View U.S. District Court Opinion

JOHN DOE #1, JOHN DOE #2, JOHN DOE #3, JOHN DOE #4, JANE DOE #1, JANE DOE #2 c/o Mark S. Zaid, Esq. 1133 21 st Street, N.W.Suite 800 Washington, D.C. 20036 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.

No. 03-707

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Pleadings 707; 2003 U.S. Dist. Ct. Pleadings LEXIS 378

March 18, 2003

Complaint

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

TITLE: [*1] **COMPLAINT**

TEXT: 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, 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 and federal employees in violation of federal law. Plaintiffs seek this relief pursuant to the Administrative Procedures Act, *5 U.S.C. § 551*, [*2] 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, National Guardsmen and DoD civilian contract employees who have been ordered, or will imminently be ordered, to take AVA as part of their military duties or employment obligations. Similarly situated individuals include current members of the active duty and selected Reserve members of the Armed Forces and current civilian DoD employees and contractors who have been ordered, or will imminently be ordered, to

take the vaccination series.

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 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. The Secretary of Defense is personally responsible for compliance with his own directives.

3. The DoD was and is heavily involved in the manufacturing [*3] and licensing process for the AVA and is considered the de facto manufacturer of AVA by Defendant Food and Drug Administration.

4. 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 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 an IND application for the AVA to amend the license, rendering AVA an IND in circumstances germane to this action. The FDA has not spoken on this issue and to date, its agents have issued only personal opinions with no legal effect concerning the status of the vaccine. [*4]

6. Plaintiffs will suffer substantial and irreparable injury if they are forced to take the vaccine, as a result of FDA's failure to define 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.

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*.

FACTUAL BACKGROUND

A. Anthrax Vaccine Adsorbed

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 [*5] *Bacillus anthracis*." See Attachment A, Anthrax Vaccine Adsorbed product insert, December 1979.

10. 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 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.

See Attachment B, 2002 Anthrax Vaccine Adsorbed 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, 0.5 mL each given at 6, 12 and 18 months." Id.

12. In 1985, the DoD (through [*6] 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.

B. FDA Failure to Finalize AVA Licensing

13. 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. However, FDA failed to complete the process and, as of yet, has not issued any final rule or labeling status for AVA. See Attachment D, August 28, 2002 letter to Russell Dingle in response to Citizen Petition Docket No. 01P-0471/CP1 ("Response to Citizen Petition").

14. FDA's failure to finalize the Proposed Rule means [*7] that the AVA is not a properly licensed vaccine under FDA regulations.

C. AVA is Not Licensed for Use Against Inhalation Anthrax

15. 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 anthrax is possible due to its low incidence." See Attachment E, Federal Register, December 13, 1985.

16. 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.

17. In March 1990, Army doctors [*8] 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*.

18. In 1995 the Army contracted with the Science Applications International Corporation ("SAIC") 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 AVA to list on the product license that AVA was effective against inhalation anthrax.

19. 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

20. 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. [*9] 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.

21. On August 26, 1996, as a precursor to changing the AVA license by filing an investigational new drug application, the Army's 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.

22. 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 [*10] for AVA. The application was prepared, in whole or in part, by a U.S. Army agency located at Fort Detrick, Maryland.

23. 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, route and vaccination schedule for AVA." See Attachment J, September 20, 1996, MBPI Letter to Dr. Kathryn C. Zoon.

24. 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.

25. 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.

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

27. Under FDA regulations, a drug may be placed in investigational new drug status, even when [*11] 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.

28. 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.

29. 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.

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

31. 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 [*12] 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.

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

E. DoD Uses AVA as an IND

33. 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.

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

35. If they refuse to comply with orders to take the AVA inoculations, 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.

36. In December 1997, the Joint Program Office for Biological Defense, an agency [*13] 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.

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

38. 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.

39. 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.

40. 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. [*14]

41. 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.

42. 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. The size of the [*15] 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

43. 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.

44. In July, 2000, DoD announced the first of several reductions in the scope of the AVIP because of a failure by Bioport Corporation to [*16] 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.

45. 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 a subsequent shot within two years of their last vaccination.

46. 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 Related to the Anthrax Vaccine Immunization Program (AVIP).

47. On October 11, 2002, the [*17] 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).

48. 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.

49. 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. [*18] Indeed, DoD is currently seeking test subjects to validate its practice of altering the shot sequence.

50. 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" 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

51.*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.

52. 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.

53. A judicial declaration that AVA is an IND [*19] does not preclude the use of AVA by DoD, as long as the appropriate consent or waiver is obtained.

54. 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.

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

56. The FDA has never issued an agency 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.

57 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.

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

59. 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 [*20] 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 to service members subject to mandatory vaccinations with AVA. The Center for Disease Control is a subordinate entity of Defendant Department of Health and Human Services.

60. 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)

61. Plaintiffs reallege the facts in Paragraphs 1 through 60 as if fully set forth in this Count.

62. Defendant Department of Defense will inoculate Plaintiffs with the AVA within the immediate [*21] future. Defendant Department of Defense notified Plaintiffs that they will be ordered to submit to AVA inoculation shortly, in

some cases within 30 days.

63. 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 preventative against inhalation anthrax.

64. The Department of Defense'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.

65. 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)

66. Plaintiffs reallege the facts in Paragraphs 1 through 60 as if fully set forth in this Count.

67. Defendant's use of an unlicensed or [*22] 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 Drug and Cosmetic Act, *21 U.S.C. § 301*, et seq., and also means that DoD is using a drug unapproved for its intended use. DoD's actions violate *10 U.S.C. § 1107*, Executive Order 13139, and DoD Directive 6200.2.

68. 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)

69. Plaintiffs reallege the facts in Paragraphs 1 through 60 as if fully set forth in this Count.

70. The Defendant'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*, *21 C.F.R. § 201.5*, Executive Order 13139 and DOD Directive [*23] 6200.2.

71. Defendant's intent to inoculate 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*. WHEREFORE, Plaintiffs and those similarly situated to them respectfully ask this Court to:

A. 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;

B. 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;

C. Find and declare that as a result of the unilateral change in vaccination schedule by Defendant in June, 2000, 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;

E. Find and declare that AVA is an unlicensed or improperly licensed biologic product under FDA regulations and, therefore, is a drug unapproved for its intended [*24] use within the meaning of *10 U.S.C. § 1107*, Executive Order

13139 and DoD Directive 6200.2;

F. Enjoin Defendant from inoculating Plaintiffs and those similarly situated to them without Plaintiffs' 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: March 18, 2003

Respectfully submitted,

John J. Michels, Jr., Esq.

D.C. Bar # 457575

McGUIREWOODS LLP

77 W. Wacker, Suite 4400

Chicago, Illinois 60601

(312) 849-8150

Mark S. Zaid, Esq.

D.C. Bar # 440532

Krieger & Zaid, PLLC

1133 21st St., N.W.

Suite 800

Washington, D.C. 20036

(202) 223-9050