

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

SONNIE BATES :
P.O. Box 195 :
Ellendale, Delaware 19941, :

and :

CAPTAIN JOHN BUCK, :
UNITED STATES AIR FORCE :
307 General Pershing Avenue :
Ocena Springs, Mississippi 35564, :

and :

OTHER SIMILARLY SITUATED :
INDIVIDUALS. :

Plaintiffs, :

vs. :

Case No. _____

DONALD H. RUMSFELD, :
SECRETARY OF DEFENSE :
DEPARTMENT OF DEFENSE :
1000 Defense Pentagon :
Washington, D.C. 20301 :

and :

TOMMY THOMPSON :
SECRETARY OF HEALTH AND HUMAN :
SERVICES :
200 Independence Avenue, S.W. :
Washington, D.C. 20201, :

and :

BERNARD A. SCHWETZ :
ACTING PRINCIPAL DEPUTY :
COMMISSIONER :
FOOD AND DRUG ADMINISTRATION :
5600 Fishers Lane :
Rockville, Maryland 20857-0001, :

and :

BIOPORT, INC. :
3500 N. Martin Luther King, Jr. Boulevard :
Lansing, Michigan 48906, :

Defendants. :

COMPLAINT

Plaintiffs, Sonnie Bates and Captain John Buck, on behalf of themselves and all other similarly situated individuals, by counsel, file this action for declaratory relief against Defendants Donald Rumsfeld, Secretary of Defense, Department of Defense, Tommy Thompson, Secretary of Health and Human Services, Department of Health and Human Services, Bernard A. Schwetz, Acting Principal Deputy Commissioner, Food and Drug Administration, and BioPort, Inc., seeking a declaration pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* (1999) that the Anthrax Vaccine Adsorbed (“AVA”), currently being involuntarily administered to U.S. Armed Forces members, is an investigational new drug (“IND”), as defined by 21 U.S.C. § 355, or a drug unapproved for its intended use pursuant to 10 U.S.C. § 1107 and Executive Order 13139.

PARTIES

1. Plaintiff Sonnie Bates (“Bates”) is a resident of Delaware and a former active-duty Air Force pilot who was discharged following disciplinary action for refusal to take the anthrax vaccine. Plaintiff John Buck (“Buck”) is a resident of Mississippi and a current active duty Air Force physician facing court-martial charges for failure to take the anthrax vaccine. Similarly situated individuals include some 500 current and former members of the Armed Forces who have been disciplined or forced to resign for failure to take the AVA after being ordered to do so, and all active duty members who may subsequently be ordered to take the vaccination.

2. Defendant Department of Defense (“DoD”), represented by the Secretary of Defense, is the principal user of AVA. The DoD has, since 1997, engaged in the practice of mass inoculations of active duty members of the Armed Forces without seeking the informed

consent of those members prior to giving the vaccination. The DoD was and is heavily involved in the manufacturing and licensing process for the AVA.

3. Defendant Department of Health and Human Services (“HHS”) through its agent, Defendant Food and Drug Administration (“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 what makes a drug or vaccine “IND” and how a drug is placed in IND status.

4. Defendant Bioport, Inc. (“BioPort”), a Michigan company with its sole place of business in Michigan, is the current owner of the license to manufacture the AVA. Preceding BioPort as vaccine manufacturer was the Michigan Department of Public Health (“MDPH”), and Michigan Biologic Products, Inc. (“MBPI”). MDPH and MBPI owned the AVA production license until September, 1998, when BioPort purchased the corporation. BioPort is the sole manufacturer and licensee for AVA, and is producing the AVA using equipment, facilities and personnel paid for solely by DoD, rendering BioPort the agent of DoD for purposes of this action.

JURISDICTION

5. Jurisdiction is proper in this Court 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.

VENUE

6. There is a legitimate matter in controversy between the named parties because Plaintiffs claim that the AVA is an IND, requiring DoD to secure their informed consent before DoD may administer the AVA to them. BioPort manufactures the AVA and has submitted an IND application for the AVA to amend the license, rendering the AVA an IND in circumstances

germane to this suit. The FDA has not spoken definitively on this issue and to date, its agents have issued only personal opinions with no legal effect concerning the status of the vaccine.

7. Plaintiffs have suffered substantial injury, and will continue to suffer substantial injury, as a result of FDA's failure to define the AVA's status as an IND and because of DoD's failure to follow presidential orders and federal law requiring informed consent prior to the administration of an IND to members of the Armed Forces.

FACTUAL BACKGROUND

8. AVA was originally licensed as a vaccine against anthrax on November 2, 1970 by the United States Public Health Service.

9. The vaccine was licensed as a preventive for 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*." See Attachment A, Anthrax Vaccine Absorbed product insert extract, December 1979.

10. A 1987 product insert revision stated that:

Immunization with Anthrax Vaccine Absorbed 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 . . . It is also recommended for high-risk persons such as veterinarians and others handling potentially infected animals. Since the risk of exposure to anthrax infection in the general population is slight, routine immunization is not recommended.

See Attachment B, 1987 Anthrax Vaccine Absorbed Product Insert.

11. The license for AVA states that "primary immunization consists of three subcutaneous injections, 0.5mL each, given two weeks apart followed by three additional subcutaneous injections, 0.5mL each given at 6, 12 and 18 months." See Attachment B.

12. In 1985, the DoD (through the Department of the Army) issued a Request for Proposals (“RFP”) No. DAMD17-85-R-0078 soliciting the development of a new anthrax vaccine. The Request for Proposals stated that there was no vaccine in current use which would safely and effectively protect military personnel against exposure to anthrax. 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. See Attachment C, RFP DAMD17-85-R-0078.

13. On December 13, 1985, the FDA published a Proposed Rule for a specific product review of the AVA, stating 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.” See Attachment D, Federal Register, December 13, 1985.

14. On August 24, 1989, Assistant Secretary of Defense Robert B. Barker wrote in a letter to Senator John Glenn that “current vaccines, particularly the anthrax vaccine do not readily lend themselves to use in mass troop immunizations for a variety of reasons . . . a higher than desirable rate of reactogenicity and, in some cases, lack of strong enough efficacy against infection by the aerosol route of exposure.” See Attachment E, Letter to Senator Glenn and excerpt.

15. In March, 1990, Army doctors Col. Takafuji and Col. Phillip K. Russell described the anthrax vaccine as a “limited use vaccine” and an “unlicensed experimental vaccine” in an article, “Military Immunizations”, in *Infectious Disease Clinics of North America*.

16. In 1991 Army Secretary Michael P. W. Stone approved a request to indemnify the anthrax vaccine manufacturer, MBPI (the predecessor to current BioPort) against all liability arising from “the unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA.” The indemnification concerns were a result of

the limited use of the vaccine on too small a scale to permit accurate assessments of types and severities of adverse reactions and insufficient experience in mass immunization programs to evaluate the efficacy of the vaccine. See Attachment F, Indemnification Agreement, September 3, 1991.

17. In 1995 the Department of the Army contracted with the SAIC Corporation to develop a plan to obtain FDA approval for a license amendment for AVA. The purpose of the license amendment was to add aerosolized anthrax exposure to the product license and to enable the manufacturer of the vaccine to list on the product license that AVA was effective against inhalation anthrax.

18. The SAIC license amendment plan states that the AVA is not licensed as protection for aerosol anthrax exposure as expected in a biological warfare environment. See Attachment G, October 5, 1995 License Amendment Plan.

19. On October 20, 1995, the Army Joint Program Office for Biological Defense met to begin the process of obtaining the FDA license modification to include an indication that the AVA was effective against inhalation anthrax. At the meeting, the participants noted that studies of the 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. See Attachment H, Minutes of October 20, 1995 Meeting.

20. On September 20, 1996, as part of the Army/SAIC plan, the vaccine manufacturer, MBPI submitted an investigational new drug application for AVA. The application was prepared, in whole or in part, by a U.S. Army agency located at Fort Detrick, Maryland. The purpose for filing the IND application was 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.” See Attachment I, September 20, 1996 Letter to Dr. Kathryn C. Zoon.

21. The Introductory Statement from the IND application states that “[t]he ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule.” See Attachment J, IND Introductory Statement.

22. 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.

23. FDA regulations found at 21 C.F.R § 312 cover the licensing requirements for biologic products such as AVA.

24. Under FDA regulations, a drug may be placed in investigational new drug status, even when the drug is properly licensed for use, if the drug is used for a different purpose or in a different manner other than that specified in the license.

25. Under FDA regulations, a drug is placed in investigational new drug status when a manufacturer files an investigational new drug application seeking a product license change reflecting a different use for the product.

26. Under FDA regulations, a manufacturer which files an IND application seeking to change the license for a vaccine to show the vaccine as effective against a different method of infection uses the vaccine in IND status if the vaccine is used for the purpose for which the license amendment is sought.

27. The investigational new drug application filed by MBPI sought a license amendment for AVA stating that AVA is effective against inhalation anthrax.

28. In December 1997, DoD announced a multi-service vaccination program for all active duty, Reserve and National Guard service members using the AVA as a preventative for inhalation anthrax.

29. As part of this program, Bates and Buck, and those similarly situated to them, were ordered to submit to involuntary anthrax vaccinations.

30. As a result of their refusal to comply with orders to take the AVA inoculations, Bates, Buck and those similarly situated to them have been subjected to military disciplinary actions, including courts-martial convictions, forfeitures of pay and allowances, incarceration, and administrative separation from the Armed Forces.

31. The AVA IND application submitted by BioPort has been supplemented and remains current and pending. See Attachment K, IND Application Supplements.

32. BioPort's subsequent submissions as part of the IND application process indicate that the license modification being sought is currently only for inhalation anthrax. Id.

33. The DoD inoculation program currently underway is designed to specifically inoculate members of the Armed Forces against inhalation anthrax.

34. The use of AVA for a purpose which is the subject of a currently pending IND application, i.e. as a preventative against inhalation anthrax, means that DoD is using AVA as an IND.

35. By Memorandum of Decision dated April 1998, Army Secretary Togo West, Jr. took steps to approve a request to indemnify the anthrax vaccine manufacturer, Michigan Biologic Products Institute (the predecessor to current BioPort) against all liability arising from "the unusually hazardous risks associated with potentially severe adverse reactions and the potential lack of efficacy of the AVA." The indemnification concerns, according to Secretary West, were a result of the limited use of the vaccine on too small a scale to permit accurate

assessments of types and severities of adverse reactions and, insufficient experience in mass immunization programs to evaluate the efficacy of the vaccine. See Attachment L, Indemnification Agreement. By Memorandum of Decision dated September 3, 1998, Army Secretary Louis Caldera again authorized indemnification of the AVA manufacturer because:

the obligation assumed by MBPI under this contract involves unusually hazardous risks associated with the potential for adverse reactions in some recipients and the possibility that the desired immunological effect will not be obtained by all recipients. Although AVA has been extensively tested under the auspices of the Food and Drug Administration, the size of the proposed vaccination program may reveal unforewarned idiosyncratic adverse reactions. Moreover, there is no way to be certain that the pathogen used in tests measuring vaccine efficacy will be sufficiently similar to the pathogen that U.S. forces might encounter to confer immunity.

36. 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 the Anthrax Vaccine Immunization Program follow FDA approved schedule.

See Attachment M, September 29, 1999 Letter to Bailey.

37. In June, 2000, DoD announced that it was suspending AVA vaccinations for all but a limited number of personnel because of a shortage of the vaccine.

38. As part of this suspension, DoD announced that members of the Armed Forces who had received at least one of the sequence 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 an additional shot within two years of their last vaccination.

39. The AVA license and labeling specifies that the product is to be used in a six-shot sequence, with three vaccinations given two weeks apart followed by three additional injections at six, twelve and eighteen-month intervals.

40. The deviation from the licensed application schedule for AVA and the use of AVA in a mass inoculation effort represent new uses of the AVA by DoD.

41. Such new uses of a product that are not in accordance with product labeling render the AVA “investigational” under FDA regulations and makes the AVA a drug “unapproved for its intended use”, and subject to the requirements of 10 U.S.C. § 1107 (2000).

42. 10 U.S.C. § 1107 (2000) provides that investigational new drugs or drugs unapproved for their intended uses may not be given to members of the Armed Forces without their prior consent except in the case of a waiver by the President of the United States.

43. 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.

44. The declaration that AVA is an IND does not preclude the use of AVA by DoD, as long as the appropriate consent or waiver is obtained.

45. 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.

46. The FDA has never officially approved the AVA for use against inhalation anthrax.

47. The FDA has never issued an official opinion that DoD's use of AVA is consistent with AVA license requirements, or that the AVA is being used in accordance with the current license for the product.

CAUSE OF ACTION

DECLARATORY JUDGMENT

48. Because of the actions of the DoD, FDA and BioPort, Plaintiffs have a real and actionable controversy requiring this Court's resolution, specifically, whether the AVA is an investigational new drug as defined by FDA's statutes and regulations.

49. The submission of an Investigational New Drug application by DoD and BioPort for AVA for inhalation anthrax renders the drug an investigational new drug if used as a preventive against inhalation anthrax.

50. The DoD's alteration of the licensed and FDA approved schedule of vaccinations and use of AVA in a mass inoculation program renders the AVA a drug unapproved for its intended or applied use within the meaning of 21 U.S.C. § 355; 10 U.S.C. § 1107 and Executive Order 13139.

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

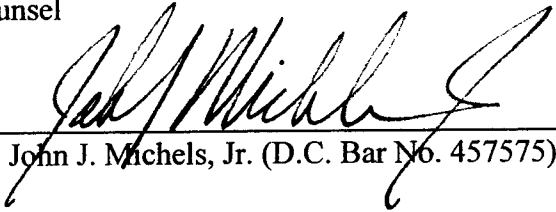
- (a) Find and declare that the AVA is an investigational new drug within the meaning of 10 U.S.C. § 1107 and Executive Order 13139;
- (b) Find and declare that the AVA has been in investigational new drug status since the original investigational new drug application was filed on September 20, 1996;

- (c) Find and declare that the AVA has also been in investigational status as a result of the unilateral change in vaccination schedule by DoD in June, 2000;
- (d) Find and declare that the AVA is a drug unapproved for its intended use within the meaning of 10 U.S.C. § 1107 and Executive Order 13139 as of December, 1997; and
- (e) Award Plaintiffs their costs and attorney's fees and any other relief this Court may find appropriate.

Respectfully submitted,

SONNIE BATES
JOHN BUCK
By Counsel

By:


John J. Michels, Jr. (D.C. Bar No. 457575)

McGUIREWOODS LLP
1750 Tysons Boulevard, Suite 1800
McLean, Virginia 22102-4215
(703) 712-5350

Of counsel

Mark S. Zaid, Esq.
Lobel, Novins & Lamont
1275 K Street, N.W.
Suite 770
Washington, D.C. 20005