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JOHN DOE # 1, JOHN DOE # 2, JOHN DOE # 3, JOHN DOE # 4, JANE DOE # 1, JANE DOE # 2, c/o Mark S. Zaid, Esq., Krieger & Zaid, PLLC, 1747 Pennsylvania Avenue, N.W., Suite 300, Washington, D.C. 20006 and OTHER SIMILARLY SITUATED INDIVIDUALS, Plaintiffs, vs. 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 MARK B. McCLELLAN, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane, Rockville, Maryland 20857-0001, Defendants.

Civil Action No. 1:03-cv-00707-EGS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Pleadings 707; 2004 U.S. Dist. Ct. Pleadings LEXIS 4434

January 6, 2004

Complaint

VIEW OTHER AVAILABLE CONTENT RELATED TO THIS DOCUMENT: U.S. District Court: Brief(s); Motion(s); Pleading(s)

TITLE: [**1] **FIRST AMENDED COMPLAINT**

TEXT: [*2] CLASS ACTION COMPLAINT

Plaintiffs John Doe # 1, John Doe # 2, John Doe # 3, John Doe # 4, Jane Doe # 1 and Jane Doe # 2, on behalf of themselves and all other similarly situated individuals, file this action against defendants Donald Rumsfeld, Secretary of Defense, Department of Defense ("DoD"), Tommy Thompson, Secretary of Health and Human Services, Department of Health and Human Services, and Mark B. McClellan, Commissioner, Food and Drug Administration ("FDA"), seeking temporary and permanent injunctive relief from the DoD's anthrax vaccination program, as well as a declaratory judgment that Anthrax Vaccine Adsorbed ("AVA"), currently being involuntarily administered to active and Reserve U.S. Armed Forces members and DoD civilian employees, 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*, 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 *2 of federal [**2] 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 DoD contractors who have been ordered, or will imminently be ordered, to take AVA as part of their military duties or employment obligations, or have been administered AVA in violation of the FDA's mandated sequence protocol. Similarly situated individuals include current members of the active duty, reserve members 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, represented by the Secretary of Defense, is the principal user of AVA. By order of the Secretary of Defense, the DoD has, since 1998, engaged [*3] in the practice *3 of mass [**3] 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. The Secretary of Defense is personally responsible for compliance with his own directives.

3. The DoD was and is heavily involved in the manufacturing and licensing process for the AVA and is considered the de facto manufacturer of AVA by the FDA.

4. Defendant Department of Health and Human Services ("HHS"), through its agent 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 an "IND" and how a drug is placed in IND status.

JURISDICTION AND VENUE

5. There is a legitimate matter in controversy between the named parties because Plaintiffs claim that AVA is a) an IND, b) an unlicensed or improperly licensed vaccine, and c) being used "off label", requiring the Secretary of Defense and DoD to secure Plaintiffs' informed consent before DoD may administer AVA to them. The AVA manufacturer has submitted *4 an [**4] IND application for the AVA to amend the license, rendering AVA an IND in circumstances germane to this action.

6. 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 an IND to members of the Armed Forces.

7. 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*.

[*4] **CLASS ACTION ALLEGATIONS**

8. 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).

9. 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 [**5] *5 or DoD contractors who have taken, been ordered to take, or will be ordered to take, the anthrax vaccine.

10. 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.

11. 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.

12. 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 [**6] *6 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.

[*5] 13. 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 Krieger & Zaid, PLLC, will actively conduct and be responsible for the conduct of the action on behalf of the plaintiff class.

14. 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. [**7] *7

15. 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.

FACTUAL BACKGROUND

A. Anthrax Vaccine Adsorbed

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

17. 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 Adsorbed product insert, December 1979.

[*6] 18. A 2002 product insert revision (the AVA is referred to as "BioThrax") stated that:

> 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 [**8] products *8 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.

See Attachment B, 2002 Anthrax Vaccine Adsorbed Product Insert.

19. 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."

Id.

20. 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 [**9] AVA was highly *9 reactogenic, required multiple boosters to maintain immunity, and might not protect against all strains of anthrax. See Attachment C, RFP DAMD17-85-R-0078.

B. FDA Failure to Finalize AVA Licensing

21. In 1985, as part of an FDA biologic and drug licensing review, the Biologics Review Panel, an independent advisory panel to the FDA, recommended that the FDA classify the AVA as "not misbranded". The FDA issued a Proposed Rule to adopt the Panel's recommendations and finalize FDA approval of the AVA license. A 2001 Citizen Petition challenge to the FDA's unreasonable delay to finalize the Rule was rejected. See Attachment D, August 28, 2002 letter to Russell Dingle in response to Citizen Petition Docket No. 01P-0471/CP1 ("Response to Citizen Petition"). However, in direct response to this litigation, after 18 years, on December 30, 2003, the FDA announced it was issuing its Final Rule and Final Order Regarding Safety and [*7] Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine. The alleged Final Rule was published in the Federal Register on January 5, 2004, at *http://www.fda.gov/cber/rules/ bvactox.pdf*.

22. The FDA's delayed [**10] issuance of *10 its Final Rule and Order was undertaken in violation of its own internal procedures and requirements, and was so arbitrary and capricious as to amount to bad faith. The circumstances that led to its issuance, and the contents of the actual Final Rule Order, are nothing less than extraordinary and are completely inconsistent with the prior history of FDA Final Rules. Upon information and belief, the FDA would never permit a private drug manufacturer to rely upon the type of information cited in the FDA's Final Rule and Order for purposes of vaccine licensing or efficacy studies. Additionally, the Final Rule and Order relies upon flawed and inconsistent data so as to nullify its application. Upon further information and belief, the FDA's Final Rule and Order was issued as a result of policy pressures by DoD and other sources.

C. AVA is Not Licensed for Use Against Inhalation Anthrax

23. In addition, on December 13, 1985, as part of its license review process, the FDA published 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 [**11] anthrax is possible *11 due to its low incidence." See Attachment E, Federal Register, December 13, 1985.

24. In early 1990, the AVA manufacturer, then the Michigan Department of Public Health ("MDPH"), modified its production process for AVA to accommodate DoD needs. U.S. Army medical research personnel from Fort Detrick, Maryland, determined in October 1990, that these changes in the AVA manufacturing process resulted in a 100-fold increase in AVA protective antigen levels. See Attachment F, Testimony of Nancy Kingsbury, United States General Accounting Office, before the Sub-Committee on National Security, Veterans' Affairs and International Relations, Committee on Government Reform, House of Representatives,

October 23, 2001, Page 5-6.

[*8] 25. In March 1990, Army doctors Colonel Ernest T. Takafuji and Colonel Phillip K. Russell described AVA as a "limited use vaccine" and an "unlicensed experimental vaccine" in an article, "Military Immunizations: Past, Present and Future Prospects", published in *Infectious Disease Clinics of North America*.

26. In 1995 the Army contracted with the Science Applications International Corporation ("SAIC") to develop a plan to obtain [**12] FDA approval for a license *12 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 AVA to list on the product

license that AVA was effective against inhalation anthrax.

27. The SAIC license amendment plan, ultimately adopted by the Army, states that 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.

D. The AVA Becomes an Investigational New Drug

28. 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 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. See Attachment H, Minutes of October 20, 1995 Meeting.

29. On August 26, 1996, as a precursor to changing the AVA license by filing an investigational [**13] new drug application, the Army's *13 Medical Research Institute of Infectious Diseases ("USAMRIID") discussed the purpose of the IND application by saying, "We wish to obtain an indication for protection against inhalation anthrax and to reduce the number of doses to two primary doses with a booster due at one year. These two goals will be studied and discussed as separate issues." See Attachment I (Col. Arthur O. Anderson, Chairman, USAMRIID Human Use Committee), "Comparative Study of the Safety and Immunogenicity of Two-Dose Priming Schedule of Human Anthrax Vaccine," August 26, 1996.

[*9] 30. 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 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.

31. The manufacturer's stated 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, [**14] route and vaccination schedule *14 for AVA." See Attachment J, September 20, 1996, MBPI Letter to Dr. Kathryn C. Zoon.

32. The Introductory Statement from the IND application states that "the ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule." See Attachment K, IND Introductory Statement.

33. 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.

34. FDA regulations found at 21 C.F.R § 312 address the requirements for IND status for biologic products such as AVA.

35. 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 than that specified in the license.

36. 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.

37. Under [**15] FDA regulations, a manufacturer *15 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.

[*10] 38. The investigational new drug application filed by MBPI sought a license amendment for AVA stating that AVA is effective against inhalation anthrax.

39. On December 13, 1996, the FDA sent a letter to the Department of the Army, following the Army's publishing of an advertisement in the Washington Post on October 15, 1996, seeking experimental test subjects for the investigation proposed in the AVA IND application. The December 13 letter advised the Army agency that it could not represent the vaccine as fully licensed when the Army was conducting tests pursuant to an IND application. Specifically, the letter advised the Army that the vaccine was not licensed for the indication for which the IND application was filed. See Attachment L, FDA letter of December 13, 1996.

40. The only indication for which the AVA IND application was filed was for inhalation anthrax.

E. DoD [**16] **Uses AVA as an IND**

41. In December *16 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.

42. As part of this program, Plaintiffs and those similarly situated to them were ordered to submit to involuntary anthrax vaccinations.

43. If they refuse to comply with orders to take the AVA inoculations, the military Plaintiffs, and those similarly situated to them, will be subject to military disciplinary actions, including courts-martial convictions, forfeitures of pay and allowances, incarceration, bad conduct discharges, and administrative separation from the Armed Forces. Civilian Plaintiffs will be fired from their positions as DoD employees or defense contractors. Those individuals who take the anthrax vaccine will be subject to significant adverse health effects, including the possibility of death or permanent disability, and will not even receive full protection given the DoD's continuing violation of the FDA required vaccination sequence schedule of six shots in 18 months followed by an annual booster.

[*11] 44. In December 1997, the Joint [**17] Program Office for Biological Defense, an agency *17 of Defendant Department of Defense, noted that "Anthrax and Smallpox are the only licensed vaccines that are useful for the biological defense program, but they are not licensed for a biological defense indication." See Attachment M, Appendix G, "Industrial Capabilities Assessment Summary Report for the Production of the Anthrax Vaccine, Preliminary Report," December 1997, Joint Program Office for Biological Defense, Falls Church, Virginia.

45. The AVA IND application submitted by MBPI (now BioPort) has been supplemented and remains current and pending. See Attachment N, IND Application Supplements.

46. 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.

47. The DoD inoculation program currently underway is specifically designed to inoculate members of the Armed Forces against inhalation anthrax, which has a high mortality rate and is identified by DoD as a military threat.

48. The use of AVA for a purpose which is the subject of a currently pending IND application, i.e. as a preventative against inhalation [**18] anthrax, means that DoD is using AVA as an IND. *18

49. 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 the current manufacturer, 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 O, Indemnification Agreement.

50. By Memorandum of Decision dated September 3, 1998, Army Secretary Louis Caldera again authorized indemnification of the AVA manufacturer because:

> [*12] 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 [**19] effect will not be obtained by all recipients. . . . *19 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.

F. DoD Deviates From the AVA License Requirements

51. 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 P, September 29, 1999 Letter to Bailey.

52. In July 2000, DoD announced the first of several reductions [**20] in the scope of the AVIP because of a failure by Bioport *20 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.

53. 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 [*13] 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.

54. 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. . . ." See Attachment Q, August 6, 2002, Memorandum on Policy on Administrative Issues [**21] Related to the Anthrax Vaccine Immunization Program (AVIP). *21

55. 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, Paragraph 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).

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

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

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

57. The deviation from the licensed application [**22] schedule for AVA and the use of AVA in a mass inoculation effort represent *22 new uses of the AVA by DoD. Indeed, DoD is currently seeking test subjects to validate its practice of altering the shot sequence.

58. 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 [*14] 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.

G. Federal Law and Regulations Prohibit the Use of INDs Without Informed Consent of Recipients

59. *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.

60. 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 [**23] of this requirement is signed by the President of the United States.

61. A judicial *23 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.

62. 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.

63. Peer-reviewed statistical analysis of adverse reactions associated with AVA vaccinations published by research physicians indicates substantial increases in joint-related medical conditions such as arthralgia, arthritis, myalgia, and others following AVA vaccination.

64. A similar analysis of adverse events for AVA shows a substantial increase in gastrointestinal adverse reactions as well.

65. Moreover, informed consent documents provided by the Center for Disease Control to civilian postal workers and congressional staff in the Fall of 2001 indicated adverse reactions including death, birth defects and a wide range of autoimmune disorders that were not included in the then-current March 1999 FDA-approved package insert. These adverse reactions were never disclosed [**24] to service members subject to mandatory vaccinations with AVA. The Center for Disease *24 Control is a subordinate entity of Defendant Department of Health and Human Services.

[*15] 66. In January 2002, the FDA-approved product insert for AVA was modified to include the above adverse reactions such as death, birth defects and autoimmune disorders, consistent with the informed consent provided to civilians in the Fall of 2001. The new FDA-approved package insert also changed the "use in pregnancy" rating from Category C ("risk cannot be ruled out") to Category D ("positive evidence of risk"). This information has not been provided to service members, and service members are not provided with a copy of the FDA-approved package insert prior to mandatory vaccination.

FIRST CAUSE OF ACTION

(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

67. Plaintiffs reallege the facts in Paragraphs 1 through 66 as if fully set forth in this Count.

68. Defendant DoD will inoculate Plaintiffs with the AVA within the immediate future. Defendant DoD notified Plaintiffs that they will be ordered to submit to AVA inoculation shortly, in some cases within 30 days.

69. The submission of [**25] an Investigational New Drug application by DoD and BioPort for AVA for inhalation anthrax *25 renders the drug an investigational new drug if used as a preventative against inhalation anthrax.

70. The DoD's actions in ordering Plaintiff's to submit to vaccination with an investigational new drug, without seeking the Plaintiff's informed consent, violate a federal statute, namely *10 U.S.C. § 1107*, as well as Executive Order 13139 and DoD Directive 6200.2.

71. The Defendant's failure to follow federal law, a presidential executive order and DoD regulations in its AVIP creates a legal wrong against the Plaintiffs. Plaintiffs are entitled to seek review of Defendant's actions under the Administrative Procedure Act, *5 U.S.C. § 702*.

SECOND CAUSE OF ACTION

(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

72. Plaintiffs reallege the facts in Paragraphs 1 through 66 as if fully set forth in this Count.

73. Defendant's use of an unlicensed or improperly licensed vaccine is a violation of Food and Drug Administration regulations found at 21 C.F.R. § 312, and a violation of the Food and [*16] Drug and Cosmetic Act, *21 U.S.C. § 301*, [**26] et seq., and also means that DoD is using a drug unapproved for *26 its intended use. DoD's actions violate *10 U.S.C. § 1107*, Executive Order 13139, and DoD Directive 6200.2.

74. Defendant's intent to inoculate Plaintiffs with an unlicensed drug, unapproved for its intended use, is a legal wrong against Plaintiffs, entitling them to judicial review under the Administrative Procedure Act, *5 U.S.C. § 702*.

THIRD CAUSE OF ACTION

(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

75. Plaintiffs reallege the facts in Paragraphs 1 through 66 as if fully set forth in this Count.

76. The DoD's intentional 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*, *21 C.F.R. § 201.5*, Executive Order 13139 and DOD Directive 6200.2. Upon information and belief, the DoD routinely only administers two or three vaccination shots based on its belief that additional shots are unnecessary to afford adequate protection. [**27] Oftentimes, individuals receive only one or two vaccinations.

77. The *27 DoD's intent to inoculate, and in fact the inoculation of, Plaintiffs with the AVA according to an unlicensed and unapproved vaccination schedule, is a legal wrong against Plaintiffs, entitling them to judicial review under the Administrative Procedure Act, *5 U.S.C. § 702*.

78. In fact, at least one plaintiff, John Doe # 3, who spent more than 30 days assigned to a military base in the Middle East and was ordered to take the vaccine, received only one shot. No follow-up by the DoD ever occurred to ensure he received his second through sixth shots, in violation of the FDA's licensing requirement for AVA.

79. The FDA has recognized the DoD as a manufacturer of the AVA. The deviation from the FDA licensing requirements governing shot sequence constitutes an off-label use prohibited by federal statute and regulation.

[*17] 80. The DoD's intentional alteration of the AVA shot sequence schedule creates a legal wrong against the Plaintiffs. Plaintiffs are entitled to seek review of DoD's actions under the Administrative Procedure Act, *5 U.S.C. § 702*.

FOURTH [**28] **CAUSE OF ACTION**

(VIOLATION OF ADMINISTRATIVE PROCEDURE ACT)

81. *28 Plaintiffs reallege the facts in Paragraphs 1 through 66 as if fully set forth in this Count.

82. In 1985, as part of an FDA biologic and drug licensing review, the Biologics Review Panel, an independent advisory panel to the FDA, recommended that the FDA classify the AVA as "not misbranded". On December 13, 1985, the FDA published in the Federal Register a Proposed Rule to adopt the Panel's recommendations and finalize FDA approval of the AVA license.

83. On October 12, 2001, a Citizen Petition was filed with the FDA challenging the FDA's unreasonable delay to finalize the Rule. The specific relief requested in the Petition was rejected by the FDA on August 28, 2002.

84. On January 5, 2004, the FDA published in the Federal Register a Final rule and final order concerning the AVA. The Final rule and final order purports to respond to matters covered in the proposed rule published in the Federal Register on December 13, 1985. The issuance of this Final rule and final order constitutes final agency action under the Administrative Procedure Act. *5 U.S.C. § 704*.

85. [**29] The FDA published the Final rule and final order in direct response to this litigation and due *29 to pressure imposed on it by DoD and other sources.

86. The FDA's 1985 Proposed Rule did not propose that the anthrax vaccine was effective against exposure to aerosolized anthrax. The review panel concluded 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." As the question of efficacy against aerosolized exposure was not at issue, the FDA did not respond to the panel's conclusion or seek public comment on this specific matter either in 1985 or 2003.

[*18] 87. In issuing its Final rule and final order, the FDA acted in bad faith and excluded evidence adverse to its determination which was known to it at the time of the decisionmaking. Additionally, it has distorted or exaggerated the scientific conclusions upon which it relied for its decision, and failed to note significant limitations asserted by the authors of anthrax-related studies. The FDA's stated rationale is but a pretext masking the true basis of its decision. It has no rational connection [**30] and is unsupported by substantial evidence. Therefore, the Final rule and final order, to the *30 extent it applies to AVA, is arbitrary and capricious.

88. The FDA's reliance on studies involving animal data to support its conclusion that the AVA is effective against inhalation anthrax is inappropriate and violates its own regulations. No scientific correlation has been demonstrated between animal studies and human reaction with respect to AVA, thereby negating its value. FDA's reliance on faulty data to justify the issuance of its Final rule and final order constitutes an abuse of discretion.

89. The FDA's judgment and analysis in issuing the Final rule and final order does not merit deference under the circumstances and is so unwarranted by the facts that it is subject to trial de novo.

90. The FDA's Final rule and final order was issued in violation of its own internal procedures and requirements, and was so arbitrary and capricious as to amount to bad faith. The issuance and contents of the Final rule and final order

are nothing less than extraordinary and demonstrate a departure from the FDA's consistent and long-standing precedents and policies. The FDA has failed to explain [**31] the reasons for its departure from precedent. The FDA's Final rule and final order was issued without *31 observance of procedure as required by law.

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

A. Certify this action as a class action, including creating any subclasses which the Court deems appropriate;

[*19] B. Designate the law firms of McGuire Woods, LLP and Krieger & Zaid, PLLC, as class counsel;

C. Find and declare that AVA, as it is being used by Defendants, is an investigational new drug within the meaning of *10 U.S.C. § 1107*, Executive Order 13139 and DoD Directive 6200.2;

D. Find and declare that AVA has been in investigational new drug status since the original investigational new drug application was filed on September 20, 1996;

E. Find and declare that as a result of the unilateral change in vaccination schedule by Defendant DoD, the AVA is a drug unapproved for its intended use within the meaning of *10 U.S.C. § 1107*, Executive Order 13139, and DoD Directive 6200.2, as of June, 2000;

F. Find and declare that AVA is an unlicensed or improperly licensed biologic product [**32] under FDA regulations and, therefore, is a drug unapproved for its intended use within the meaning of *32 *10 U.S.C. § 1107*, Executive Order 13139 and DoD Directive 6200.2;

G. Find and declare that the FDA's Final rule and final order was issued in violation of the Administrative Procedure Act, thereby voiding its application, and remand the matter to the FDA for further evaluation;

H. Enjoin Defendant from inoculating 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

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

Date: January 6, 2004

[*20] Respectfully submitted,

/s/

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