UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, JOHN DOE #2,	*	
JOHN DOE #3, JOHN DOE #4,	*	
JOHN DOE #5, JANE DOE #1	*	
c/o Mark S. Zaid, Esq.	*	
Mark S. Zaid, P.C.	*	
1920 N Street, N.W.	*	
Suite 300	*	
Washington, D.C. 20036	*	
	*	
and	*	
	*	
OTHER SIMILARLY SITUATED	*	
INDIVIDUALS	*	
	*	
Plaintiffs,	*	
	*	Civil Action No. 06-_____
vs.	*	
	*	
ANDREW C. VON ESCHENBACH	*	
COMMISSIONER	*	
FOOD AND DRUG ADMINISTRATION	*	
5600 Fishers Lane	*	
Rockville, Maryland 20857-0001,	*	
	*	
and	*	
	*	
ROBERT GATES	*	
SECRETARY OF DEFENSE	*	
DEPARTMENT OF DEFENSE	*	
1000 Defense Pentagon	*	
Washington, D.C. 20301	*	
	*	

and *

*

MIKE LEAVITT *
SECRETARY OF HEALTH AND *
HUMAN SERVICES *
DEPARTMENT OF HEALTH AND *
HUMAN SERVICES *
200 Independence Avenue, S.W. *
Washington, D.C. 20201, *

*

Defendants. *

* * * * * * * * * * * * *

COMPLAINT

Plaintiffs John Doe #1, John Doe #2, John Doe #3, John Doe #4, John Doe #5 and Jane Doe #1, on behalf of themselves and all other similarly situated individuals, file this action against defendants Andrew C. Von Eschenbach, Commissioner, Food and Drug Administration ("FDA"), Robert Gates, Secretary of Defense, Department of Defense ("DoD"), and Mike Leavitt, Secretary of Health and Human Services, Department of Health and Human Services.

Plaintiffs seek temporary and permanent injunctive relief from the DoD's anthrax vaccination program, as well as a declaratory judgment that Anthrax Vaccine Adsorbed ("AVA" or "BioThrax"), which will imminently or is currently being involuntarily administered to active and Reserve U.S. Armed Forces members and DoD civilian employees, is a drug unapproved for its applied/intended use, pursuant to 10 U.S.C. § 1107, Executive Order 13139, DoD Directive 6200.2, and 21 C.F.R. § 201.5, and is being administered to United States service members, federal employees and civilian defense contractors in violation of federal law. Plaintiffs seek this relief pursuant to the Administrative Procedures Act, 5 U.S.C. § 551, et seq., the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 and the All Writs Act, 28 U.S.C. § 1651.

PARTIES

1. Plaintiffs are active duty service members, Reservists, National Guardsmen and civilian employees and/or DoD contractors who have been ordered, or will be ordered, perhaps imminently, to take AVA as part of their military duties or employment obligations. If administered the vaccine it is likely, as has been the case in the past, that they will be administered the AVA in violation of the FDA's mandated shot sequence protocol. Similarly situated individuals include current members of the active duty and Reserve forces of the Armed Forces, National Guardsmen and current civilian DoD employees and contractors who have been ordered, or will imminently be ordered, to take the vaccination series, or who have been administered the vaccine in violation of the FDA's mandated sequence protocol.

2. Defendant Department of Defense is the principal user of AVA. By order of the Secretary of Defense, the DoD is engaged in the practice of mass inoculations of active duty and reserve members of the Armed Forces, and civilian employees, without seeking the informed consent of those individuals prior to giving the vaccination.

3. Defendant Department of Health and Human Services ("HHS"), through its agent the FDA, is the federal agency responsible for licensing and quality control of drugs and biologic products, such as vaccines like the AVA. The FDA is responsible for promulgating federal regulations that describe whether a drug or vaccine is safe, effective, and not misbranded, or a drug unapproved for its applied use.

CLASS ACTION ALLEGATIONS

4. This action is brought by the plaintiffs, on their own behalf and on behalf of the class of all others similarly situated, under the provisions of Fed. R. Civ. P. 23(a) and (b).

5. The class so represented by the plaintiffs in this action, and of which they are members, consists of active duty, reservists and national guardsmen of the United States Armed Forces, as well as any civilian federal employees or DoD contractors who have taken, been ordered to take, or will be ordered to take, the anthrax vaccine.

6. The exact number of members of the class, as hereinabove identified and described, is not known, but it is estimated that there are in excess of 2.5 million members. The class is so numerous that joinder of individual members is impractical.

7. The relief sought is common to the entire class, and there are common questions of law and fact that relate to and affect the rights of each member of the class. These common questions include and involve whether the AVA is an IND, as defined by 21 U.S.C. § 355, or a drug unapproved for its intended use, pursuant to 10 U.S.C. § 1107, Executive Order 13139, DoD Directive 6200.2, and 21 C.F.R. § 201.5, or is being administered to United States military service members, federal employees and civilian defense contractors in violation of federal law. Certain defenses raised by the defendants would apply equally to all members of the class.

8. The claims of the plaintiffs are typical of the claims of the class in that the claims of all members of the class depend on a showing of the acts and omissions of defendants as giving rise to rights to the relief sought herein. There is no conflict as between the plaintiffs and other members of the class with respect to this action, or with respect to the claims for relief contained herein.

9. The plaintiffs are representative parties for the class, and are able to and will fairly and adequately protect the interests of the class. The attorneys for the plaintiffs are experienced and capable in litigating the claims at issue and have successfully represented claimants in other litigation matters of this nature. Attorneys John J. Michels, Jr. of McGuire Woods, LLP, and

Mark S. Zaid of Mark S. Zaid, P.C. will actively conduct and be responsible for the conduct of the action on behalf of the plaintiff class.

10. This action is properly maintained as a class action in that the prosecution of separate actions by individual members of the class would create a risk of adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of others not parties to the adjudications, or would substantially impair or impede their ability to protect their interests.

11. This action is properly maintained as a class action inasmuch as the questions of law and fact common to the members of the class predominate over any questions affecting only individual members, and a class action is superior to other available methods for the fair and efficient adjudication of the controversy.

JURISDICTION AND VENUE

12. There is a legitimate matter in controversy between the named parties because plaintiffs' claim that AVA is a drug unapproved for its applied use in the DoD vaccination program, requiring the Secretary of Defense and DoD to secure informed consent before DoD may administer AVA to them.

13. Plaintiffs will suffer substantial and irreparable injury if they are forced to take the vaccine because of defendants' failure to follow presidential orders and/or federal law requiring informed consent prior to the administration of a drug unapproved for its applied use to members of the Armed Forces.

14. Jurisdiction is proper in this Court under the Administrative Procedures Act, 5 U.S.C. § 702, and under 28 U.S.C. § 2201, which states that actions involving controversies with federal

agencies may be pursued in any United States District Court, and under 28 U.S.C. §§ 1331 and 1346.

FACTUAL BACKGROUND

A. Licensing History of Anthrax Vaccine Adsorbed

15. Anthrax Vaccine Absorbed ("AVA") is the only vaccine in the United States licensed as a prophylactic against any version of anthrax.

16. The vaccine was originally licensed as a preventive for cutaneous anthrax for "individuals who may come in contact with imported animal hides, furs, bone meal, wool, hair (especially goat hair), and bristles; for all personnel and factories handling these materials and for individuals contemplating investigational studies involving *Bacillus anthracis*."

17. The vaccine is licensed to be given in the following intervals: three 0.5 mL subcutaneous inoculations given two weeks apart followed by three 0.5 mL subcutaneous inoculations given at six, twelve and eighteen months.

18. A 2002 product insert revision (wherein AVA is referred to as "BioThrax") lists the categories of people who would benefit from immunization that is nearly identical to categories listed in the 1979 insert:

> BioThrax is indicated for the active immunization against Bacillus anthracis of individuals between 18 and 65 years of age who come in contact with animal products such as hides, hair or bones that come from anthrax-indemic areas, and that may be contaminated with Bacillus anthracis spores. BioThrax is also indicated for individuals at high risk of exposure to Bacillus anthracis spores such as veterinarians, laboratory workers, and others whose occupations may involve handling potentially infected animals or other contaminated materials. Since the risk of anthrax infection in the general population is low, routine immunization is not recommended.

19. The only human field trial of an anthrax vaccine ("the Brachman Study") was conducted in the 1950s at four mills where goat hair was processed.

20. The Brachman study involved approximately 1,200 mill employees of whom about 40 percent received the vaccine and the remainder received a placebo or nothing. The average yearly incidence of clinical anthrax in this population was 1 percent. During the evaluation period, 26 cases of anthrax occurred. Twenty-one of the affected individuals received no vaccine, four had incomplete immunizations and one completed the immunization process.

21. Based on analysis of attack rates per 1,000 person-months, the Brachman study indicated that the vaccine gave 93 percent (lower 95 percent confidence limit = 65 percent) protection against cutaneous anthrax based on comparison with the control group.

22. However, recent studies have concluded that Brachman's analysis is flawed and that the vaccine's effectiveness was not statistically significant in 75% of the mills studied.

23. Prior to licensing, the National Institute of Health ("NIH"), the federal licensing authority for biological products such as AVA, made clear that no existing studies (including the Brachman study) established the efficacy of AVA.

24. Notwithstanding the lack of proper evidence reflecting efficacy, NIH licensed AVA on November 2, 1970.

25. In 1972, the authority to regulate and license biologics (including vaccines like AVA) was transferred to FDA. In order to determine exactly what NIH-licensed products were actually effective, FDA promulgated regulations to evaluate the safety, effectiveness, and labeling of all NIH licensed biologics. Specifically, the regulations require the Commissioner to appoint an advisory panel, which must include qualified experts capable of reaching responsible medical

and scientific findings, to review the labeling of the products, and to advise the Commissioner "on which of the biological products under review are safe, effective, and not misbranded."

26. In accordance with the newly promulgated regulations, an advisory panel (the "Expert Panel"), independent of FDA, evaluated the entire AVA record and submitted its report in 1980.

27. The Expert Panel indicated in its report that although the vaccine appeared to offer protection against cutaneous anthrax under the limited circumstances for which it was employed, there was insufficient evidence to support an indication of its effectiveness against inhalation anthrax. However, it recommended that the FDA classify the AVA as safe and effective for its limited role in protecting commercial animal hide processing operations.

28. On December 13, 1985, the FDA issued a Proposed Final Rule and Order to adopt the Expert Panel's report verbatim and finalize FDA approval of the AVA license. However, after the closure of the 90-day comment period on March 13, 1986, the FDA took no further action on the panel's report until December 30, 2003.

29. Averring that there was no vaccine in current use which would safely and effectively protect military personnel against exposure to anthrax, the DoD (through the Department of the Army) issued a Request for Proposals ("RFP") No. DAMD17-85-R-0078, in 1985, soliciting the development of a new anthrax vaccine. Additionally, the Request for Proposals noted that AVA was highly reactogenic, required multiple boosters to maintain immunity, and might not protect against all strains of anthrax.

30. On October 20, 1995, the Army Joint Program Office for Biological Defense met to begin the process of obtaining FDA approval to modify its license to include an indication that AVA was effective against inhalation anthrax. At the meeting, the participants noted that studies

of AVA effectiveness in people working in tanneries showed protection against skin contact anthrax, but that there was insufficient data to demonstrate protection against inhalation anthrax.

31. On September 20, 1996, as part of the Army/SAIC plan, the AVA manufacturer, Michigan Biologic Products Institute ("MBPI", the successor to MDPH) submitted to the FDA an IND for AVA. The application was prepared, in whole or in part, by a U.S. Army agency located at Fort Detrick, Maryland.

32. The submission of the IND application was accompanied by a testing protocol designed to demonstrate effectiveness against inhalation anthrax in animals and correlate that effectiveness with comparable effectiveness in human subjects.

33. In December 1997, DoD announced a multi-service vaccination program for all active duty, Reserve and National Guard service members using AVA as a preventative for inhalation anthrax (the Anthrax Vaccine Immunization Program or "AVIP"). As part of this program, Plaintiffs and those similarly situated to them were ordered to submit to involuntary anthrax vaccinations.

34. In 2002, a Citizen Petition challenge to the safety and efficacy of AVA, noting FDA's unreasonable delay to finalize the 1985 Rule, was rejected. In the rejection letter, the FDA erroneously combined statistical categories to reach a combined number to validate the effectiveness of the vaccine against inhalation anthrax.

35. In March 2003, affected members of the U.S. military and several DoD employees filed suit, John Doe#1 et al. v. Rumsfeld et al., Civil Action No. 03-707, in the U.S. District Court for the District of Columbia asking the Court to enjoin the Anthrax Vaccine Immunization Program (AVIP) of the DoD, and to declare AVA an investigational drug when used for inhalation anthrax.

36. On December 22, 2003, the Court first granted the plaintiffs' Motion for Preliminary Injunction and enjoined the defendants from inoculating service members under AVIP in the absence of informed consent or a Presidential waiver of informed consent. Later, on October 27, 2004, the Court permanently enjoined the defendants from inoculating service members under AVIP because the vaccine was not properly licensed on procedural grounds, specifically that FDA failed to allow public comment, despite a substantial change in the basis for FDA's action. However, the Court explicitly declined to decide the substantive issues at that time.

37. In response, the FDA reopened the comment period for 90 days on the Bacterial Vaccines and Toxoids efficacy review document. As a result of the Court's decision, the DoD initiated a "voluntary" vaccination program.

38. On December 19, 2005, the FDA announced it was issuing its Final Rule and Order on characterization of AVA. FDA declared AVA to be safe, effective, and not misbranded, as protection against all forms of anthrax, and placed it in Category I.

39. The FDA based these findings in substantial part on the 1950s Brachman study and a CDC open label study performed in the 1960s. However, the FDA's Final Rule and Order failed to address the substantive licensing issues raised by plaintiffs in the first *Doe* litigation.

40. On October 16, 2006, DoD announced the resumption of the mandatory Anthrax Vaccine Immunization Program for military personnel and emergency-essential DoD civilians and contractors serving in the Iraq, Afghanistan and South Korea theatres (which would include individuals who could be deployed to such areas).

B. The FDA's reasoning for placing AVA in Category I is analytically flawed.

41. In its 2005 Final Rule and Order, the FDA asserts that the Brachman Study shows that AVA is effective against anthrax regardless of exposure. The FDA came to this conclusion by improperly combining the outcome of cutaneous anthrax cases with the small number of

inhalation anthrax cases. While admitting that there "are too few [inhalation anthrax cases] to support a meaningful statistical conclusion," the FDA still claimed that "the calculated effectiveness level against all reported cases of anthrax combined in those subjects was 92.5%."

42. Contrary to the FDA's averments, modern statistical analysis of Brachman data reveals that there is no statistical correlation between vaccination with AVA and inhalation anthrax protection. Indeed, Brachman himself admitted that "no assessment of effectiveness of the vaccine against inhalation anthrax could be made [from his study] because there were too few cases." The FDA's analysis of combining two difference outcomes (cutaneous and inhalation anthrax infection) to obtain a statistically favorable result for inhalation anthrax is statistically flawed, incompatible with normal FDA procedure, and represents an arbitrary and capricious decision-making process that violates the APA.

C. The current version of AVA is significantly different than the originally licensed version.

43. The original vaccine, manufactured by Defendant DoD at Fort Detrick, Maryland, went through significant manufacturing and formulaic changes to arrive at its current formulation. In fact, there are four different variations of the vaccine, produced by three different manufacturers. Subsequent to the completion of Brachman's study, the vaccine has undergone the following substantial alterations:

> (1) The strain of bacteria used to produce the vaccine was changed from R1-NP, a nonencapsulated, nonproteolytic mutant form of *B. anthracis* to V770-NP1-R.
>
> (2) The active and component ingredients were altered. The production process was changed "to increase the concentration of the active ingredient, known as 'protective antigen' (increasing the vaccine's potency), and to decrease the amount of other bacterial components in the vaccine thus increasing purity");
>
> (3) The AVA manufacturing method changed from using an aerobic method to using an anaerobic method.

(4) The AVA manufacturers changed from DoD personnel at Fort Detrick, to Merck Sharp & Dohme from 1960 to 1961, and finally to the Michigan Department of Public Health ("MDPH") in the mid-1960s.

(5) Further changes were made to the manufacturing process in order to scale up production. For example, in the 1960s, after the completion of the Brachman Study, the DoD changed the mutant B. anthracis strain used to produce the vaccine and use of an anaerobic culture method.

44. U.S. Army medical research personnel from Fort Detrick, Maryland determined in October 1990 that changes in the AVA manufacturing process (specifically to the fermenters and filters) resulted in a 100-fold increase in AVA protective antigen levels from previous versions of the vaccine.

45. The vaccine which FDA found to be safe, effective, and not misbranded based on the Brachman study is not the same vaccine as is currently being administered to the members of the military.

46. The FDA regulations mandate that changes in manufacturer, changes in manufacturing, and other alterations like those associated with AVA, require new clinical trials. However, the only human field trial conducted on AVA was performed with the earliest version of the vaccine and is now more than 40 years old.

47. FDA's failure to require new trials or re-licensing of the AVA is an abuse of discretion and an arbitrary and capricious failure to follow its own regulations.

D. The Anthrax Vaccine Immunization Program.

48. The MDPH, in its 1996 IND, expressed interest in pursuing certain labeling changes which would "affect the specific clinical indication, route and vaccination schedule for AVA." The FDA has not determined that any changes in the vaccination schedule are proper or consistent with the current license. On September 29, 1999, Dr. Kathryn Zoon, Director, FDA

Center for Biologic Evaluation and Research, wrote to Dr. Sue Bailey, Assistant Secretary of Defense Health Affairs and stated:

> We reiterate our previous statement made to DoD on December 16, 1997, that FDA approval of the anthrax vaccine is based on the six-dose regimen found in the approved labeling. Because we are unaware of any data demonstrating that any deviation from the approved intervals of doses found in the approved labeling will provide protection from anthrax infection, we strongly recommend that Anthrax Vaccine Immunization Program follow FDA approved schedule.

49. Beginning in July of 2000, the first of several reductions in the scope of the AVIP took place because of a failure by Bioport Corporation to meet federal manufacturing standards. DoD stated that it was suspending AVA vaccinations for all but a limited number of personnel because of a shortage of the vaccine.

50. As part of this suspension, DoD announced that members of the Armed Forces who had received at least one of the sequences of six vaccinations required by the AVA product license would be subject to a modified vaccination schedule that is inconsistent with the vaccination schedule required by the AVA license. Specifically, DoD announced that members who had received one or more vaccinations, but who had not completed the six shot sequence of vaccinations, would not be required to restart the inoculation sequence as long as they received a subsequent shot within two years of their last vaccination.

51. This modified schedule was never approved by the FDA. DoD's current vaccination program also intends to implement a schedule that is unapproved by the FDA.

52. Following an initial suspension in 2001 because of insufficient stock of AVA, DoD formally resumed the AVIP in June 2002. On August 6, 2002, DoD published policy guidance to component services. In part, the guidance stated that, "Those individuals that have had their doses deferred shall resume the series when directed …."

53. On October 11, 2002, the Chief of Staff, United States Air Force, promulgated an AVIP policy and guidance for all active duty and reserve units. The policy states, in Annex B, Paragraphs 4b:

> The Anthrax vaccine is a six-dose schedule [sic] followed by an annual booster. The vaccine doses are given at 0, 2 and 4 weeks, followed by doses at 6, 12, and 18 months, and an annual booster thereafter. The vaccine must be given in accordance with the above dosing schedule, as approved by the Food and Drug Administration (emphasis in original).

54. Notwithstanding the guidance to follow the licensed vaccination schedule, Paragraph 4c of Annex B states:

> Personnel whose vaccination series was interrupted during the pervious AVIP slowdown will not need to repeat any doses already received in the vaccine series or received extra doses. Once these individuals are identified as requiring the vaccine, they will just continue with the next dose in the series.

55. Upon information and belief, similar policies have been adopted by all other military services.

56. Following the FDA's Final Rule and Order of December 19, 2005, DoD issued a memorandum on October 12, 2006, to the Secretaries of the Military Departments, the Chairman of the Joint Chiefs of Staff, the Under Secretaries of Defense, the Assistant Secretaries of Defense, General Counsel for the DoD, the Inspector General of the DoD, the Directors of Defense Agencies, and the Commandant of the U.S. Coast Guard, regarding the resumption of the mandatory Anthrax Vaccine Immunization Program. In part, this memorandum stated: "Individuals whose vaccine series was interrupted are not required to restart the vaccine series, but will proceed in accordance with appropriate medical practice." Upon information and belief, the sentence means that service members who already had inoculations, no matter how long ago, will not take the shots in the FDA approved sequence.

57. The deviation from the licensed application schedule for AVA and the use of AVA in a mass inoculation effort represent an "off-label" use of the AVA by DoD. Indeed, DoD is currently seeking test subjects to validate its practice of altering the shot sequence.

58. The use of the AVA outside the licensed application schedule makes the AVA a drug unapproved for its applied use under 10 U.S.C. § 1107.

FIRST CAUSE OF ACTION
(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

59. Plaintiffs reallege the facts in Paragraphs 1 through 58 as if fully set forth in this Count.

60. To support its categorization of AVA as safe, effective, and not misbranded, FDA's 2005 Final Rule relies upon the Brachman Study, a field trial conducted in the 1950's, and a CDC observational safety study conducted from 1966 to 1971.

61. However, these studies are not scientifically sound and therefore cannot be used to prove that AVA is effective.

62. In its 2005 Final Rule and Order, FDA avers that the Brachman Study shows that AVA is effective against anthrax regardless of the route of exposure. In so finding, the FDA expressly rejects the Expert Panel's Report, which concluded "that the protection was limited to cutaneous anthrax cases," yet the FDA never conducted any new scientifically sound study. Rather, the FDA improperly combines the outcome of cutaneous anthrax cases with the small number of inhalation anthrax cases – which the FDA admits "are too few to support a meaningful statistical conclusion" if analyzed separately – and claims that "the calculated effectiveness level against all reported cases of anthrax combined in those subjects was 92.5%."

63. Contrary to the FDA's assertion, modern statistical analysis of Brachman data reveals that there is no statistical correlation between vaccination with AVA and inhalation anthrax protection.

64. In fact, Brachman himself admitted that "no assessment of the effectiveness of the vaccine against inhalational anthrax could be made [from his study] because there were too few cases." The Brachman "data simply do not provide statistically significant evidence of protection against inhalation anthrax…. [e]ven taking both cutaneous and inhalation anthrax into account, we found that the vaccine's protective effects were not significant in 75% of the mills tested."

65. FDA's analysis—combining two different outcomes (cutaneous and inhalation anthrax infection) to obtain a statistically favorable result—is incompatible with normal FDA procedure, and represents an arbitrary and capricious decision-making process that violated the APA.

66. Additionally, the CDC surveillance data from the observational safety study was much less well controlled than the Brachman field study. Its use was incompatible with normal FDA procedure and represents an arbitrary and capricious decision-making process that violated the APA.

67. FDA's 2005 Final Rule and Order also relies on animal studies to prove efficacy, which is an improper analysis under the requirements of 21 CFR § 601.25(d)(2). No correlate of immunity has ever been found between any of the animals tested and human beings, a requirement for the use of or reliance upon animal studies.

68. The FDA issued its Final Rule and Order in violation of its own internal procedures and requirements, and was so arbitrary and capricious as to amount to a violation of the APA.

69. The process that led to its issuance, and the factual support for the contents of the actual Final Rule Order, are completely inconsistent with FDA procedure and requirements.

70. The FDA has deviated from the procedures it uses for vaccines used in a civilian capacity. Additionally, the Final Rule and Order relies upon flawed and inconsistent data so as to nullify its validity.

71. Upon further information and belief, the FDA's Final Rule and Order was issued as a result of pressure by DoD and other sources to approve AVA.

72. Defendant's reliance on flawed scientific studies in licensing AVA is a violation of the Administrative Procedure Act.

SECOND CAUSE OF ACTION
(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

73. Plaintiffs reallege the facts in Paragraphs 1 through 58 as if fully set forth in this Count.

74. Statutory requirements at the time of AVA's initial licensing did not require that it be tested for efficacy.

75. When AVA was licensed in 1970 under the Public Health and Safety Act ("PHSA"), a manufacturer needed only to demonstrate safety, purity, and potency in support of a licensing decision. However, after 1972, under the Food, Drug, and Cosmetic Act ("FDCA"), a manufacturer must demonstrate that its vaccine is safe, effective, and not misbranded.

76. The standards articulated under the PHSA and the FDCA are different. Potency and efficacy are not synonymous. In order for a biological product to be licensed, it must be tested to ensure that it is "safe, pure, potent, and effective"

77. Thus, under its original 1970 license, AVA was never tested for efficacy.

78. In an attempt to rectify this oversight, FDA avers in its 2005 Final Rule and Order that the tests conducted prior to AVA's licensing, namely the Brachman Study and the CDC observational safety study show that AVA is effective to protect against anthrax infection regardless of the route of exposure.

79. However, these studies provide no scientific evidence of the AVA's efficacy.

80. Prior to licensing, NIH made clear that no existing studies (including the Brachman study) provided sufficient proof that AVA was effective.

81. FDA noted in its 1985 review of AVA that the vaccine's "efficacy against inhalation anthrax is not well documented ... no meaningful assessment of its value against inhalation anthrax is possible due to its low incidence."

82. Similarly, in 1999, Dr. Friedlander, an Army expert, observed that "[n]o assessment of the effectiveness of the vaccine against inhalation anthrax could be made because there were too few cases" in the original Brachman study.

83. Likewise, a 2002 Institute of Medicine ("IOM") Report stated that "the small number of inhalation anthrax cases in those studies provides insufficient information to allow a conclusion about the vaccine's efficacy against inhalation infection to be made."

84. Thus, no study utilized by FDA has shown that AVA is effective against inhalation anthrax, which means the vaccine is a drug unapproved for its applied used under 10 U.S.C § 1107.

85. Defendant's failure to prove that AVA is effective is a violation of the Administrative Procedure Act.

THIRD CAUSE OF ACTION
(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

86. Plaintiffs reallege the facts in Paragraphs 1 through 58 as if fully set forth in this Count.

87. Although the original version of the anthrax vaccine underwent a human field trial (the "Brachman study"), the current version of the vaccine (AVA) has never been employed in a controlled field trial.

88. Since the Brachman study, the anthrax vaccine has undergone significant manufacturing and formulaic changes.

89. However, FDA has approved AVA without requiring additional trials to ensure that the vaccine in its current state is safe and effective.

90. No single manufacturer of AVA created a successor product, and so the FDA's "comparability policy" does not apply. The FDA's "comparability policy" simply allows a single manufacturer to make minor manufacturing changes to a product without performing additional clinical studies to demonstrate the safety and efficacy of the successor product. Rather, four different variations of AVA were manufactured by three different manufacturers. Since the vaccine's inception, DoD, Merck, Sharp & Donne, and the Michigan Department of Public Health each have manufactured different variations of AVA.

91. Defendants approved the altered vaccine without subjecting it to further clinical trials.

92. The FDA's actions violated its own rules and regulations and are therefore a violation of the Administrative Procedure Act.

FOURTH CAUSE OF ACTION
(VIOLATION OF 10 U.S.C. § 1107)

93. Plaintiffs reallege the facts in Paragraphs 1 through 58 as if fully set forth in this Count.

94. 10 U.S.C. § 1107 (2000) provides that investigational new drugs or drugs unapproved for their applied uses may not be given to members of the Armed Forced without their informed consent except in the case of a waiver by the President of the United States.

95. Similarly, Executive Order 13139 states that before administering an investigational drug or a drug unapproved for its intended use to members of the Armed Forces, the DoD must obtain informed consent from each individual unless a waiver of this requirement is signed by the President of the United States.

96. DoD has adopted the requirements of 10 U.S.C. § 1107 and Executive Order 13139 and set up procedures to follow these requirements in DoD Directive 6200.2 dated August 1, 2000.

97. AVA's license sets forth a specific vaccination schedule.

98. Since 2000, DoD has been following a vaccination schedule inconsistent with the schedule required by the AVA license.

99. Therefore, DoD is or will be inoculating the plaintiffs and all similarly situated individuals “off-label.” This deviation from the required vaccination schedule is a new and unapproved use of AVA by DoD.

100. Such new uses of a product that are not in accordance with product labeling render AVA a drug “unapproved for its intended use” under 21 C.F.R. § 201.5, and subject to the requirements of 10 U.S.C. § 1107 (2000), Executive Order 13139 and DoD Directive 6200.2.

101. Under 10 U.S.C. § 1107, a drug unapproved for its intended use may not be given to members of the Armed Forces without their prior consent.

102. Plaintiffs are part of an inoculation program first instituted by DoD in 1997, and reconstituted in October 2006, and have not been given nor will be given the opportunity for informed consent before being inoculated. In fact, DoD is not providing informed consent to any of its service members prior to inoculating them.

103. Therefore, the Defendant’s failure to comply with the vaccination schedule coupled with its mandatory inoculation program is a violation of 10 U.S.C. § 1107.

WHEREFORE, Plaintiffs, and those similarly situated to them, respectfully ask this Court to:

A. Find and declare that as a result of the unilateral change in vaccination schedule by defendant DoD, AVA is a drug unapproved for its applied use within the meaning of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2;

B. Find and declare that AVA is an improperly licensed biologic product under FDA regulations and, therefore, is a drug unapproved for its applied use within the meaning of 10 U.S.C. § 1107, Executive Order 13139 and DoD Directive 6200.2;

C. Find and declare that AVA is an improperly licensed biologic product under FDA regulations as there is no valid evidence of human efficacy;

D. Find and declare that AVA is an improperly licensed biologic product under FDA regulations as it is being used in a manner that is inconsistent with the license and product labeling;

E. Vacate the FDA's Final Rule and Order of December 19, 2005, as being arbitrary and/or capricious and not based on the facts under the Administrative Procedure Act;

F. Enjoin defendant DoD from inoculating the plaintiffs, and those similarly situated to them, without informed consent, or in accordance with the provisions of 10 U.S.C. § 1107, Executive Order 13139 and DoD Directive 6200.2; and

G. Award plaintiffs their costs and attorneys' fees and any other relief this Court may find appropriate.

Date: December 13, 2006

Respectfully submitted,

/s/

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