defense for Personnel and Readiness, letter to Dr. Gerard Burrow, 17 Dec 1997.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
From remarks by Mr. de Leon to US troops in Kuwait, quoted in an Armed Forces Press Service report, 16 Apr 1998: "**De Leon said it is safe and effective**, and has been in use for years. "**We asked an outside expert panel, led by the dean of the medical school at Yale University, to take a fresh look at the vaccine," De Leon said. They certified the program as safe**, he said." *From Dr. Burrow's report to Undersecretary of Defense De Leon, 19 Feb 1998*:[71] "The Safety and Efficacy of the Department's Stockpile- The vaccine has been approved by the FDA, and there are an adequate number of doses in the current anthrax vaccine stock pile. **As directed by DOD, a supplemental testing program started in January 1998 and all batches are scheduled to be tested by November 1998**. 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. **These results of this review should be available in the near future. There appear to be procedures in place to assure the integrity of the system.**"	1. In testimony before the Senate Armed Service Committee on 12 Jul 2000, FDA's director of the Center for Biologics Evaluation and Research, Dr. Kathryn Zoon, acknowledged: "The February [1998] inspection, as stated, disclosed many significant deviations to FDA regulations. In addition, **the inspection resulted in the request by FDA that Michigan quarantine 11 lots of anthrax vaccine** held in storage pending review of additional information to be submitted by Michigan **regarding the lack of investigations into possible problems with potency sterility in particulate matter**."[72] This FDA-ordered quarantine occurred prior to the submission of the report by Dr. Burrow, DoD's "independent expert.", Dr. Burrow asserted in his report that, "there appear to be procedures in place to assure the integrity of the [stockpile] system." Significantly, DoD representatives were aware of the quarantine and were allowed to participate in conference calls between the manufacturer and the FDA. It is unclear whether they ever informed their "independent expert" of the lot quarantine or of the "significant deviations" from manufacturing practices mandated in federal law found during FDA's 4-19 Feb 1998 inspection of the manufacturer. 2. Based on statements in his report to Mr. de Leon, it appears that Dr. Burrow relied on DoD to provide him with the information necessary to determine the

[71] Dr. Gerard Burrow, M.D., report to Undersecretary of Defense Rudy de Leon, 19 Feb 1998. See: http://www.defenselink.mil/other_info/burrows.html

[72] Kathryn Zoon, Ph.D., Federal News Service transcript, FDA testimony before Senate Armed Services Committee, 12 Jul 2000.

Statement	Fact
	safety and efficacy of the anthrax vaccine in general, and the existing stockpile, in particular: "… **I would like to thank Dr. Edward Martin [deputy Assistant Secretary of Defense for Health Affairs] for facilitating my access to information. I am particularly indebted** to CAPT John Mateczun, MC, USN for his assistance and **to the dedicated men and women in the various services who shared their knowledge with me**. I hope this report is helpful to you and would be glad to provide assistance during implementation."[73]

[73] Dr. Gerard N. Burrow, M.D., report to Undersecretary of Defense Rudy DeLeon, 19 Feb 1998. See: http://www.defenselink.mil/other_info/burrows.html

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Allied/Non-U.S. use of the anthrax vaccine**. Misrepresenting to Congress the use of the anthrax vaccine by a U.S. ally.
Question(s):	Why did Mr. de Leon imply to the Senate Armed Services Committee that the British were using the anthrax vaccine when the British vaccine policy is voluntary and over 70% of their servicemembers do not submit to the vaccine?
Who said it:	**Hon. Rudy de Leon**, then-Undersecretary of Defense for Personnel and Readiness (now Deputy Secretary of Defense)

Statement	Fact
In testimony before the Senate Armed Services Committee, 12 Jul 2000:[74] SEN. WARNER Quickly, other nations, how are they facing this threat? I mean, it knows no boundaries in terms of military forces. most of our operations today are joint operations with our principal allies. What are they doing, Mr. Secretary? MR. DE LEON: The British are immunizing their forces. They, too, have gotten in the same bind that we are in. SEN. WARNER: I understand they have had to suspend their source. MR. DE LEON: Right. This is not a high profit market, and so -- SEN. WARNER: We understand that, but in other words our allies only one ally so far, you mentioned. MR. DE LEON: The British. SEN. WARNER: -- encountering the same problems.	8. **United Kingdom**. The anthrax vaccination program in the British military is voluntary, and over 70% of British servicemembers choose not to be vaccinated. [75] 9. **Canada**. In May 2000, the Canadian military suspended court-martial charges against a Canadian Air Force career servicemember who had refused the anthrax vaccine. **Canada's chief military judge stated the anthrax vaccine was**: "…**unsafe and hazardous** and could be responsible for the important symptoms reported by so many persons who took that vaccine."[76] 10. **France**. In Sep 2000 the French ministry of defense announced the creation of an independent commission that will look into the health of French military servicemembers who served in the Gulf War attached to US forces. A physician spokesman for the French military reiterated that:

[74] Rudy De Leon, Deputy Secretary of Defense, verbal testimony before the Senate Armed Services Committee, Federal News Service, 12 Jul 2000
[75] A. Gilligan, "British Troops Mutiny Over Gulf Anthrax Jab", The Sunday Telegraph (London), 7 Jun 1998.
[76] Ruth Walker, "Last week, a military judge issues a precedent-setting ruling on individual rights", The Christian Science Monitor, 9 May 2000. See: http://www.majorbates.com/news/09may00_csm.htm

Statement	Fact
MR. DE LEON: Correct.	"…France's belief that allied troops were victims of their own protective measures were based on a long series of meetings with U.S. medical experts."[77] The French military physician noted that while about 16% of US Gulf War veterans have complained of ailments associated with Gulf War syndrome, less than 1% of French troops had similar symptoms. The French did not use the anthrax vaccine, but will study whether their servicemembers stationed with US forces took the vaccine and other biowarfare drugs. 11. **South Korea**. Does **not** use the anthrax vaccine, despite being labeled by DoD as a so-called "high-threat" area and DoD efforts to convince them to use it.[78] 12. **Israel**. Does **not** use the anthrax vaccine, despite being labeled by DoD as a so-called "high-threat" area. 13. **Other U.S. NATO or non-NATO allies**. None uses the anthrax vaccine.

[77] "French to Check Liaison Officers for Gulf Syndrome", Reuters, 14 Sep 2000
See: http://www.majorbates.com/news/14sept00_reuters.htm
[78] MGen Randall West, USMC, comments during a DoD press conference, 13 Dec 1999.
See: http://www.defenselink.mil/news/Dec1999/t12141999_t213anth.html

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Safety of the anthrax vaccine**. Misrepresenting to medical professionals in the Journal of the American Medical Association, that credible studies have proven the anthrax vaccine to be safe.
Question(s):	1. Why didn't Col Friedlander inform fellow medical professionals that there were no long-term studies of the anthrax vaccine's safety in the article he wrote in the Journal of the American Medical Association in Dec 1999? 2. Isn't it misleading for Dr. Friedlander to state in a medical journal that there is no evidence of adverse health effects from the anthrax vaccine when, as the Institute of Medicine reported last March, there have been no peer-reviewed long-term studies of the vaccine? 3. Why didn't Col Friedlander identify himself as a colonel in the U.S. Army in the byline of the article he wrote in the Journal of the American Medical Association in Dec 1999?
Who said it:	**Col (Dr.) Arthur Friedlander**, chief, bacteriology division, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID)

Statement	**Fact**
In the Journal of the American Medical Association, 8 Dec 1999: "All the serious adverse events noted, other than local reactions, occur in the absence of immunization [i.e. after the injection needle is withdrawn from the servicemember] and **it may not be possible to demonstrate a cause and effect relationship**... While the possibility of a rare, previously unknown adverse effect occurring during large-scale use of AVA [anthrax vaccine] exists, **there is no evidence that such problems have occurred in nearly 30 years of use...** "[79]	*From the Institute of Medicine preliminary report on the safety of the anthrax vaccine, 30 Mar 1999:*[80] • "**There is a paucity of published peer-reviewed literature on the safety of the anthrax vaccine**. The committee located only one randomized peer-reviewed study of the type of anthrax vaccine used in the United States (Brachman et al., 1962). However, the formulation of the vaccine used in that study differs from the vaccine currently in use." • "**There have been no studies of the anthrax vaccine in which the long-term health outcomes have been systematically evaluated** with active

[79] Colonel (Dr.) Arthur Friedlander, et.al., "Evidence for Safety and Efficacy Against Inhalational Anthrax", JAMA (Journal of the American Medical Association), Vol. 282 No. 22, 8 Dec 1999

[80] "An Assessment of the Safety of the Anthrax Vaccine", Committee on Health Effects Associated with Exposures During the Gulf War, Institute of Medicine, 30 Mar 2000.
See: http://www.nap.edu/html/anthrax_vaccine/

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	surveillance." • "The committee concludes that in the peer-reviewed literature there is inadequate/ insufficient evidence to determine whether an association does or does not exist between anthrax vaccination and long-term adverse health outcomes. This finding means that the evidence reviewed by the committee is of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association between the vaccine and a health outcome in humans."

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Purpose of the Investigational New Drug application**. Misrepresenting, under oath, to a Canadian court-martial in March 2000, knowledge that one of the purposes of the Investigational New Drug application submitted by the anthrax vaccine manufacturer on 20 Sep 1996 was to modify the product license to add an indication for inhalation anthrax.
Question(s):	1. Why did Col (Dr.) Friedlander testify under oath during a court-martial this year in Winnipeg, Canada, that he was "not aware" that one of the three purposes for the Investigational New Drug application submitted to FDA by the manufacturer on 20 Sep 1996, and prepared for the manufacturer by the Army, was to change the product license to include an indication for inhalation anthrax? 2. Didn't Col (Dr.) Friedlander present briefings to DoD colleagues on three separate occasions on 20 Oct 1995, on 9 Feb 1996, and on 10 Nov 1997 during which he specifically discussed the three purposes for the manufacture's 20 Sep 1996 Investigational New Drug application, including a new licensed indication for inhalation anthrax? 3. Was Col (Dr.) Friedlander's concealment of his knowledge of the key purpose of the Investigational New Drug application -- to obtain a new licensed indication for inhalation anthrax -- an attempt to keep a Canadian court from understanding that the US Army knew that the anthrax vaccine was never licensed for inhalation anthrax?
Who said it:	**Col (Dr.) Arthur Friedlander**, chief, bacteriology division, U.S. Army Medical Research Institute for Infectious Diseases (USAMRIID)

Statement	**Fact**
From the trial testimony, under oath, to a Canadian court-martial on 30 March 2000, specifically that he was unaware of the change to indicate inhalation exposure:[81] Defense counsel: If I'm going to suggest to you, sir, that the drug was licensed for cutaneous anthrax only and that there has been a subsequent amendment for coverage for inhalation anthrax, would you agree with me or disagree with me? Colonel Friedlander: **I'm not aware of that**.	Despite his assertion that he was "not aware" of the purpose of the Investigation New Drug application filed by the manufacturer on 20 Sep 1996, Col (Dr.) Friedlander was personally involved on three occasions in DoD meetings during which he specifically briefed the three reasons for the IND application, including an FDA license amendment to add an indication for inhalation anthrax: 1. **20 Oct 1995 briefing**. COL Friedlander presented a briefing at a meeting held by

[81] Col (Dr.) Arthur Friedlander, testimony given during the trial of Ex-Sergeant Michael Richard MINUTES OF PROCEEDINGS STANDING COURT MARTIAL for the trial of K72 142 802 Ex-Sergeant Michael Richard Kipling, Canadian Forces, Regular Force, held at 17 Wing, Winnipeg, Manitoba, before Colonel G.L. Brais, Office of the Chief Military Judge, 30 Mar 2000

Statement	Fact
(later…) Defense counsel: If I suggest to you, sir, that we've heard evidence that the vaccine was licensed for cutaneous anthrax and that there was an application placing the drug into IND status with the FDA for three reasons: one, is to change for inhalational anthrax; two, was to change the route of administration; and, three, to change the scheduling of the drugs, would you agree with that or do you know? Colonel Friedlander: **I know that there have been studies dealing with trying to reduce the number of doses and to look at the route of administration**. Defense counsel: So are you saying, sir, that you're not familiar with what I've said, or you disagree with it? Colonel Friedlander: No, no. I don't know that I'd have to look back at the documents you're referring to. Defense counsel: Okay. So you're not saying the drug is not in an IND status for those three variations? Colonel Friedlander: You know, I'm not clear what you're saying in terms of I mean, I'm not clear what that means, in other words. There are studies that have been done, that **I'm involved with, looking at reducing the number of doses and changing the route of administration**. Defense counsel: Okay. That's not actually what I'm asking, sir?	the Joint Program Office for Biological Defense on 20 Oct 1995. The meeting was a strategy session held by DoD and manufacturer representatives to develop a gameplan for "Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet Military Requirements."[82] According to the meeting minutes, Col Friedlander: • "…presented a briefing covering the three topics: (1) evidence for a reduction in the number of doses of anthrax vaccine, (2) evidence for vaccine efficacy against an aerosol challenge [inhalation anthrax], and (3) progress towards an *in vitro* correlate of immunity." • "**Dr. Friedlander agreed that the surrogate animal model needed to be established**", which followed his acknowledgment that "**there was insufficient data to demonstrate protection against inhalation disease**." • Last, a briefing slide from this meeting titled, "Immediate Objectives for Anthrax Vaccine Licensure", explained: "To obtain a {FDA] Product License Application Supplement approval for a specific immunization schedule change…and for a labeled indication change [such as the indication for use in protection against aerosol challenge)."

[82] 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.
[83] Col (Dr.) Arthur Friedlander, Minutes of the Anthrax License Amendment Issues Meeting , briefing titled "Research Plan to Support Reduction in Dosage of Licensed Anthrax Vaccine (AVA) and Indication for Aerosol Exposure", 9 Feb 1996.
[84] Col (Dr.) Arthur Friedlander, briefing titled "Supplement to AVA License" (slides), meeting attended by USAMRIID and contractor representatives, 10 Nov 1997

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
Colonel Friedlander: Yes. Defense counsel: Okay. Maybe if I can make myself clearer. We've heard evidence that he drug was licensed for cutaneous anthrax and that it's now been proposed, presumably by DOD, to make three changes: one, is make it a countermeasure for inhalational anthrax as opposed to cutaneous; two, change the route of administration; and, three, the schedule of dosages, and that because it's an amendment, the drug has gone into IND status for that purpose? Colonel Friedlander: You know, I can't answer that question. You have to talk to the people actually directing that study. Defense counsel: **So you're saying you're not sure?** Colonel Friedlander: **That's right.**	2. **9 Feb 1996 briefing**. At a follow-up meeting on 9 Feb 1996 Col Friedlander presented another briefing titled "Research Plan to Support Reduction in Dosage of Licensed Anthrax Vaccine (AVA) **and Indication for Aerosol Exposure**". This clearly demonstrates that Col. Friedlander was integrally involved in the preparation of the investigation protocol prepared by the US Army, and which the manufacturer ultimately submitted to the FDA on 20 Sep 1996. The meeting minutes show that Friedlander discussed the need for the study to show a correlation between animal and human immune response to the vaccine -- a recognition that the anthrax vaccine had never demonstrated efficacy for inhalation anthrax in humans.[83] • **10 Nov 1997 briefing**. Col (Dr.) Friedlander presented another briefing to DoD and contractor representatives on 10 Nov 1997 titled: "Supplement to AVA License". This was 14 months after the submission of the IND application by the manufacturer. The briefing slides clearly show the three changes sought (including an indication for inhalation anthrax] and that Col (Dr.) Friedlander was responsible for the pre-clinical portions of these studies intended to obtain FDA approval for these changes.[84]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Investigational New Drug application**. Misrepresenting to the House Government Reform Committee the significance of the Investigational New Drug (IND) application submitted by the anthrax vaccine manufacturer (MBPI) on 20 Sep 1996.
Question(s):	1. Was the Investigational New Drug (IND) application submitted by the anthrax vaccine manufacturer on 20 Sep 1996 intended simply "to "improve administration" of the anthrax vaccine? 2. Didn't both the manufacturer, and the Army, seek to obtain an amendment to the anthrax vaccine product license to include a specific clinical indication for inhalation anthrax? 3. Are there any scientifically valid efficacy tests of the anthrax vaccine that meet federal regulatory requirements for a license amendment to include a specific clinical indication for inhalation anthrax?
Who said it:	**Mr. Fuad El-Hibri**, President and Chief Executive Officer, BioPort Corporation

Statement	**Fact**
Before the Subcommittee on National Security, Veterans Affairs, and International Relations of the House Committee on Government Reform 30 June 1999: "We continue to hold an Investigational New Drug application -- IND 6847 -- to improve administration of the anthrax vaccine. Further work is currently on hold while the parties consider the costs and benefits of proceeding in the context of overall program priorities (such as getting the upgraded facility in operation). This IND was started by MBPI in tandem with the DoD in 1996. It has two major objectives: to reduce the number of doses in the current anthrax vaccination schedule and to further evaluate an immunological correlate of protection."[85]	1. Mr. El-Hibri's assertion that the purpose of the IND was simply to "improve administration of the anthrax vaccine" is disproved by the cover letter written by his Chief Operation Office, Dr. Robert Myers to the FDA on 20 Sep 1996. Dr. Myers explained: • "The purpose for filing this IND is to conduct clinical investigations designed **to investigate changes in the approved labeling for the licensed product**. The potential labeling **changes would affect the specific clinical indication**, route, and vaccination schedule for AVA [anthrax vaccine absorbed]."[86] 2. This letter by Bioport's current Chief Operating Officer is a tacit acknowledgement that the FDA license for anthrax vaccine does not include an

[85] See: http://www.house.gov/reform/ns/hearings/testimony/testimony_of_mr_630.htm
[86] Robert C. Myers, Executive Director, Michigan Biologic Products Institute (now COO of Bioport, Inc.), letter to Dr. Kathryn Zoon, FDA CBER director, 20 Sep 1999

Statement	Fact
	indication for inhalation anthrax (i.e. it is not licensed for inhalation anthrax). According to both the FDA and Bioport, this IND (#6847) is still active, and the FDA has never approved an amendment to the license to include an indication for inhalation anthrax. 3. Further, the IND Introductory Statement, prepared by the US Army (USAMRIID) states reaffirms the actual purpose of the IND application: "**The ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax** and a reduced vaccination schedule."[87]

[87] Investigational New Drug application, IND 6847, submitted by Michigan Biologic Product Institute, 20 Sep 1996, Section 3.1, "Introductory Statement, General"

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Significance of failed FDA inspections**. BioPort Corp. corporate officers misrepresenting the significance of the FDA's March 1997 Notice of Intent to Revoke letter, and the FDA's subsequent 20 Feb 1998 inspection report that found the "The manufacturing process for Anthrax Vaccine is not validated."
Question(s):	1. Does a Notice of Intention to Revoke (NOIR) letter, as was sent by FDA to the Michigan Biologic Products Institute in March 1997, constitute the result of a successfully passed FDA inspection? 2. Does an inspection report that states that "the manufacturing process for Anthrax Vaccine is not validated", as was stated in FDA's 20 Feb 1998 report on the anthrax vaccine manufacturer, constitute the result of a successfully passed FDA inspection? 3. If Bioport had passed the Nov 1999 FDA inspection of its new manufacturing facility, wouldn't it be allowed to sell and ship vaccine today? 4. So, when Dr. Myers, the Chief Operating Officer of Bioport, Inc. asserted in the Washington Post last February that the anthrax vaccine plant has never failed an FDA inspection, is that a true statement? When he said that a failed inspection leads to "immediate closure of a facility and/or seizure of product", was that true in the case of the anthrax vaccine manufacturer? 5. A general officer, who declined to be named, asserted in a DoD press conference on 5 Aug 1999 that a forced shutdown of the old anthrax vaccine manufacturing facility was simply an "urban legend".[88] Isn't it true that had the manufacturer not voluntarily shut down production, the FDA would have forced its closure for failing to comply with the terms of the March 1997 Notice of Intent to Revoke letter? 6. Is it true that Pentagon officials were allowed to participate in a call from the FDA to the anthrax vaccine manufacturer in Feb 1998 to discuss the plants failure to correct deviations identified in the March 1997 inspection report and the possible revocation of the manufacturer's license? Why did the FDA, as a federal regulator, allow a consumer of the product -- the Department of Defense -- to have a say in its enforcement of the Food, Drug and Cosmetic Act? 7. Wasn't part of the agreement reached during that Feb 1998 conference call with the manufacturer and DoD officials that no more anthrax

[88] DoD press briefing by anonymous general and flag officers and senior civilian officials, 5 Aug 1999
See: http://www.defenselink.mil/news/Aug1999/x08051999_x0805ant.html

	vaccine would be produced in the former manufacturing facility, as well as a quarantine of 11 lots of vaccine? 8. What bearing does the anthrax vaccine manufacturer's status as a sole-source producer have on the laws governing the manufacture of vaccines? Does the Food, Drug and Cosmetic Act allow a lower standard for sole-source producers of a vaccine consumed almost exclusively by the Department of Defense?
Who said it:	**Robert Myers**, D.V.M., Chief Operating Officer, BioPort Corp. and former Executive Director, Michigan Biologic Products Institute

Statement	**Fact**
In a letter to the editor published in the Washington Post, 7 Feb 2000: "A failed inspection leads to immediate closure of a facility and/or seizure of product to protect the public health and safety. This has never happened…The FDA has noted, at several hearings and in communications with Congress, that BioPort has made progress in achieving its compliance goals."[89]	1. Contrary to Dr. Myers' assertions, in a 25 Jun 2000 press report, Mr. Mark Elengold, director of operations, FDA Center for Biologics Evaluation and Research, explained the actual import of the anthrax vaccine manufacturer having failed FDA inspections in Mar 1997 and again in Feb 1998. [90] The Vancouver "Province" article stated: "In 1997, the FDA gave notice that it would revoke the manufacturer's license if it did not comply with regulations. The Canadian military largely dismissed the notice… "…**In the three years I have been in this job, I have done it about three times**," said Elengold, deputy director for operations for the FDA's Center for Biologic Evaluation Research. **"It is a very serious tool. We view it . . . to be equivalent to an injunction . . .where we get a court to order compliance."** The company failed to comply completely and a year later still faced the possibility of losing its license,

[89] Robert Myers, Bioport Corp., letter to the editor, Washington Post, 7 Feb 2000
See: http://www.bioport.com/PressReleases/bioport/PR03.htm
[90] Ann Rees, "Their Dangerous Dose", The [Vancouver] Province, 25 Jun 2000 See:

Statement	Fact
	according to Elengold. **The FDA held off pulling the license, in part because it would have left the U.S. Department of Defence** -- which had just announced that all soldiers were to receive anthrax vaccine -- with **no domestic source**. **"This is a one-source product so we tend to try to work with firms and put additional monitoring steps in to avoid revoking the license," said Elengold.** The prestigious British medical journal **Lancet reported at the time that "a plea from the Pentagon has prevented an 'eleventh-hour' closure of the only U.S. producer of anthrax vaccine**," according to an e-mail to DND medical headquarters in February 1998. **Elengold confirmed the Pentagon sat in on a crucial call to the company in which he discussed revoking the license.** A compromise was reached when the company agreed to voluntarily quarantine 11 questionable vaccine lots containing more than one million doses." 2. In testimony before the Senate Armed Service Committee on 12 Jul 2000, FDA's director of the Center for Biologics Evaluation and Research, Dr. Kathryn Zoon, acknowledged: "**The February [1998] inspection, as stated, disclosed many significant deviations to FDA regulations**. In addition, **the inspection resulted in**

[91] Kathryn Zoon, Ph.D., Federal News Service transcript, FDA testimony before Senate Armed Services Committee, 12 Jul 2000.

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	the request by FDA that Michigan quarantine 11 lots of anthrax vaccine held in storage pending review of additional information to be submitted by Michigan **regarding the lack of investigations into possible problems with potency sterility in particulate matter**. FDA continues to work closely with BioPort to resolve issues concerning the use of these lots. If satisfactory resolution is not obtained, BioPort stated that lots will be rejected."[91]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Shipping adulterated and misbranded product**. Bioport corporate officers misrepresenting whether the anthrax vaccine manufacturer has shipped products quarantined by FDA or subject to recall.
Question(s):	1. BioPort's Dr. Myers has asserted that the anthrax vaccine manufacturer will never release a product that is not safe and effective. Isn't it true that Canadian military was shipped a lot of contaminated vaccine (lot FAV 016) that was quarantined by the FDA? 2. Why did the FDA not issue a recall of the 11 lots of vaccine quarantined as part of a Feb 1998 agreement to allow the anthrax vaccine manufacturer to remain operating (which included the Canadian vaccine)? 3. Does a vaccine with particles of rubber gasket material, as lot FAV 016 delivered to the Canadian military had, constitute an adulterated product under federal law? 4. Does a vaccine labeled with an incorrect expiration date six months after its actual expiration date constitute a misbranded product under federal law? 5. If so, isn't the delivery for introduction into interstate commerce of any drug or vaccine that is adulterated or misbranded a felony violation of the Food, Drug, and Cosmetic Act?
Who said it:	**Robert Myers**, D.V.M., Chief Operating Officer, BioPort Corp. and former Executive Director, Michigan Biologic Products Institute

Statement	**Fact**
In a letter to the editor in the Washington Post, 7 Feb 2000: "We will never release a product that is not safe and effective. Our record has proven that in the past and our high standards will assure that in the future."[92]	1. Contrary to Dr. Myers' assertion that the manufacturer would never release an unsafe product, both the Michigan Biologic Products Institute and Bioport have shipped quarantined and mislabeled products. Mr. Mark Elengold, deputy director of operations, FDA Center for Biologics Evaluation and Research, revealed in a

[92] Robert Myers, Bioport Corp., letter to the editor, Washington Post, 7 Feb 2000
See: http://www.bioport.com/PressReleases/bioport/PR03.htm

Statement	Fact
	25 Jun 2000 article in the Vancouver (Canada) newspaper, *The Province*[93] that the anthrax vaccine manufacturer (MBPI) shipped about 100 doses of a quarantined lot (FAV 016) that was given to the Canadian Defense Minister and Canadian soldiers. The article stated: **"We asked** [the manufacturer] **to suspend lot release and rather than force a recall, we asked that they agree to voluntarily hold it and agree not to distribute it without further clearance from us," said Mark Elengold, deputy director for operations in the FDA's Center for Biologic Evaluation Research.** **"They** [the manufacturer] **should have stopped using it once it is quarantined," said another FDA spokesman."** [end quote from article]. 2. On 30 Aug 2000 the FDA issued a recall of lot FAV 044 of the anthrax vaccine because it had been mislabeled. According to the FDA: "A portion of the lot was labeled with an expiration date of September 8, 2001, rather than the correct expiration date of February 3, 2001. **Bioport employees will be traveling to distribution points and correcting the mislabeled vials.** [94] 3. On 28 Sep 2000 the Lansing (MI) State Journal reported that the local medical

[93] Ann Rees, " Art goes out on a limb: Defence minister's anthrax shot meant to prove military vaccine was safe", by Ann Rees, The [Vancouver] Province, 25 Jun 2000 See: http://www.majorbates.com/news/25jun00_province2.htm

[94] "Voluntary Recall of Anthrax Vaccine Adsorbed", FDA Center for Biologics Evaluation and Research, 30 Aug 2000. See: http://www.fda.gov/cber/fprecalls/anthbio083000.htm

[95] A.J. Evenson and Tim Martin, "Medical examiner links death to anthrax vaccine", Lansing State Journal 28 Sep 2000

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	examiner had "officially tied" the death of an employee of the anthrax vaccine manufacturer, Bioport Corporation, to the vaccine following an autopsy. According to the medical examiner, The autopsy, Joyce said, the deceased employee "had an "inflammatory response" to the vaccine throughout his body."[95]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Manufacturer (DoD contractor) competence**. Misrepresenting the competence and qualifications of a defense contractor's management to the Senate Armed Services Committee, despite the contractor having repeatedly abrogated the terms of its contract and requiring several financial bailouts from DoD.[96,97]
Question(s):	1. Why did Mr. Oliver describe the anthrax vaccine's personnel in glowing terms when they had repeatedly failed, over a period of at least seven years, to comply with the FDA manufacturing standards (current Good Manufacturing Practices) that are required by law? 2. Do Mr. Oliver's clearly biased statements in favor of a defense contractor that has failed to comply with the terms of its contract, and which has required several multi-million dollar bailouts by DoD, reflect an appropriate relationship between DoD and a contractor? 3. Besides both being Naval Academy graduates and former submariners, what relationship, if any, exists between Mr. Oliver (who is a retired rear admiral) and Admiral William Crowe (USN, ret.) who owns approximately 13% of the manufacturer, BioPort, Inc.?[98] Could this be a possible reason for Mr. Oliver's lack of objectivity?
Who said it:	**Mr. David Oliver (RADM, USN, ret.),** Principal Deputy Under Secretary Of Defense For Acquisition And Technology

Statement	Fact
In testimony before the Senate Armed Services Committee, 13 Apr 2000:[99] Mr. Oliver: "...**The interesting thing about it [Bioport] is the director is really excellent, a guy named Dr. Bob Myers** [sic]. And I think that everybody at the FDA and we and everybody else respects him and understands what he is doing. It is great." *Mr. Oliver made a similar supportive comments*	1. Prior to becoming Chief Operating Officer of Bioport, Inc., Dr. Robert Myers was the Executive Director of the Michigan Biologic Products Institute. Dr. Myers is a veterinarian..[101] 2. Dr. Myers , who Mr. Oliver described as "really excellent" has run the anthrax vaccine production facility beginning in 1990. His tenure as an executive of both owners of the plant has been a period of

[96] GAO report, "Contract Management: DoD's Anthrax Vaccine Manufacturer Will Continue to Need Financial Assistance", testimony before the Subcommittee on Personnel, Senate Committee on Armed Services. GAO/T-NSIAD-00-140, 13 Apr 2000.
[97] GAO report, "Medical Readiness: DOD Continue to Face Challenges in Implementing Its Anthrax Vaccine Immunization Program", testimony before the Senate Committee on Armed Services. GAO/T-NSIAD-00-157, 13 Apr 2000.
[98] DoD Inspector General, "Contracting for Anthrax Vaccine", Report No. D-2000-105, Appendix C, BioPort's Ownership Structure and Financial Relationships, 22 Mar 2000
[99] Mr. David Oliver, (RADM, USN, retired), testimony before the Senate Armed Services Committee, 13 Apr 2000.

Statement	Fact
about this defense contractor during a DoD press briefing on 13 Dec 1999:[100] Reporter: But if they're the only producers in the country, what's the stick for getting this solved? Why does it -- what avoids it (sic) from just drifting on and being a problem forever? Mr. Oliver: **Because I think the [Bioport] people are inherently good people. The people are inherently good people.** People understand the problem. We're going to put a lot of assets in this. This is no different than all the depots that exist across this great country and lots of other things for which the government runs, because it feels like it must. It's absolutely no different. **And the reason that works is because you have good people**."	repeated failed FDA inspections that ultimately resulted in the FDA issuing a "Notice of Intent to Revoke" (NOIR) the license of the facility which Dr. Myers managed. 3. The seriousness of Dr. Myers' failure to meet regulatory standards was explained by the FDA Deputy Director for Biologics, Mr. Mark Elengold, in a Jun 2000 news interview. He stated about the FDA's March 1997 Notice of Intent to Revoke the manufacturer's license: "**It is a very serious tool. We view it . . . to be equivalent to an injunction . . .where we get a court to order compliance**."[102] 4. In order to retain its license, Dr. Myers and MPBI, and the Department of Defense, had to agree to quarantine 11 of 40 existing lots of the anthrax vaccine stockpile because of "significant deviations" from FDA manufacturing practices in a Feb 1998 agreement with FDA[103]

[100] Mr. David Oliver, (RADM, USN, retired), comments during DoD press briefing, 13 Dec 1999. See: http://www.defenselink.mil/news/Dec1999/t12141999_t213anth.html
[101] Dr. Myers biography, BioPort Corp. website. See: http://www.bioport.com/Bios/Robert_Myers.htm
[102] "Their Dangerous Dose", by Ann Rees, The [Vancouver, BC, Canada] Province, 25 Jun 2000
[103] Ibid.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Regulatory compliance**. Misleading the press and military servicemembers about the anthrax vaccine manufacturer's long history of regulatory non-compliance.
Question(s):	1. Why did Mr. Oliver, a DoD acquisition official and retired admiral, assert that the manufacturing facility operated by a defense contractor that was guilty of persistent and well-documented violations of federal regulatory standards was "tried and proven"? 2. Why did Mr. Oliver describe the manufacturing facility as producing a "safe and effect vaccine" when the manufacturer had demonstrated repeated failure to adhere to federal laws intended to guarantee the manufacture of safe and effective vaccines and drugs? 3. If the manufacturing facility was, as Mr. Oliver described, "tried and proven", then why did the FDA report in both Mar 1997 and again in Feb 1998 that "the manufacturing process for Anthrax Vaccine is not validated"? 4. Why did Mr. Oliver state that the anthrax vaccine manufacturing facility was "tried and proven" when in Feb 1998 the FDA forced DoD and the manufacturer to quarantine 11 of 40 lots of in the anthrax vaccine stockpile at the beginning of the anthrax vaccine immunization program? 5. Why did Mr. Oliver give evasive replies to reporters questions as to why DoD destroyed the former so-called "tried and proven" manufacturing facility, when it was the sole-source producer of a supposedly vital defense commodity?
Who said it:	**Mr. David Oliver (RADM, USN, ret.),** Principal Deputy Under Secretary Of Defense For Acquisition And Technology

Statement	**Fact**
Statements at a DoD press briefing, 13 Dec 1999:[104] Mr. Oliver: " In addition, **what you had was a facility in which you were doing a safe and effective vaccine** for a fairly limited number of people for years and years and years, and you have a use demonstrated…. Essentially what we did was tore down **that tried and proven facility**, which is the same facility that's produced all the vaccine that people have taken	1. The former so-called "tried and proven" anthrax vaccine production facility, operated by the State of Michigan and the veterinarian who is now BioPort's chief operating officer, was destroyed by DoD and Bioport before the FDA certified the new facility. 2. The former so-called "tried and proven" anthrax vaccine production facility failed FDA inspections with consistent

[104] DoD press briefing, 13 Dec 1999.
See: http://www.defenselink.mil/news/Dec1999/t12141999_t213anth.html

Statement	Fact
and will take under phase one, and we're building a whole new facility."[105] (later…) Reporter: I guess that brings me back to Jim's question, which is, Why tear it down? **You said it was a tried-and-true facility that was working. Why tear it down before you have another tried-and-true facility?** When you look back on the decision, do you think that was a smart -- Mr. Oliver: **I was driving west at the time** -- (laughter). Q: Do you think it was a smart decision? Mr. Oliver: **I was driving west, I was looking at the sunset -- I don't know.** Q: You have -- Q: Can you answer that, please?	"significant deviations" from manufacturing practices (CGMP) required by FDA regulations on the following inspection dates: • May 4 - May 7, 1993 • May 31- June 3, 1994 • April 24 - May 5, 1995 • Nov 18 - Nov 27, 1997 • Feb 4 - Feb 20, 1998 3. The seriousness of these deficiencies in the so-called "tried and proven" facility was emphasized to the manufacturer (Michigan Biologic Products Institute) in: • An FDA inspection report letter dated December 22,1993. • An FDA inspection report and Warning Letter dated August 31, 1995 • An FDA inspection report and "Notice of Intent to Revoke" (NOIR) MBPI's license dated 11 Mar 1997 • An FDA inspection report finding "The manufacturing process for Anthrax Vaccine is not validated" dated 20 Feb 1998.[106]

[105] Oliver, comments during DoD press briefing, 13 Dec 1999.
See: http://www.defenselink.mil/news/Dec1999/t12141999_t213anth.html
[106] FDA inspection report, BioPort Corporation, 23 Nov 1999.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Squalene in anthrax vaccine**. Misleading servicemembers, military families, and the American public about the existence of an unapproved substance in the DoD anthrax vaccine.
Question(s):	Why does the Department of Defense still have categorical denials of the existence of squalene in the anthrax vaccine on their AVIP website over 15 months after FDA experts found it in five lots of anthrax vaccine?
Who said it:	**Maj Guy Strawder**, former director of the US Army AVIP Agency

Statement	Fact
An article *still on the DoD Anthrax Vaccine website on 28 Sep 2000 -- 15 months after the FDA found squalene in five lots of the anthrax vaccine*:[107] "It's beyond speculation," Strawder said. "It's just pure fiction. There is absolutely nothing to hide about this program… **There has never been squalene in the anthrax vaccine, not now, not back during the Gulf War, not ever**," Strawder said. *Major Strawder's denial of the existence of squalene in the anthrax vaccine is just one of many untrue documents relating to the presence of squalene currently on the DoD AVIP website. Another, titled "Anthrax Ingredients", states the following in Q/A format*: **8. Does the anthrax vaccine contain squalene?** **No. The anthrax vaccine does not use squalene and never has**. Scientists have been testing squalene as a way of increasing antibody responses to vaccines, but **it has never been used in human anthrax vaccines**. Reports of squalene in the anthrax vaccine have been published on web sites of groups opposed to the AVIP and, recently, in an article in *Vanity Fair*	1. Contrary to Dr. Bailey's assertion, the FDA has found squalene in five of five lots it has tested for the presence of squalene. These tests were performed in Jun 1999, but were not disclosed by FDA until 20 Mar 2000, in a letter to Congressman Jack Metcalf (R-WA).[108] 2. According to representatives from the FDA's Center for Biologic Evaluation and Research, the FDA did find squalene in the five lots of anthrax vaccine on 23 and 24 June 1999. The test results are the following:[109] AVA 020 11 ppb squalene AVA 030 10 ppb AVA 038 27 ppb AVA 043 40 ppb AVA 047 83 ppb Diphtheria 22 ppb Tetanus 29 ppb 3. While the physiological impact of these amounts of squalene is subject to debate, it is clear that **DoD was wrong about the presence of squalene in the vaccine. And it has never issued a statement correcting their denials to either**

[107] JO2(SS) Dave Kaylor , "Allegations of Mystery Substance in Anthrax Vaccine Unfounded", Pacific Fleet Public Affairs, undated. (Accessed on the DoD AVIP website at 2130EDT, 28 Sep 2000).
[108] Melinda Plaisier, FDA Associate Commissioner of Legislation, letter to Congressman Jack Metcalf, 20 Mar 2000.
[109] Telephone interview with FDA CBER, 28 Sep 2000.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
magazine. None of these claims has any objective evidence associated with them	**servicemembers or to Congress**.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Retention impact of anthrax vaccine**. Misrepresenting to the House Government Reform Committee, under oath, the impact of the anthrax vaccination immunization program (AVIP) on Air National Guard retention..
Question(s):	1. Why did MGen Weaver repeatedly make the same unqualified false statement to members of Congress over a period of several months -- that only one member of the Air National Guard had left because of anthrax vaccine when DoD press briefings, internal USAF documents, and news reports clearly indicated otherwise? 2. Does MGen Weaver's false statement represent contempt by a military officer for Congress' Constitutional oversight role and does this represent an attempt to undermine civilian control of the military?
Who said it:	**MGen Paul Weaver**, Director of the Air National Guard

Statement	**Fact**
Before the House Government Reform Subcommittee chaired by Congressman Shays on 29 September 1999: "So, when I hear all of these other figures about these mass resignations, and what not, they're just not there. There are challenges with explaining, with discussing, as they all are, with the members of their unit, on the anthrax issue. **But when it really gets down to it, we've had 10,700 people inoculated for anthrax in the Air National Guard, with one known refusal**."[110] (statement above is available on videotape) *MGen Weaver made a similar statement to Rep Benjamin Gilman of New York, who wrote to the DoD office of Legislative Affairs on 16 May 1999*: [111]	The following losses had occurred in the Air National Guard prior to MGen Weaver's statement, under oath, to Congress on 29 Sep 1999*:* 1. Nine (9) pilots in the CTANG retired, transferred, or resigned concurrent with the mandatory vaccination of their unit in Jan 1999. Eight of these pilots sent a letter to Senator Dodd in Feb 1999 stating anthrax vaccine as the reason for their leaving the Guard.[112] 2. ASD/PA Mr. Ken Bacon acknowledged "eight or nine" resignations from the CTANG in a DoD press briefing on 21 Jan 1999.[113] 3. An internal USAF AVIP integrated process team briefing, dated 28 Apr 1999, showed eight losses in the CTANG

[110] Weaver, verbal testimony before National Security Subcommittee of the House Government Reform Committee, 29 Sep 1999
[111] Rep Benjamin Gilman, letter to Ms. Sandra Stuart, DoD Assistant Secretary for Legislative Affairs, 16 Sep 1999
[112] Letter from CTANG officers to Sen Christopher Dodd, submitted to Rep Christopher Shays' office (Mr. Larry Halloran) in Feb 1999
[113] See: http://www.defenselink.mil/news/Jan1999/t01211999_t121asd_.html

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
"In a meeting in my office approximately six weeks ago, **General Weaver made the incredible claim that only one Air National Guard pilot has quit due to anthrax**. Never mind that my staff has met with twenty of the more than thirty pilots who resigned from the 301st Airlift Squadron stationed at Travis AFB in California, and has talked with numerous other pilots from units around the country."	alone attributable to the anthrax vaccine.[114] 4. In Jun 1999 press reports documented seven pilots in the Wisconsin ANG resigning or transferring to non-mobility positions due to the anthrax vaccine.[115] 5. Additional losses had occurred in the Air Force Reserve unit at Travis AFB, CA, and elsewhere, but these reservists were not in the Air National Guard.

[114] LtCol Marti Rossi, et.al., Headquarters USAF, Anthrax IPT (Integrated Process Team), PowerPoint slide presentation, Slide # 16 , 28 Apr 1999 (this IPT had weekly meetings and issued quarterly reports to the Chief of Staff and the Secretary of the Air Force)

[115] "6 Guard Pilots Might Refuse Anthrax Vaccine", by Richard W. Jaeger Wisconsin State Journal, 19 Jun 1999

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Retention impact of anthrax vaccine**. The Director of the Air National Guard misrepresenting his false sworn testimony to Congress to thousands of ANG personnel when asked about it during a closed-circuit video-teleconference on the AVIP policy on 26 Oct 1999.
Question(s):	1. Why did MajGen Weaver falsely assert to his subordinates in the Air National Guard that he had somehow qualified his testimony to the House Government Reform Committee on 29 Sep 1999 that there had only been one known refusal due to the anthrax vaccine policy? 2. What is the impact of such obviously false statements to subordinates on the perceptions servicemembers have of the military leadership? 3. Are senior commanders who so blatantly mislead their troops qualified to retain their leadership position or to continue service in the military?
Who said it:	**MGen Paul Weaver**, Director of the Air National Guard

Statement	**Fact**
During a closed-circuit Air National Guard video-teleconference, 26 Oct 1999: "So, I was very much aware, **when I said one refusal…that was a refusal of a person who had a commitment to the Air National Guard. My additional testimony also reflects that I was also very much aware that people did….did walk** who…again…were volunteers of our Air National Guard Family."[116] (statement is available on videotape)	Review of MGen Weaver's written and verbal testimony to the House Government Reform Committee on 29 Sep 1999 revealed that he did not in any way qualify his remarks which asserted only "one know refusal." • Maj Gen Weaver said nothing during his Congressional testimony of "one refusal with a commitment." • Maj Gen Weaver also did not acknowledge during his testimony to Congress that other members of the Air National Guard had "walked".

[116] VHS Tape of segment #2 of the closed circuit TV Warrior broadcast by the Director of the ANG on the Anthrax Vaccination Immunization Program (AVIP).

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Efficacy of anthrax vaccine for inhalation anthrax**. Misrepresenting to the Senate Armed Services Committee that the Bioport vaccine is the same as the vaccine tested in the 1962 Brachman study and that the Brachman study inferred efficacy against inhalation anthrax.
Question(s):	1. Did the authors of 1962 Brachman study of millworkers demonstrate that the anthrax vaccine was effective against inhalation anthrax sufficient to satisfy federal legal requirements for vaccine efficacy under the Food, Drug, and Cosmetic Act? 2. Was the anthrax vaccine tested in the 1962 Brachman study the same as the vaccine produced by the Michigan Biologic Products Institute, or its successor, BioPort, Inc.? 3. Would the FDA license a vaccine today using an efficacy study for a vaccine which was a different formulation than that which was to be licensed? In other words, by today's regulatory standards is the 1962 Brachman study of any relevance?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	**Fact**
In testimony before the Senate Armed Services Committee, 12 Jul 2000: Dr. Zoon: Yes. Well, the BioPort vaccine is the only licensed anthrax vaccine in the United States. I am not familiar with other countries' licensed vaccines, but I can comment on the anthrax vaccine absorbed here in the United States, the one produced by BioPort. Clearly, there is a lot of interest in looking at other vaccines on an investigational level for new approaches to immunization against anthrax, but this particular vaccine, as mentioned, has been licensed since 1970. **There is a fair amount of clinical data that was generated by Brachman**, et al., back in the fifties with millworkers looking at protection of this vaccine for both cutaneous and in several	1. In 1969 efficacy data on the current anthrax vaccine, initially produced by the Michigan Department of Public Health, was submitted to the FDA's predecessor, the U.S. Public Health Service for pre-licensure review. The Public Health Service Ad Hoc Committee on vaccines reported: "The lack of cases of anthrax in an uncontrolled population of approximately 600 persons in the Talladega mill can hardly be accepted as scientific evidence for the efficacy of the vaccine."[117] Despite concluding that "the assumption of efficacy appears speculative", the Public Health Service licensed the vaccine in 1970 without receiving any

[117] John C. Feeley, Ph.D., et.al., Ad Hoc Committee on Vaccines, "Michigan Department of Health Anthrax Vaccine Evaluation of Clinical Data" , memorandum Ref. No. 67-70 to Dr. Margaret Pittman (Chief, LBP), U.S. Public Health Service, 6 Feb 1969

Statement	Fact
cases of inhalation anthrax, and **the data from that particular study showed a protection against both the cutaneous and the inhalation anthrax**, the numbers, though, being small with the inhalation anthrax.	additional efficacy data on the Michigan anthrax vaccine. Instead, they accepted information on a different anthrax vaccine, produced by Merck, and used in the 1962 Brachman study. 2. The 1962 Brachman efficacy study of a similar, but different, vaccine than that used by DoD today concluded: "The statistical analysis of the data indicates that the vaccine was effective in protecting against cutaneous anthrax infections. When inhalation anthrax is considered, the limited experience with this form of the disease makes the data less significant in showing effectiveness of the vaccine."[118] 3. In 1994 and again in 1999, Dr. Philip S. Brachman, author of the 1962 Brachman study and Col (Dr.) Arthur Friedlander, the Army's chief anthrax researcher, co-authored the anthrax vaccine chapter in the medical text "Vaccines". They reiterated in both the 1994 edition[119] and the 1999 edition[120]: "**No assessment of the effectiveness of the vaccine against inhalation anthrax could be made because there were too few cases**." 4. In testimony during a Canadian court-martial on 30 Mar 2000, Col. (Dr.) Arthur Friedlander, the Army's chief

[118] Philip S. Brachman, M.D. et.al., "Field Evaluation of a Human Anthrax Vaccine", American Journal of Public Health, Vol. 52, No. 4, April 1962 (p. 643)
[119] Plotkin and Mortimer "Vaccines, second edition" (Philadelphia: W.B. Saunders), 1994. See: P.S. Brachman and A.M. Friedlander, chapter 26, "Anthrax Vaccine" (p. 736)
[120] Plotkin and Orenstein "Vaccines, third edition" (Philadelphia: W.B. Saunders), 1999. See: P.S. Brachman and A.M. Friedlander, chapter 24, "Anthrax Vaccine" (p. 635)
[121] Col (Dr.) Arthur Friedlander, testimony given during the trial of Ex-Sergeant Michael Richard MINUTES OF PROCEEDINGS STANDING COURT MARTIALfor the trial of K72 142 802 Ex-Sergeant Michael Richard Kipling, Canadian Forces, Regular Force, held at 17 Wing, Winnipeg, Manitoba, before Colonel G.L. Brais, Office of the Chief Military Judge, 30 Mar 2000

Statement	Fact
	anthrax researcher, testified about the Brachman study as follows: Col. (Dr.) Friedlander: "…So the conclusion they [Brachman, et.al.] drew was that it was protective against cutaneous disease, **not sufficient cases statistically to say whether it was effective, in that setting, against inhalational anthrax because there weren't enough cases**. There was a suggestion it was, but not any proof that it was. That's the only data that exists in humans in any study. Defense counsel: "Is this the Brachman study that ..." Col. (Dr.) Friedlander: "This is the Brachman study."[121]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**DoD pressure on FDA to allow AVIP**. Misrepresenting to Congress that FDA had "no official role" in DoD's implementation of the anthrax vaccination immunization program (AVIP).
Question(s):	1. Why did the FDA's Dr. Zoon tell two committees of the House of Representatives that FDA had no "official role" in the DoD decision to implement an anthrax vaccination program when FDA officials, including staff attorneys, attended meetings with DoD in Feb and Mar 1997? 2. Would DoD have implemented the anthrax vaccine implementation program without the letter provided to DoD by the FDA's Lead Deputy Commissioner, Dr. Michael Friedman, on 13 Mar 1997, stating that the use of the vaccine for inhalation anthrax was "not inconsistent" with the product license? -- If so, would the implementation have required DoD to obtain a Presidential waiver of informed consent required under federal law (10 USC 1107)? 3. Does the standard of approval used by the FDA's Dr. Friedman in his 13 Mar 1997 letter to DoD -- "because the current package insert does not preclude its use" -- meet the regulatory threshold for safe and effective use, if, as Dr. Friedman stated, there was "a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax"? -- Does the FDA approve other products for unproven uses simply because the current product label does not preclude their use, even though there is a "paucity" of data to support a change?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	**Fact**
In written testimony before the House Government Reform Committee, 12 Oct 1999:[122] FDA has not had an official role in the development or operation of the Department of Defense's Anthrax Vaccine Immunization Program, including the AVIP tracking system or	1. Despite Dr. Zoon's statement that FDA did not have an "official" role in the DoD anthrax vaccine program, the FDA provided DoD the key official sanction which was critical to DoD's implementation of the program without having to obtain Presidential waiver of informed consent. This included:

[122] Kathryn Zoon, Ph.D., FDA testimony before House Government Reform Committee, 12 Oct 1999. (accessed on FDA website 28 Sep 2000)
[123] Kathryn Zoon, Ph.D., FDA testimony before House Armed Services Committee subcommittee on Military Personnel, 13 Jul 2000.

Statement	Fact
the program's adverse event reporting system. In March 1997, DoD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to the FDA approved labeling for six doses administered on a specified schedule over eighteen months. Subsequently, FDA learned that the DoD plan had been adopted. *In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000*: [123] "**FDA did not have an official role in the development or operation of the DoD's Anthrax Vaccine Immunization Program**, including the AVIP tracking system or the program's adverse event reporting system…" "In March 1997, DOD briefed FDA about their draft plan for the possible use of the anthrax vaccine to inoculate U.S. military personnel according to the FDA-approved labeling for six doses administered on a specified schedule over 18 months. Subsequently, FDA learned that DOD had formally adopted this plan."	• Calls by the deputy Assistant Secretary of Defense for Health Affairs, ADM (Dr.) Ed Martin, to FDA in Feb 1997 suggesting that DoD wanted to use the vaccine for mass inoculations of servicemembers.[124] • FDA officials attending meetings with DoD in Feb and Mar 1997 to discuss the proposed use of the anthrax vaccine for a mass inoculation program. One FDA official noted in an interoffice memo to a colleague: "This is a scientific/legal issue; just be sure to document what was asked, and what you decided. **It is important for General Counsel to be there**."[125] • A letter from former Assistant Secretary of Defense for Health Affairs, Dr Stephen Joseph, to FDA on 4 Mar 1997 specifically suggesting that DoD has "long interpreted the scope of the license to include inhalation exposure." This assertion was directly contravened by the Investigational New Drug application prepared by the Army for submission by the manufacturer to FDA on 20 Sep 1996 -- just six months prior. A specific objective of the IND application was to obtain a new indication for inhalation anthrax in the product license. • A reply letter from acting FDA Commissioner Dr. Michael Friedman to DoD on 13 Mar 1997, which DoD has used as a legal guise to assert their use of

See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html

[124] Karen L. Goldenthal, MD, FDA Interoffice Memo, "Subj.: re: telephone call from ADM Martin about the anthrax vaccine", 18 Feb 1997

[125] Mary Pendergast, FDA Interoffice Memo, "Subject: re: Meeting with DoD -- Anthrax Mass Vaccination", 26 Feb 1997

[126] LTG Ronald Blanck, testimony before House Armed Services Committee subcommittee on Military Personnel, 30 Sep 1999.

Statement	Fact
	the anthrax vaccine is not investigational, and is therefore not a violation of the informed consent requirements of federal law. In the letter Dr. Friedman justifies a DoD's use of the vaccine for inhalation anthrax "because the current package insert does not preclude its use, and despite "a paucity of data regarding the effectiveness of Anthrax Vaccine for prevention of inhalation anthrax..."
	• The letter by acting FDA Commissioner Friedman represents an abandonment of FDA's regulatory responsibilities under federal law, which require a demonstration of efficacy in humans before a vaccine can be licensed for that indication, and for which substitute efficacy tests with animals are not allowed under the law. Even if animal tests were allowed, the Army has acknowledged in numerous internal documents that no scientifically valid "correlate of immunity" has ever been established between animals and humans.
	2. Former Army Surgeon General, LTG Blanck, acknowledged in testimony before the House Armed Services Subcommittee on Military Personnel that without the "approval" rendered by the FDA's Dr. Friedman, DoD would have had to implement the anthrax vaccine policy with informed consent: Mr. **JONES (R-NC).** Thank you. General Blanck let me ask you, would you implement this same program if FDA did not approve the vaccine? General **BLANCK.** Yes, I would, but **we would implement it differently because then the vaccine would be in an investigational new drug status, an IND status**, and while I would have the same confidence in the vaccine

Accountability of DoD, FDA and BioPort Officials For the Anthrax Vaccine Immunization Program (AVIP)

Statement	Fact
	from reasons that I have already described, **we would then have to use informed consent and take other measures** as part of our implementation program.[126]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Adverse reactions**. Misrepresenting the statistical significance of adverse reactions reported through the VAERS passive reporting system.
Question(s):	1. Based on testimony from DoD and FDA officials, from Mar 1999 until Jul 2000, the number of VAERS adverse event reports have increased by 34 times with only a three-fold increase in immunization doses administered. How are the FDA and the DoD responding to this dramatic increase in the rate of adverse reactions? 2. Why are the Department of Defense and the FDA relying on statistics from a passive system -- VAERS -- as a measure of the safety of the anthrax vaccine, when it is widely reported in the medical community that these statistics underreport adverse reactions by a factor of 100? 3. If a military vaccination program initiated by the Secretary of Defense is labeled as a so-called "commander's program" which becomes a de facto test of a military officer's leadership ability, are military physicians likely to report adverse reactions at the same rates as civilian physicians reporting on other vaccines?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	**Fact**
In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000:[127] "Since the beginning of VAERS operations in 1990, through June 30, 2000, 1404 reports of adverse events associated with use of the anthrax vaccine have been reported to VAERS. FDA understands that from 1990 to present, approximately 2,000,000 doses of the vaccine were distributed. Of those reports, 73 are considered serious events, which are events considered either fatal, life threatening, or resulting in hospitalization or permanent disability. These reports are for diverse conditions, such as hospitalization for severe	1. Dr. Zoon's testimony does not place the number of adverse reaction reports in perspective, because it ignores a dramatic increase in the rate of reports submitted by servicemembers since early 1999: • In March 1999 Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, testified to 42 VAERS reports having been filed out of 634,000 anthrax immunizations given by DoD.[128] As of July 2000 Dr. Zoon testified to 1404 VAERS reports filed out of approximately 2,000,000 doses of the vaccine. **This means that in 16 months the number of VAERS adverse**

[127] Dr. Kathryn Zoon, written testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000. See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html

[128] Dr. Sue Bailey, testimony before the National Security, Veterans Affairs, and International Relations Subcommittee of the House Government Reform Committee, 24 Mar 1999. See: http://www.house.gov/reform/ns/hearings/subfolder/baileytest324.htm

Statement	Fact
injection-site reaction, Guillain-Barré syndrome, widespread allergic reaction, aseptic meningitis and multi-focal inflammatory demyelinating disease… **None of these events, except for the injection site reactions, can be attributed to the vaccine with a high level of confidence**, nor can contribution of the vaccine to the event reported be entirely ruled out."	**reaction reports increased by 34 times with only a three-fold increase in immunizations**. The limitations of the VAERS reporting system have been widely reported in medical literature, including by the FDA: • Former FDA Commissioner Dr. David Kessler has written in the Journal of the American Medical Association in 1993: [129] "Although the FDA receives many adverse event reports, these represent only a fraction of the serious adverse events encountered by providers…**Only about 1% of serious events are reported to the FDA, according to one study**." • Former FDA Commissioner Dr. David Kessler also observed: "Another factor inhibiting physician reporting physician reporting is that **it is not in the culture of US medicine to notify the FDA about adverse events** or product problems." In a military population where a vaccination program is labeled as "a commander's program", reporting of adverse reactions is likely to be even lower than in the general population (i.e. less than 1%). • Despite FDA's Dr. Zoon using a "high level of confidence" as the standard to ascribe causality of adverse reactions to the anthrax vaccine, medical literature suggests a more reasonable standard.

[129] Dr. David A. Kessler, The Journal of the American Medical Association, Vol. 269 No. 22, 2 Jun 1993
[130] Robert T. Chen, et.al., The Vaccine Adverse Event Reporting System (VAERS), Vaccine, Vol. 12 No. 6, 1994. (Note All authors worked for the FDA Center for Biologics Evaluation and Research or the Centers for Disease Control).

Accountability of DoD, FDA and BioPort Officials
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Statement	Fact
	According to a 1994 article written by FDA and CDC experts in the medical journal "Vaccine": "The greatest limitation of VAERS, however, is the general inability to determine whether a vaccine actually caused the reported adverse event. **Vaccines can be said to cause the event if…epidemiological evidence exists that vaccinated persons are at higher risk for an adverse event than a comparison group**, and that other supportive evidence is also consistent, for example, a plausible biological mechanism and a reasonable interval between vaccination and onset (e.g. 1976 swine influenza vaccine and GBS [Guillian-Barre syndrome]."[130]

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Efficacy**. Misrepresenting the efficacy of the anthrax vaccine
Question(s):	1. Why has Dr. Zoon testified that the DoD anthrax vaccine is "effective prevention" when this vaccine -- produced by the Michigan plant currently owned by BioPort -- has never proven efficacy in humans and has never proven efficacy in animals in tests for which a scientifically valid "correlate of immunity" exists? 2. Why did Dr. Zoon tell Congress that the anthrax vaccine is "effective prevention" when a CDC official stated within a week of her testimony that, "we do not have specific information on the efficacy of the existing vaccine for the prevention of inhalation anthrax and we probably never will"?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	**Fact**
In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000:[131] "The only known effective prevention against anthrax is the anthrax vaccine."	1. During a July 2000 conference sponsored by the Centers for Disease Control, Dr. David Ashford of the CDC said: "For those of us working with the [anthrax] vaccine, **we do not have specific information on the efficacy of the existing vaccine for the prevention of inhalation anthrax and we probably never will**."[132] 2. Dr. Zoon's use of the word "prevention" is misleading in that it ignores DoD medical protocol that even vaccinated servicemembers who are exposed to weaponized anthrax would require treatment with antibiotics. According to an Army Reserve colonel who worked at the Army's research facility at Ft. Detrick, MD: "Soldiers who are exposed to anthrax may become quite sick and be incapacitated for up to two weeks, even if

[131] Dr. Kathryn Zoon, written testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000. See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html
[132] "Anthrax Vaccine Is Safe, U.S. Health Experts Say", by Eliza Bussey, Reuters, 10 July 2000

Statement	Fact
	they have received the full set of six inoculations."[133] • Dr. Zoon's statement that the anthrax vaccine is the only "effective prevention" carefully avoids the distinction of effective treatment. An internal Army document from the Gulf War period observed that post-exposure treatment with antibiotics (penicillin, doxycycline, or ciprofloxacin) combined with post-exposure vaccination was an effective treatment: "…**the initiation of vaccination in concert with antibiotics after exposure should enable an infected individual to generate an immune response** that could react in a similar way [to pre-exposure vaccination], albeit with somewhat less certainty. **In primate experiments summarized above, this strategy proved effective**."[134] In the tests referenced in the quote above, conducted by Army's chief anthrax researcher, Col (Dr) Arthur Friedlander in 1990, **100% of infected primates survived after post-exposure treatment with doxycycline and anthrax vaccine**.

[133] Col George Robertson, USAR, quoted in: Thomas E. Ricks, "Anthrax Shots' Effect Challenged", Washington Post, 18 July 2000

[134] (No author listed), "Rationale for Antibiotics in Prophylaxis Against Inhalation Anthrax", internal US Army briefing paper (circa 1990-91), declassified by SecArmy(DAMH), 31 Oct 1996.

Accountability of DoD, FDA and BioPort Officials
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Issue:	**Scope of licensed usage**. Misrepresenting that military personnel, other than those conducting research, fall into the categories of persons indicated in the FDA approved license to take the anthrax vaccine.
Question(s):	1. Why does Dr. Zoon repeatedly infer that DoD military personnel, other than those performing biowarfare research, are among those indicated to take the anthrax vaccine, when the FDA-approved product label clearly states otherwise? 2. Why does Dr. Zoon infer that DoD's use of the anthrax vaccine is within the scope of the product license, when the FDA advisory review panel that reviewed the vaccine in 1985 found that "no meaningful assessment of it's value against inhalation anthrax is possible"? 3. Why does Dr. Zoon infer that DoD's use of the anthrax vaccine is within the scope of the product license, when the 1985 advisory review panel found the benefit-to-risk assessment is "satisfactory under the prevailing circumstances of use" -- which was limited use for a small, high-risk population, not a mass inoculation program for 2.4 million servicemembers?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	Fact
In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000: [135] "FDA continues to view the anthrax vaccine as safe and effective for individuals at high risk of exposure to anthrax, when used in accordance with the approved labeling."	1. The FDA-approved product label makes no mention or inference of using anthrax vaccine for protection from weaponized anthrax: "Immunization with Anthrax Vaccine Adsorbed is **recommended for individuals who may come in contact with animal products such as hides, hair, or bones** which come from anthrax endemic areas and may be contaminated with *Bacillus anthracis spores;* **and for individuals engaged in diagnostic or investigational activities** which may bring them into contact with *B. anthracis spores* (1,5). **It is also recommended for high-risk persons such as veterinarians and others handling potentially**

[135] Kathryn Zoon, Ph.D., FDA testimony before House Armed Services Committee subcommittee on Military Personnel, 13 Jul 2000.
See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html

Statement	Fact
	infected animals. Since the risk of exposure to anthrax infection in the general population is slight, **routine immunization is not recommended**[136] 2. In 1985 a panel appointed by FDA to review the safety and efficacy of all vaccines made the following observations about the current anthrax vaccine:[137] "This product is intended **solely for** immunization of high-risk of exposure industrial populations such as **individuals who contact imported animal hides, furs, bone meal, wool, hair (especially goat hair), and bristles. It is also recommended for laboratory investigators** handling the organism." "**No meaningful assessment of it's value against inhalation anthrax is possible** due to its low incidence." " Benefit / risk ratio. This vaccine is **recommended for a limited high-risk of exposure population** along with other industrial safety measures designed to minimize contact with potentially contaminated material. **The benefit-to-risk assessment is satisfactory under the prevailing circumstances of use**."

[136] Anthrax vaccine absorbed product label, Rev. 3/99, Bioport, Inc.
See: http://www.bioport.com/PrincipleProducts/AVAInsert/AVAins01.htm
[137] Federal Register, Vol. 50, No. 240. Pg. 51059, "Biologic Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review; Proposed Rule" (the final rule was never published), Fri.,13 Dec 1985

Accountability of DoD, FDA and BioPort Officials
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Issue:	**Enforcement of licensed shot protocol**. Misrepresenting to the House Armed Services Committee that FDA has compelled DoD into regulatory compliance with the shot protocol in the approved product license, when it has told the House Government Reform Committee that it has does not have the power to do so.
Question(s):	Why did Dr. Zoon tell the House Armed Services Committee that she and the FDA Commissioner had written DoD in Sep 1999 to chastise them for not following the FDA-approved shot protocol without also telling the HASC that she had acknowledged in testimony on 12 Oct 1999 that FDA does "not have authority", in law, to regulate DoD's use of the vaccine?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	**Fact**
In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000: [138] " Upon learning last year that some DoD personnel reported they had been told that they were fully protected against anthrax after receiving three doses of the anthrax vaccine, both Jane E. Henney, M.D., Commissioner of Food and Drugs, and I, sent letters to DoD. In the letters we asked DoD to expeditiously investigate this matter as we are unaware of any data demonstrating that any deviation from the approved schedule found in the approved labeling will provide protection from anthrax infection."	1. During a DoD press briefing on 11 Jul 2000, Adm (Dr.) Jarrett made the following tacit acknowledgement that DoD planned off-label use of the anthrax vaccine: • "We have discussed this with the FDA and advised them that we plan to follow the Center for Disease Control's expert group on this issue. It's called the Advisory Committee for Immunization Practices, which has a statement, which states you do not need to re-start the whole series. Rather, you just pick up where you were. So, indeed, if an individual had two shots, didn't have access to the third, waited six months, then they would start the third and go right back on the schedule again."[139] • This statement acknowledging that DoD does will not follow the FDA-approved shot protocol according to

[138] Kathryn Zoon, Ph.D., FDA testimony before House Armed Services Committee subcommittee on Military Personnel, 13 Jul 2000.
See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html

[139] ADM (Dr.) J. Jarrett Clinton, M.D., Assistant to the Assistant Secretary of Defense (Health Affairs), DoD press briefing, 11 Jul 2000
See: http://www.defenselink.mil/news/Jul2000/t07112000_t0711asd.html

Statement	Fact
	the product license means that its use of the vaccine is investigational, and subject to the informed consent requirement under federal law in 10 USC 1107. 2. Dr. Zoon testified before the House Government Reform Committee on 12 Oct 1999 that FDA did not have the authority to compel DoD to comply with the FDA-approved shot protocol:[140] Mr. Shays. Have you not given DOD the right to use this vaccine? Dr. Zoon. This is a licensed vaccine. If a physician uses it, or DOD uses it that does not really fall under our jurisdiction. Mr. Shays. So it's your statement before us now that if DOD doesn't abide by the protocol, you have no responsibility, that you have set out a requirement--who is responsible then? Who is going to make sure that DOD abides by the protocol, if you don't do it? Dr. Zoon. **We don't have the authority**.

[140] Kathryn Zoon, Ph.D., FDA verbal testimony before House Government Reform Committee, 12 Oct 1999. See: http://www.gpo.gov/congress/house/house07.html

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Safety and efficacy**. Misrepresenting that the stockpiled vaccine used to-date is safe and effective and has been subject to FDA regulatory enforcement of CGMP's (current good manufacturing practices) required by federal law.
Question(s):	Why does Dr. Zoon assert that the vaccine from the stockpile produced in the former manufacturing facility is safe and efficacious when it was produced under circumstances of repeated failed FDA inspections?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	Fact
In testimony before the Senate Armed Services Subcommittee on Military Personnel, 12 Jul 2000:[141] Sen. Levin: And are you satisfied that the 2 million doses that have been given were safe and efficacious? Dr. Zoon: The material that has been released and distributed we believe meet all the specifications of the manufacturer and what we have on the license. *In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000:* [142] "By manufacturing products in a facility that is operating in a full state of GMP compliance, we can help assure that any product that is released by the company is safe and effective."	1. Dr. Zoon has never explained why the FDA has had a double standard for the stockpiled vaccine used to-date made in the former production facility and new vaccine made in the new manufacturing facility completed in May 1999, and as yet still not certified. The deviations from current good manufacturing practices (CGMP) in the former facility are far more numerous than those deviations found during FDA's Nov 1999 inspection of the new facility, which is still not allowed to manufacture vaccine. 2. According to the FDA's inspection reports from the division Dr. Zoon heads, the previous anthrax vaccine production facility that made all of the vaccine used to date was in gross non-compliance with federal GMP (good manufacturing practices) standards. It failed FDA inspections with consistent "significant deviations" from manufacturing practices (GMP) required by FDA regulations on the following dates: • May 4 through May 7, 1993

[141] Kathryn Zoon, Ph.D., Federal News Service transcript, FDA testimony before Senate Armed Services Committee, 12 Jul 2000.

[142] Kathryn Zoon, Ph.D., FDA testimony before House Armed Services Committee subcommittee on Military Personnel, 13 Jul 2000.
See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html

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Statement	Fact
	• May 31 through June 3, 1994 • April 24 through May 5, 1995 • Nov 18 through Nov 27, 1997 • Feb 4 through Feb 20, 1998 • Seriousness of these deficiencies was emphasized to MBPI in an FDA letter dated December 22,1993, • an FDA Warning Letter dated August 31, 1995 • an FDA letter and "Notice of Intent to Revoke" MBPI's license dated 11 Mar 1997 • an FDA letter finding "The manufacturing process for Anthrax Vaccine is not validated" dated 20 Feb 1998. This letter was sent three weeks after the manufacturer "voluntarily" ceased production on the eve of the Feb 1998 FDA inspection.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**Scope of FDA's legal authority**. Misrepresenting to Congress that FDA has regulatory oversight responsibility for DoD's deviation from the FDA-approved anthrax vaccine shot protocol, by implying that if FDA had an objection to DoD's off-label use of the vaccine that it would or could exercise regulatory authority to stop DoD.
Question(s):	1. Why did Dr. Zoon testify to the Senate Armed Services Committee that FDA does "not object" to DoD's deviation from the FDA-approved shot schedule when she has previously testified that FDA has no authority over the end-users use of drug or vaccine products? 2. Why did Dr. Zoon testify to the Senate Armed Services Committee that it does "not object" to DoD's deviation from the FDA-approved shot schedule, when on 30 Sep 1999 she and the FDA Commissioner sent a letter to DoD specifically counseling them on the necessity of adhering to the shot schedule?
Who said it:	**Kathryn Zoon**, Ph.D., Director, FDA Center for Biologics Evaluation And Research

Statement	Fact
In testimony before the Senate Armed Services Subcommittee on Military Personnel, 12 Jul 2000:[143] SEN. LEVIN: Dr. Zoon, what you are saying is, FDA approves picking up the series where somebody left off, if they only had one or two or three shots in the series of six, is that correct? DR. ZOON: What I said, we do not object to the plan that DOD has outlined. *In testimony before the House Armed Services Subcommittee on Military Personnel, 13 Jul 2000:* [144] " Upon learning last year that some DoD	• Dr. Zoon previously testified to the House Government Reform Committee that the FDA has no authority to regulate DoD's use of drugs or vaccines. Therefore, stating that FDA does "not object" evades the real issue: Even if FDA did object, it lacks the regulatory authority to circumscribe off-label use of drugs or vaccines by the military. Dr. Zoon's testimony before the House Government Reform Committee on 12 Oct 1999 makes this point clear:[145] **Dr. Zoon. We have control over the manufacturer, which is BioPort. We don't have control over the users.** Mr. Shays. Have you not given DOD

[143] Kathryn Zoon, Ph.D., FDA testimony before Senate Armed Services Committee, Federal News Service transcript, 12 Jul 2000.
[144] Kathryn Zoon, Ph.D., FDA testimony before House Armed Services Committee subcommittee on Military Personnel, 13 Jul 2000.
See: http://www.house.gov/hasc/testimony/106thcongress/00-07-13zoon.html
[145] Kathryn Zoon, Ph.D., testimony before the House Government Reform Committee, 12 Oct 1999.
See: http://www.gpo.gov/congress/house/house07.html

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Statement	Fact
personnel reported they had been told that they were fully protected against anthrax after receiving three doses of the anthrax vaccine, both Jane E. Henney, M.D., Commissioner of Food and Drugs, and I, sent letters to DoD. In the letters we asked DoD to expeditiously investigate this matter as we are unaware of any data demonstrating that any deviation from the approved schedule found in the approved labeling will provide protection from anthrax infection."	the right to use this vaccine? Dr. Zoon. This is a licensed vaccine. If a physician uses it, or DOD uses it that does not really fall under our jurisdiction. Mr. Shays. So it's your statement before us now that if DOD doesn't abide by the protocol, you have no responsibility, that you have set out a requirement--who is responsible then? Who is going to make sure that DOD abides by the protocol, if you don't do it? Dr. Zoon. **We don't have the authority**.

Accountability of DoD, FDA and BioPort Officials
For the Anthrax Vaccine Immunization Program (AVIP)

Issue:	**DoD's mantra of routine use by veterinarians nationwide**. Misrepresenting to Congress, Commanders, and Servicemembers that veterinarians in the United States have widely used the anthrax vaccine for over thirty years in order to package and sell a policy to the troops.
Question(s):	1. Why have DoD officials provided information to their Commanders to relay to subordinates that the anthrax vaccine has been widely used in the United States for years? 2. Why didn't the DoD explain to their Commanders that the anthrax vaccine patent and facility are primarily owned by the government, that military researchers were instrumental in the patent and the license amendments, and that military researchers in DoD laboratories are the ones that have routinely used the anthrax vaccine?
Who said it:	**Literally every Commander in the United States Armed Forces**

Statement	**Fact**
Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, to Subcommittee on National Security, Veterans Affairs and International Relations Committee on Government Reform; U.S. House of Representatives, March 24, 1999 clear:[146] "The Department is confident, as is the Food and Drug Administration (FDA), that the FDA-licensed anthrax vaccine is safe and efficacious for its intended.... The anthrax vaccine has been licensed by the FDA since 1970 and has been recommended for veterinarians, laboratory workers, and livestock handlers in the US for more than 25 years. There have been no long-term side effects reported with the FDA-licensed anthrax vaccine." (And no long-term studies, according to the GAO and the IOM).	• Army Times Published on 5 Apr 99 that the "…'ROUTINE' ON ANTHRAX / ARMY BROCHURES OVERSTATE USE OF VACCINE." The article by Deborah M. Funk revealed one of the first of many misrepresentations that caused concerns in the ranks. The Army is rethinking the wording of its anthrax vaccine brochures. From the article: "The brochures assert the vaccine "has been safely and routinely administered in the U.S. to veterinarians, laboratory workers, and livestock handlers for more than 25 years. But civilian veterinarians say it's not routinely used in this country, except in laboratories… As far as veterinarians being routinely vaccinated, that is not the case," said David Huxsoll, Dean at Louisiana State University School of Veterinary Medicine. Veterinarians who work in research labs there receive the

[146] Dr. Sue Bailey, Assistant Secretary of Defense for Health Affairs, In testimony to the Subcommittee on National Security, Veterans Affairs and International Relations Committee on Government Reform, U.S. House of Representatives, March 24, 1999;
See: http://www.house.gov/reform/ns/hearings/subfolder/baileytest324.htm

Statement	Fact
	shots… Now Army officials say they never meant to imply there was frequent and widespread use among civilian veterinarians. We are considering changing the language since some people may be interpreting the word 'routine' differently than we intended," said Army Medical Command spokeswoman Cynthia Vaughan, who added**, 'We did not intend to mislead or confuse people.'**'":[147] **<u>Bottom-line</u>: Institutional tendencies to protect policies and the chain of command have promoted a seriously questionable force protection initiative instead of protecting the troops that are the object of the policy. In the meantime, ill troops are abandoned, healthy troops are punished, and the integrity of the military institution is tarnished. External from the DoD, this smear on our militaries' integrity occurred through false testimony to Congress and inaccurate reporting to the American media. Internal within the DoD, an aggressive propaganda campaign of subtle misrepresentations and half-truths to the nation's subordinate military commanders and troops has replaced the trust and integrity essential to command. Clearly, the Congress recognizes that the DoD "*did not intend to mislead or confuse people,*" initially, but regardless, DoD officials must now immediately and unilaterally end the AVIP, care for the inoculated ill, and expunge all punishments. Otherwise, Congress will be compelled to intervene, exercising its oversight authority and responsibility as the elected legislators for the American people.**

[147] Army Times, "New 'routine' On Anthrax / Army Brochures Overstate Use Of Vaccine," pg. 2, See: http://www.mco.com/mem/archives/army/1999/at0405xr.htm

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