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JOHN DOE # 1 et al., Plaintiffs, vs. DONALD H. RUMSFELD et al., Defendants.

Civil Action No. 03-00707(EGS)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Motions 707; 2003 U.S. Dist. Ct. Motions LEXIS 6304

April 25, 2003

Motion for Preliminary Injunction

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TITLE: [**1]

REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

TEXT: Rather than directly confront the law and/or facts facing it, the government -- in this case represented by the Secretary of the Department of Defense ("DoD"), Secretary of the Department of Health & Human Services ("HHS") and the Commissioner of the Food & Drug Administration ("FDA") -- seeks to paint a picture exaggerated in danger and designed to avoid adjudication of the merits. In response to the plaintiffs' motion, defendants rely on a mixture of unsupported speculation and outright misrepresentations in an effort to stymie service members and civilian employees from asserting protections granted to them by Congress and the President -- notably, the right to require their informed consent before treatment with experimental drugs.

The plaintiffs in this case, two active duty military members, two national guardsmen, one DoD civilian employee and one DoD civilian contractor -- present the simple question of whether one branch of the government must abide by the legal obligations statutorily imposed upon it by another. n1 Nothing less, nothing more.

n1 The plaintiffs also brought this case on behalf of all others similarly situated. See Complaint at P 1 (filed March 18, 2003). The government objects to this characterization and notes that the plaintiffs have not sought class certification under *Rule 23 of the Federal Rules of Civil Procedure*. See Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 36 fn.22 (dated April 9, 2003)("Defs' Memo"). The plaintiffs are more than willing to pursue this route. Frankly, the government cannot escape from the fact that at least one or more plaintiffs will be deemed to have proper standing. All that is needed for this Court to adjudicate the merits of plaintiffs' claims is one plaintiff.

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[*2] Specifically, this case challenges the mandatory inoculations with anthrax vaccine absorbed ("AVA") faced by the plaintiffs through DoD's implementation of the Anthrax Vaccination Immunization Program ("AVIP"), which under present circumstances is occurring in violation of a clear Congressional mandate forbidding such action. Such a finding is undeniable if this Court determines the anthrax vaccine is either in an investigational new drug status or a drug unapproved for its use when administered for protection against inhalation anthrax exposure. As is evident, without the granting of preliminary injunctive relief to prevent imminent inoculation, the plaintiffs will face irreparable harm at the hands of final agency action.

The Administrative Procedure Act, *5 U.S.C. § 701* et seq., permits the plaintiffs to challenge the final agency action of the DoD for implementing the AVIP, and the arbitrary and capricious decision of HHS and FDA to support it; each of which is in violation of a federal statute -- *10 U.S.C. § 1107*. This Court has the unquestionable authority to not only hear this case, but should be persuaded to decide [**3] in favor of the plaintiffs.

ARGUMENT

Ironically, although the defendants' brief is replete with references to numerous cases, FDA regulations, and questionable declarations from unqualified sources, the defendants fail to cite the language of the very statute that will begin and end the analysis in this case -- *10 U.S.C. § 1107*. A simple review of the statutory language conclusively demonstrates that defendants' justiciability arguments, as well as those attacking the merits of the plaintiffs' request for a preliminary injunction, should be rejected. The statute clearly demonstrates Congressional intent to eliminate military discretion *in military combat operations*; the time when DoD is most likely to use investigational new drugs or drugs unapproved for a certain use on those under its control.

[*3] The clear language of the statute in question -- *10 U.S.C. § 1107* -- states:

> In the case of the administration of an investigational new drug or a drug unapproved for its applied use to a member of the armed forces in connection with the members' participation in a particular military operation, the requirement [**4] that the member provide prior consent to receive the drug in accordance with the prior consent requirement imposed under Section 505(i)(4) of the Federal Food, Drug and Cosmetic Act (*21 U.S.C. § 355(i)(4)* may be waived only by the President.

This unambiguous statutory language, reaffirmed by Presidential Executive Order 13139 and DoD's own regulations n2, demonstrates that Congress intended to prevent the unbridled and unrestrained use of military discretion in using certain drugs during military operations. To accept the defendants' arguments renders this statutory language meaningless and ineffective. Essentially, the defendants ask this Court to override the express direction of Congress and the President by ruling in their favor.

> n2 See e.g., Department of Defense Directive 6200.2 (August 1, 2000)(http://*www.dtic.mil/whs/directives/corres/html/62002.htm*).

Once *10 U.S.C. § 1107* is taken into consideration, it should become evident that by [**5] being ordered to take the anthrax vaccine, each of the plaintiffs are suffering a "legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute" thereby entitling them to judicial review thereof. See *5 U.S.C. § 702*. Thus, this Court has been presented with, and it should decide, a relevant question of law and statutory provision. Id. at § 706. Based on this authority, it can "hold unlawful and set aside agency action . . . found to be -- (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; . . . (C) in excess of

statutory jurisdiction, authority, or limitations, or short of statutory right; (D) without observance of procedure required by law; . . . or (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court." Id.

The APA erects a "presumption of judicial review" at the behest of those adversely affected by agency action. *Abbott Laboratories v. Gardner, 387 U.S. 136 (1967);* Dennis [*4] *Dickson, et al v. Secretary of Defense, et al., 68 F.3d 1396 (D.C.Cir. 1995).* [**6] The only statutory exceptions to this rule are if a particular statute "precludes judicial review" or if "agency action is committed to agency discretion by law." See §§ 701(a)(1),(2). Here, no statute precludes judicial review. n3 Nor does any exception of the APA apply thereby permitting judicial review.

n3 The mere fact that a statute is silent on the issue of review is not controlling. To the contrary, we "begin with the strong presumption that Congress intends judicial review of administrative action." *Bowen v. Michigan Acad. of Family Physicians, 476 U.S. 667, 670 (1986).* Thus, "judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress." *Abbott Labs., 387 U.S. 136, 140 (1967)*(collecting cases).

I. THE PLAINTIFFS' CHALLENGE TO THE GOVERNMENT'S FAILURE TO FOLLOW ESTABLISHED LAW IS JUSTICIABLE EVEN WHEN THE MILITARY IS INVOLVED

From the outset the [**7] defendants challenge this Court's ability to resolve this dispute by claiming it is non-justiciable. See Defs' Memo at 14-22. In pursuing this route, they mischaracterize the plaintiffs' challenge as requiring "this Court to engage in review of military decisions regarding the battlefield activities of troops engaged in combat." Id. at 15. This is untrue. Let it be perfectly clear that neither the merits of the government's decision to inoculate the plaintiffs with the anthrax vaccine, or the soundness of the policy that led to that decision, are questions before this Court. Still, as this Court may likely come to realize, the AVIP is nothing more than an obscene loyalty test. It has little to do with military or medical readiness. n4

n4 That being said, there are numerous factual inaccuracies contained throughout the government's brief regarding the safety and efficacy of the anthrax vaccine, most of which relate to the policy decision to utilize the anthrax vaccine. Because these issues are little more than peripherally related, if at all, to the narrow legal issue underlying the plaintiffs' claim, the plaintiffs will not seek to distract the Court with a point by point rebuttal of these facts. The plaintiffs can address any factual questions during oral arguments or in a supplemental pleading if requested.

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[*5] Instead, the sole question that requires adjudication by this Court is representative of the typical dispute brought before an Article III judge; whether agencies of the Executive Branch are properly following requirements enacted into law by the Legislative Branch and the President. In this specific case, the question pertains to enforcing Congressional intent to ensure DoD does not experiment on military service members without informed consent, as history has revealed the military has done too many times in the past. See S.Rpt. 103-97: "*Is Military Research Hazardous To Veterans' Health: Lessons Spanning Half A Century*", 103d Cong., 2d Sess. (1994)(http://*www.gulfwarvets.com/senate.htm*). n5

> n5 Both the FDA and the Presidential Advisory Committee on Gulf War Illnesses have criticized the Pentagon for its past history of using experimental drugs and vaccines during the Gulf War and exercises in Bosnia. The FDA criticized the Pentagon for "failing to document immunizations in soldiers' permanent medical records and for touting the vaccine in handouts given to troops as very safe and extremely effective' when the FDA never authorized such glowing language." Patrick Pexton, *Pentagon Can't Be Trusted With Experimental Drugs*, Navy Times, Feb. 16, 1998. The President's Committee went even further and declared that the Pentagon "currently is incapable" of handling unapproved drugs. Id.

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The relief sought by the plaintiffs will have absolutely no impact upon military discipline or duty. Nor does it interfere with military judicial proceedings. Strictly speaking, all that would occur is that DoD would be required to either obtain informed consent from those that it wished to be inoculated with the anthrax vaccine, or a waiver of informed consent from the President. Such a ruling would not require the cessation of the AVIP, nor jeopardize any military missions or the life of a soldier. The government has failed to explain how such relief questions or challenges a military decision, much less the military justice system.

The Constitution explicitly conferred upon Congress the power, inter alia, "to make Rules for the Government and Regulation of the land and naval Forces," U.S. Const. Art. I, 8, cl. 14, thus showing that "the Constitution contemplated that the Legislative Branch have plenary control over rights, duties, and responsibilities in the framework of the Military Establishment. . . . ." *Chappell v. Wallace, 462 U.S. 296, 301 (1983)*. Congress [*6] exercised that authority to "establish a comprehensive internal system of justice to regulate [**10] military life, taking into account the special patterns that define the military structure." *Id. at 302*. In furtherance of its oversight of the military and in light of past misconduct, Congress enacted *10 U.S.C. § 1107*, thereby indicating its unequivocal intent to ensure the military does not undertake experimentation on individuals under the exercise of its control. The Judiciary is, most obviously, the appropriate branch of government to ensure timely compliance with this statute; otherwise, its purpose would be lost forever.

Yet the defendants assert that courts "traditionally have been reluctant to intervene in the conduct of military affairs," see Defs' Memo at 15, because judges "are not given the task of running [the military], and that they are ill-equipped' to determine the impact of judicial intrusion on military authority." Id. (citations omitted). To be sure, under certain circumstances this is true. The Constitution vests "the complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force" exclusively in the Legislative and Executive branches. *Gilligan v. Morgan, 413 U.S. 1, 10 (1973)*. [**11] Thus, under *Feres v. United States, 340 U.S. 135 (1950),* and its progeny, the courts have often disallowed damage claims by servicemen against the United States under the Federal Tort Claims Act. And Bivens claims are not available to remedy injuries suffered by service members in the course of military service. *United States v. Stanley, 483 U.S. 669 (1987)*. Yet, neither type of claim is presented here.

In any event, the government's argument paints with far too broad a brush. There are countless examples of the Judiciary adjudicating claims involving the military, and this case clearly falls among them. For example, in *John F. Kreis, v. Secretary of the Air Force, 866 F.2d 1508 (D.C.Cir.1989),* the D.C. Circuit Court of Appeals addressed the very issue [*7] of "second-guessing" military decisions with respect to officer promotions. n6 The Court declined to adjudicate that issue because:

> Appellant's request for retroactive promotion falls squarely within the realm of non-justiciable military personnel decisions. To grant such relief would require us to second-guess the Secretary's decision about how best to allocate [**12] military personnel in order to serve the security needs of the Nation. This court is not competent to compare appellant with other officers competing for such a promotion. Not only is that task inherently unsuitable to the judicial branch, but also Congress has vested in the Secretary alone the authority to determine whether the original selection boards erred in comparing appellant to the

other candidates for promotion.

Id. at 1511. Yet the Court's analysis did not stop there. It noted that there

> is also a more modest request in appellant's complaint, however. While all his efforts are aimed ultimately at securing his promotion to lieutenant colonel, his alternative claims require the district court merely to evaluate, in light of familiar principles of administrative law, the reasonableness of the Secretary's decision not to take certain corrective action with respect to appellant's record. Adjudication of these claims requires the district court to determine only whether the Secretary's decision making process was deficient, not whether his decision was correct. To grant the relief implicit in these claims would not require the district court to [**13] substitute its judgment for that of the Secretary regarding the allocation of military personnel in light of the security needs of the Nation. n7

> n6 In their Memorandum in Support of Motion for Temporary Restraining Order and/or Preliminary Injunction (filed March 18, 2003), the plaintiffs relied upon the justiciability test enunciated in *Mindes v. Seamen, 453 F.2d 197 (5th Cir. 1971),* affirmed on appeal after remand, *501 F.2d 175 (5th Cir. 1974)*. For the record, the plaintiffs note that the D.C. Circuit has not expressly adopted this test, although neither has it rejected it under such circumstances as presented in this instant matter. See *Kreis, 866 F.2d at 1512*. A reading of the defendants' Opposition appears to support the plaintiffs' premise that the Mindes' factors are appropriate for consideration. n7 The Court further stated wrote that "The Secretary would remain free, following this reevaluation, to reaffirm his original determination to deny appellant further relief. In short, once we dispose of the request for a judicially ordered promotion, the review sought by appellant looks like nothing more than the normal review of agency action, in which we require only that the agency exercise its discretion in a reasoned manner, but we defer to the agency's ultimate substantive decision." *Kreis, 866 F.2d at 1512,* citing *Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416 (1971).*

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[*8] Id.

Although the defendants assert that "at least five courts of appeals have held that Chappell and [Stanley], categorically preclude soldiers from seeking injunctive relief against their commanding officers", see Defs' Memo at 17, it is far more persuasive that the D.C. Circuit is not among them. Indeed, the D.C. Circuit has repeatedly interpreted the Supreme Court's ruling in Chappell as anything but a categorical rule. See e.g. *Brannum v. Lake, 311 F.3d 1127 (D.C.Cir. 2002); Kreis, 866 F.2d at 1511, Gay Veterans Association, Inc. v. Secretary of Defense, 850 F.2d 764, 768 (D.C.Cir. 1988); Bois v. Marsh, 801 F.2d 462, 467 n.9 (D.C.Cir. 1986); Roelofs v. Secretary of Air Force, 628 F. 2d 594, 599-601 (D.C.Cir 1980).* n8

> n8 The defendants seek to distinguish the D.C. Circuit's ruling in *Doe v. Sullivan, 938 F.2d 1370 (1991),* which dealt with similar factual issues. See Defs' Memo at 18-19. However, that dispute dealt primarily with whether FDA was appropriately exercising its discretionary authority under its own regulations. In the instant matter, the plaintiffs are expressly challenging DoD's deliberate non-discretionary rejection of an explicit statute requiring certain conduct, and the FDA/HHS's failure to ensure DoD's compliance with the statute, as well as their arbitrary and capricious litigation support for DoD's actions.

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The government argues that "when a judicial decision affects conduct on the battlefield by the military (and its civilian leadership), the consequences of judicial error are potentially ruinous, especially when the court's decision involves prospective injunctive relief (as in this case) rather than damages after the event (as in Stanley and Feres)." See Defs' Memo at 18. Such a broad statement, if applied to this specific case, would have the perverse effect of rendering the Legislative Branch's enactment of *10 U.S.C. § 1107* null and void.

The government attempts to further shield its unlawful mandatory inoculation program by claiming that *5 U.S.C. § 701(b)(1)(G)* precludes judicial review. See Defs' Memo [*9] at 20. This provision, which excludes "military authority exercised in the field in time of war or in occupied territory" from the definition of "agency," is inapplicable. n9

n9 Another peripherally relevant exclusion is "courts-martial and military commissions". *5 U.S.C. § 551(1)(F)*. However, none of the plaintiffs are involved with either.

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First, the AVIP was first announced in December 1997, implemented in certain areas in March 1998, and then force-wide in May 1998. See Secretary of Defense Memorandum, "Implementation of the Anthrax Vaccine Program for the Total Force", May 18, 1998, at *http://www.anthrax.osd.mil/media/pdf/implementationpolicy.pdf*. "A vaccine shortage in 2000 caused the scope of AVIP to be reduced from 70,000 shots per month to approximately 100 per month by mid-2001. Consequently, few of the service members who fought in combat operations in Afghanistan (against terrorists who potentially possessed weaponized anthrax) in 2001-2003 were vaccinated at all, and it appears that for the few that have been they are not current in their vaccination schedule; a fact that has obviously not hindered successful mission accomplishment. The recommencement of the AVIP program was announced on June 29, 2002, which predates the Congressional authorization for the use of force in Iraq by four months, and the current hostilities by nearly a year. See Assistant Secretary of Defense (Health Affairs) Dr. William Winkenwerder, June 29, 2002, DoD press briefing transcript, at *http://www.defenselink.mil/news/Jun2002/t06292002_t0628ww*. [**17] *html*.

Second, the plaintiffs are not challenging "military authority exercised in the field in time of war or in occupied territory." None of the plaintiffs are presently in the "field" or in "occupied territory." See Declaration of Mark S. Zaid, Esq. (dated March 17, 2003)(identifying plaintiffs and their presently known locations)(filed under seal)("Zaid Decl."), accompanying Plaintiffs' Ex-Parte Motion for Leave to File Complaint Using "John Does" and "Jane Does" and Counsel's Address in Violation of LCvR 5.1(e) and to Seal Declaration of Mark S. Zaid, Esq. (filed March 18, 2003). Moreover, the policy in question was issued by the Secretary of Defense, not commanders in the field. Any [*10] modifications to the AVIP will originate from the Office of the Secretary of Defense. Obviously, the Secretary is neither in the "field" or in "occupied territory." n10

n10 To the extent the defendants repeatedly rely on the threat of anthrax use on the battlefield, this Court should note that there has not been one iota of evidence of Iraq's use of anthrax in the current conflict, much less any indications that an attack was contemplated or that Iraq is even still in possession of anthrax spores. London Financial Times, "*Iraq After Saddam: Finding Iraq Arms Evidence Rests On Taking Full Control*", April 23, 2003. Since the filing of the government's Opposition on April 9, 2003, significant favorable events have transpired in Iraq that defuses much of the alleged risk. By April 14, 2003, DoD officials were declaring victory was at hand, and begun recalling troops starting with two aircraft carriers. Indeed, the only use of weaponized anthrax against this country has been against civilians by a perpetrator that is widely believed to be a member of the American bioweapons establishment. See "Anthrax: The Hunt Narrows," Time, February 4, 2002.

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There are very few, if any, court decisions that analyze the applicability of § 701(b)(1)(G). The Honorable Colleen Kollar-Kotelly recently referenced the lack of case law or substantive analysis in *Rasul v. Bush, 215 F. Supp. 2d 55 (D.D.C. 2002),* aff'd *321 F.3d 1134 (D.C.Cir. 2003);* a case that determined the claims of aliens incarcerated at Guantanamo Bay, Cuba, for allegedly participating in hostilities against the United States in Afghanistan were nonjusticiable. Judge Kollar-Kotelly noted:

> Plaintiffs argue that Section 702 of the Administrative Procedure Act provides such a waiver. Assuming that Section 702 of the Administrative Procedure Act provides a waiver, the Court finds that the actions of the government in this case would be exempt by *5 U.S.C. § 701(b)(1)(G)* (providing an exemption for, "military authority exercised in the field in time of war or in occupied territory"). Cases that have analyzed Section 701(b)(1)(G) have had occasion to address it only in the context of "judicial interference with the relationship between soldiers and their military superiors." *Doe v. Sullivan, 938 F.2d 1370, 1380 (D.C.Cir. 1991).* [**19] Despite the absence of pertinent case law, the language of Section 701(b)(1)(G) supports the view that this Court is unable to review the claim Plaintiffs make under the Administrative Procedure Act. There is no dispute that Plaintiffs were captured in areas where the United States was (and is) engaged in military hostilities pursuant to the Joint Resolution of Congress. Am. Compl. P 16 ("the Kuwaiti Detainees were seized against their will in Afghanistan or Pakistan"). This situation plainly falls within Section 701(b)(1)(G). The Court was unable to find any material in the legislative history that addressed Section 701(b)(1)(G) [*11] of the Administrative Procedure Act, see, e.g., S. Rep. No. 89-1350, at 32-33 (1966); H.R. Rep. No. 89-901, at 16 (1965), and the parties have not provided any legislative history, that would change the Court's view of this provision.

Rasul, 215 F. Supp. 2d at 64 fn.11.

However, for the reasons expressed throughout this pleading, § 701(b)(1)(G) simply does not prevent this Court's consideration of the present dispute.

B. The Plaintiffs Have No Other Adequate Remedy Except For This Court

Whether or not each and [**20] every plaintiff sufficiently can prove standing, or has exhausted any necessary alternative remedies, is irrelevant for purposes of this Court to adjudicate the underlying substantive question. At least one, and undoubtedly more, of the plaintiffs fit both descriptions thereby allowing this Court to reach the merits of the dispute. If the Court decides in favor of the defendants, the standing issues for the other plaintiffs are moot. However, if the Court recognizes standing for even one plaintiff and then rules in their favor on the merits, additional information can be provided to the Court, and if necessary to the defendants, in order to demonstrate individual applicability.

Therefore, the specific case of John Doe # 4 supplies the Court with an appropriate plaintiff. John Doe # 4 is a national guard member who was activated to Title 10 status and ordered to take the anthrax vaccine, but had refused. See Zaid Decl. at P 5d. Since the filing of this litigation, he changed his mind and began the shot series. However, he remains a legitimate plaintiff because he opposes the mandatory AVIP requirement as being in violation of the law. Therefore, under the D.C. Circuit's analysis [**21] in *New v. Cohen, 129 F.3d 639 (D.C.Cir. 1997)* and the Supreme Court's decision in *Goldman v. Weinberger, 475 U.S. 503 (1986),* this Court can adjudicate the merits of his dispute. As was recognized in New:

> upon receiving the orders which he thought to be illegal, New had two options. He could have chosen to obey the orders and then sought judicial review of the military's policies. Cf. *Goldman v. Weinberger, 475 U.S. 503 (1986)*(suit to enjoin application of Air Force regulation [*12] that forbade officer from wearing yarmulke while on duty and in uniform). Or he could follow the path that he took: disobey the orders and challenge their validity in the subsequent disciplinary proceedings. n11

n11 With respect to the two civilian plaintiffs in this litigation, a person need not exhaust remedies in a military tribunal if the military court has no jurisdiction over him. In other words, the military has no authority to subject civilians to court-martial proceedings. See, e.g., *McElroy v. Guagliardo, 361 U.S. 281 (1960); Reid v. Covert, 354 U.S. 1 (1957); Toth v. Quarles, 350 U.S. 11 (1955).*

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It is the former that John Doe # 4 does now, and this fact permits this Court to adjudicate the merits of this dispute.

II. PLAINTIFFS ARE ENTITLED TO INJUNCTIVE RELIEF

A. Plaintiffs Have Made A Substantial Likelihood Of Showing They Will Prevail On The Merits Of Their Claims

Defendants start out by misstating and deliberately misconstruing Plaintiffs' arguments. They claim, erroneously, that Section 1107 "is inapplicable here because AVA's license covers use against inhalation anthrax." See Defs' Memo at 28. This is incorrect, and the heart of this dispute. Section 1107 proscribes the use of "investigational new drugs" and "drugs unapproved for their applied use" on service members without their consent only if excused by a Presidential waiver. Whether a vaccine is licensed is irrelevant because, as defendants must admit, a vaccine may be licensed for one purpose and investigational for another. Indeed, the AVA is the subject of at least two investigational studies now, one of which provides the basis for this litigation.

It is the plaintiffs' contention that the license for the vaccine does not incorporate inhalation anthrax because it fails to comply with [**23] established drug laws and FDA regulations, particularly given that there has never been a sufficient study of the vaccine that would validate this role. This was even expressly noted by the independent advisory panel of scientific experts relied upon by the defendants. In 1985, that panel found that the license was not broad enough to include inhalation anthrax because inhalation cases were far too scarce to provide any meaningful data. See Complaint, Attachment "E". This [*13] determination was based, at least in part, on the so-called Brachman Study itself, which noted that there were too few cases of inhalation anthrax in the mill in which the study was taking place to make a determination of the efficacy of the vaccine. See Brachman and Friedlander, Vaccines 736 (ed. Plotkin and Mortimer)(1999). In fact, Brachman noted that there have been "no controlled clinical trials in humans of the efficacy of the currently licensed U.S. vaccine." *Id. n12*

n12 On October 12, 1999, Kwai-Cheung Chan, GAO, testified before the House Committee on Gov't Reform and stated:

> "A study on the efficacy of the earlier vaccine concluded that it provided protection to humans against anthrax penetrating the skin but did not provide information to determine its effectiveness against inhalation anthrax. In the 1980's, DOD began testing the efficacy of the licensed vaccine in animals, focusing on its protection against inhalation anthrax. The studies showed that the vaccine protected some animals against inhalation anthrax. However, the level of protection varied for different species and the results cannot be extrapolated to humans. DOD recognizes that correlating the results of animal studies to humans is necessary and told us that it is planning research in this area. DOD also plans to develop a second generation anthrax vaccine and, as part of this effort, will need to address whether strains of deliberately engineered or naturally occurring anthrax can overcome the protective immunity of such a vaccine."

See *http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=106_house_ hearings &docid=f: 65604. wais*

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What this means is that the vaccine license does not encompass inhalation anthrax, at least not since 1985, when FDA finally published the findings of its advisory panel as a proposed rule. There have been no subsequent human studies on the efficacy of the vaccine against inhalation anthrax, and while there are numerous animal studies in place, none of these studies have found a link between the vaccine's protective qualities in animals and a corresponding marker for protection in human beings. See "*Department of Defense, Chemical and Biological Defense Program, FY2001-2003 Performance Plan* ", April 2002, at *http://www. acq. osd. mil/cp/nbc02/vol2-2002cbdpperformanceplan.pdf* (Page 100, CB.33).

[*14] Although the government now points to the Friedman letter of March 13, 1997, and subsequent declarations (including the Goodman Declaration in this case) as providing a basis for its legal claim that the license is valid for inhalation anthrax, none of these opinions have been issued in accordance with FDA's own regulations for a formal FDA opinion. See *21 C.F.R. § 10.85(k)(2000)*("A statement made or advice provided by an FDA employee constitutes an advisory [**25] opinion only if it is issued in writing under this Section. A statement or advice given by an FDA employee orally or given in writing but not under this section or § 10.90 is an informal communication that represents the best judgment of that employee at the time, but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.")

Under these circumstances, the opinions of Drs. Friedman, Goodman and any other FDA official concerning the vaccine are merely the personal opinions of those individuals. They are not binding on the agency, and are not entitled to any particular deference by this Court. See *Christensen, et al. v. Harris County, et al., 529 U.S. 576 (2000)*(Agency statutory interpretations contained in opinion letters entitled to respect but only to extent interpretations have power to persuade). In this case, although having years of opportunity in which to do so, the FDA has refused to provide a formal opinion as to the IND status of AVA. The opinions that have been expressed in response to litigation fly in the face of the [**26] documentary trail created by the defendants before the plaintiffs challenged the status of the vaccine in court. Thus, the FDA's recent statements should not be accorded any significant weight by the Court.

The best evidence of what the vaccine license encompasses is the 1985 pronouncement by the FDA's advisory panel, which was charged to review the adequacy of the licensing language, that the license did not encompass inhalation anthrax because there was insufficient data to do so. See Complaint, Attachment "E". Although the FDA has been on [*15] notice for years concerning this determination, it has yet to issue an official opinion -- in the form of a required Final Rule -- that the vaccine license encompasses inhalation anthrax. FDA's inaction has persisted, despite a decade of controversy over the use of the anthrax vaccine during the 1991 Gulf War, and the 1994 finding of the Senate Committee on Veterans Affairs that the use of AVA for inhalational anthrax was, in fact, investigational.

The failure to provide agency guidance on a critical issue, in the face of conclusive statements by the FDA's own independent review panel of experts, is conclusive that the vaccine's [**27] license does not incorporate inhalation anthrax.

B. The Anthrax Vaccine Is Either An Investigational New **Drug Or A Drug Unapproved For Its Applied Use**

Even if the vaccine license was not at issue, it is clear that the AVA is either an investigational new drug or drug unapproved for its applied use within the meaning of *10 U.S.C. § 1107*, thereby requiring informed consent before its administration to personnel involved in military operations. n13

n13 The statute defines the term "investigational new drug" as a drug covered by section 505(i) of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. § 355(i)*) and the term "drug unapproved for its applied use" means a drug administered for a use not described in the approved labeling of the drug under section 505 of the Federal Food, Drug, and Cosmetic Act (*21 U.S.C. § 355*).

The defendants do not dispute that DoD initiated a 1996 investigational new drug application for AVA; an application [**28] that is still open and current with the FDA. However, in discussing this matter, the defendants again misstate the issue. The question before the Court is not whether the IND application establishes that "DoD considers use of AVA for inhalation anthrax to be an unlicensed use." See Defs' Memo at 30. The issue is whether the IND application means that the AVA is investigational with regard to the subject matter of the application. Simply put, the issue before the Court concerning the IND status is as follows: When a drug manufacturer files an IND application with the FDA to [*16] permit a specific indication or purpose for a vaccine, is the vaccine investigational if it is used in the manner, or for a purpose, identical to that set forth in the IND application?

The defendants implicitly admit that the answer to this question is "yes," because they take great pains to conceal the original purpose of the 1996 IND application, and especially their interpretation of its meaning. Id. Fortunately, this Court does not need to decide between the parties' differing positions. The defendants own documents explicitly support the plaintiffs' view. Consider the following:

. [**29] On October 5, 1995, the U.S. Army Medical Research and Materiel Command wrote the Michigan Department of Public Health (manufacturer)("MDPH") that they were enclosing a plan "to expand the indication for use to include protection from aerosol exposure to B. anthraces spores." The "plan" specifically asserts that "this vaccine is not licensed for aerosol exposure expected in a biological warfare environment." It was designed to "obtain licensure of an additional indication for protection against aerosol exposure to anthrax." The approach was to amend the anthrax vaccine license through an IND submission. See Complaint, Attachment "G".

. On October 20, 1995 (as reflected in a November 13, 1995 memorandum from the Dept of Army's Joint Program Office for Biological Defense), a meeting was held to discuss modifying the anthrax vaccine license "to expand the indication to include protection against an aerosol challenge of spores." The vaccine manufacturer specifically noted "there are a number of challenges to obtaining a Product License Application (PLA) Supplement . . . for a labeled indication change (aerosol challenge)". See Complaint, Attachment "H".

. On July 2, 1996, FDA [**30] held a meeting to consult with and provide guidance to DoD and MDPH (manufacturer) officials who were formulating the forthcoming September 1996 IND application. See Exhibit "1". The Army presented information showing that although a millworker's study (Brachman Study) indicated that AVA was "93% effective in preventing cutaneous anthrax . . . there were insufficient cases of inhalation anthrax in the unvaccinated group to draw any conclusions for a specific indication for inhalation anthrax." The Army also "presented plans in progress to develop correlates of immunity in animals and then in humans vaccinated with MAVA in order to obtain a specific indication for inhalation anthrax." Id. at P 5. The FDA participants in this meeting told DoD that" . . . there were insufficient cases of inhalation anthrax to warrant a specific indication for this route. . . ." The FDA also advised DoD that it was undecided as to whether animal studies would be adequate for a specific indication for inhalation anthrax without a link [*17] to the vaccine response in humans. Id. at P 8. Nowhere in this preplanning document is there a statement linking the IND application for inhalation [**31] anthrax with the two-shot inoculation IND.

. 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 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 Complaint, Attachment "I".

. On September 20, 1996, Michigan Biologic Products Institute (the successor to MDPH) submitted to the FDA an investigational new drug application. The application was prepared, in whole or in part, by a component of the Department of the Army. 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 Complaint, Attachment "J".

. The Introductory Statement from the IND application states [**32] that "the ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule," not to obtain an indication for inhalation anthrax with a reduced vaccination schedule. 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. See Complaint, Attachment "K".

. 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 IND application. The letter advised the Army that it could not represent the vaccine as fully licensed when the Army was conducting tests pursuant to an IND application. Specifically, the FDA stated the "Anthrax vaccine is approved for the indication specified in the labeling of the vaccine, but not for the indication currently under investigation." To represent otherwise "would be a violation of the Agency's regulations concerning the promotion of investigational [**33] drugs and of investigational devices." See Complaint, Attachment "L". n14

[*18] On December 4, 1998, BioPort Corporation, the new manufacturer of AVA, sent FDA an annual report documenting its progress on the 1996 IND application. The sole reason listed on the attached FDA Form for the IND is "Inhalation Anthrax". No mention was made of a change in either dosage or route of administration. The timing of this annual report, and the sole rationale noted therein, is important because it occurred more than six months after DoD initiated the so-called "Total Force" AVIP in May 1998. See Exhibit "2".

n14 Interestingly, in a 1990, article entitled "*Military Immunizations: Past, Present, and Future Prospects*", and co-written by Drs. Ernest T. Takafuji and Philip K. Russell, both former Commanders of the U.S. Army Medical Research and Development Command at Fort Detrick, it was concluded that:

> Limited use vaccines and products are defined as those unlicensed experimental vaccines, toxoids, and immunoglobulins that have been developed against specific military threats associated with high morbidity. These products would be used in specific contingency situations. Some of the limited use vaccines could be considered to be experimental deployment vaccines since they are directed against serious region-specific endemic diseases. Limited use vaccines include . . . anthrax.

4 Infectious Disease Clinics of North America 156 (1990).

[**34]

It is also quite noteworthy that the government's attempted refutation of the plaintiffs IND argument comes not from FDA -- the agency that possesses the necessary expertise on the subject -- but instead from a DoD representative who is neither qualified in this field nor was involved in the original IND application process. The attempt to disguise the true nature of the IND application is even more galling given the high level involvement by both defendants DoD and FDA in the IND planning process. In fact, the defendants' litigation argument that the 1996 IND application linked the inhalation anthrax indication to the proposed new shot regimen has never been made by either DoD or FDA in even one of more than a dozen Congressional hearings or numerous DoD press briefings about AVIP since 1998. For the defendants to come forward now and try to alter this clear record merely highlights the legal and factual insufficiency of their case. n15

n15 The defendants' reliance on the district court's decision in *O'Neil v. Secretary of the Navy, 76 F. Supp. 2d 641 (W.D.Pa. 1999),* is misplaced. It is undisputed that the district court in O'Neil did not consider the legal implications of the IND or *10 U.S.C. § 1107*, particularly since it was not aware of the filing of the IND application. Nor, of course, is this Court bound by any factual determinations reached in O'Neil.

[**35]

[*19] Though internal FDA and DoD documents, many of which were concealed from the public for years, time and time again refute the legal arguments placed before this Court by the defendants, the plain-speaking FDA regulations that have existed for years governing labeling additionally demonstrate the fallacy of the defendants' claims. The government's unsupported conclusion that because the "indication section of the labeling does not specify the route of exposure" means it "includes both cutaneous and inhalation exposure" simply does not comport with established law. See Defs' Memo at 11. As previously detailed, there is no scientifically accepted evidence, at least by FDA's current standards, that demonstrate the anthrax vaccine protects against inhalation anthrax exposure. Thus, the government's claims violate fundamental precepts of drug law.

21 CFR § 201.56 (General requirements on content and format of labeling for human prescription drugs) requires, in relevant part, that:

> (a) The labeling shall contain a summary of the essential scientific information needed for the safe and effective use of the drug.
>
> (b) The labeling shall be informative and accurate [**36] and neither promotional in tone nor false or misleading in any particular.
>
> (c) The labeling shall be based whenever possible on data derived from human experience. No implied claims or suggestions of drug use may be made if there is inadequate evidence of safety or a lack of substantial evidence of effectiveness. Conclusions based on animal data but necessary for safe and effective use of the drug in humans shall be identified as such and included with human data in the appropriate section of the labeling, headings for which are listed in paragraph (d) of this section.

There can be no question that the anthrax vaccine violates this provision with respect to claims it can be utilized to protect against inhalation anthrax. But the violations do not stop there.

21 C.F.R. § 201.57 (Specific requirements on content and format of labeling for human prescription drugs) requires, in relevant part:

[*20] (c) Indications and Usage.

(1) Under this section heading, the labeling shall state that:

(i) The drug is indicated in the treatment, prevention, or diagnosis of a recognized disease or condition, e.g., penicillin is indicated for the treatment of pneumonia [**37] due to susceptible pneumococci; and/or

(ii) The drug is indicated for the treatment, prevention, or diagnosis of an important manifestation of a disease or condition, e.g., chlorothiazide is indicated for the treatment of edema in patients with congestive heart failure; and/or

(iii) The drug is indicated for the relief of symptoms associated with a disease or syndrome, e.g., chlorpheniramine is indicated for the symptomatic relief of nasal congestion in patients with vasomotor rhinitis; and/or

(iv) The drug, if used for a particular indication only in conjunction with a primary mode of therapy, e.g., diet, surgery, or some other drug, is an adjunct to the mode of therapy.

(2) All indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) of this chapter unless the requirement is waived under § 201.58 or § 314.126(b) of this chapter.

The government cannot identify, for example, that "substantial evidence of effectiveness based on adequate and well-controlled studies" exists for the anthrax vaccine with respect to protection against inhalation anthrax. If it could do so under [**38] the guise of law, surely the FDA and/or DoD would have identified for this Court the language in the label that serves to meet the legal requirements, or stated that the 1996 IND, which is designed to comply with this legal requirement, had been approved. It has not, and most assuredly cannot, do either.

Any way this issue is viewed, the defendants are in violation of the law with respect to the anthrax vaccine. Based on the DoD and FDA's own regulations and documents, the anthrax vaccine must be considered either an investigational new drug or one unapproved for use against inhalation anthrax. Therefore, *10 U.S.C. § 1107* applies, and the plaintiffs are entitled to their preliminary injunction. n16

n16 The FDA has repeatedly shirked its lawful responsibilities when overseeing use of the anthrax vaccine. Thirty years ago, the FDA published a Proposed Rule Making notice governing the "Legal Status of Approved Labeling for Prescription Drugs; Prescribing for uses unapproved by the Food and Drug Administration", *37 Fed. Reg. No. 158* (Aug. 15, 1972), 21 CFR Part 130. It read, in pertinent part, that "where the unapproved use of an approved drug becomes widespread or endangers the public health, the Food and Drug Administration is obligated to investigate it thoroughly and to take whatever action is warranted to protect the public." The fact that the anthrax vaccine has been administered to nearly one million people without informed consent in just the last five years alone is a sad demonstration of the FDA's interest in enforcing its own regulations and policies.

[**39]

[*21] **C. The Defendants Are Not Following The Licensed Vaccine Schedule For Shot Sequences**

As an initial matter, this Court can readily determine that defendants are not adhering to the licensed schedule for

the vaccine. That schedule calls for a specified shot sequence of 0, 2, and 4 weeks, followed by 6, 12 and 18 month inoculations. In fact, the defendants admit that they are not following this schedule, but attempt to explain it away by noting that the license itself does not specifically address dosing in the event of a "shortage." See Defs' Memo at 33-34.

Although the AVA license may be silent on every single possible thing that might go wrong with AVIP, the FDA has not allowed this silence to stifle the exercising of its lawful authority. FDA officials specifically informed the DoD that any deviation from the shot schedule was inappropriate and outside of the approved licensing. See Complaint P 43 and Attachment P. In 1999, at the time this statement was made, it was clear from representations made by the manufacturer to the Army that there was going to be a shortage of the vaccine sometime in the year 2000. In fact, at a meeting on December 17, 1997, between [**40] MBPI, its consultant SAIC, Army and FDA regulatory officials, MBPI's Executive Director (and later BioPort's Chief Operating Officer), Dr. Robert Myers, stated "that within 18 to 24 months after immunization begins, the vaccine will be in short supply." See Exhibit "3".

Moreover, the justification offered by the defendants in support of the interrupted schedule is baseless. The DoD's declarant, Colonel Grabenstein, is not a physician, but a pharmacist. There is no study of AVA showing that the vaccination schedule could be interrupted and then resumed without loss of efficacy. Colonel Grabenstein's assessment of [*22] what is medically appropriate or inappropriate should be given no weight as he is unqualified to testify to that point.

In short, the defendants' evidence now directly contradicts statements made by the same government agencies at a time when there was no lawsuit and when the impending vaccine shortage was well-known. n17

n17 It is the plaintiffs' current understanding that DoD has failed to continue the anthrax inoculations for those individuals who are currently on the "battlefield" in either Iraq or Afghanistan, notwithstanding repeated promises to the FDA that it would abide by the required shot sequence. The Court may wish to inquire of the defendants for confirmation of this fact at oral arguments since, if true, it impugns the government's credibility even further. If necessary, the plaintiffs can supply sworn declarations attesting to these facts.

[**41]

D. Public Interest Militates In Favor Of Granting The Injunction

The defendants emphasize that "armed combat with Iraq has begun and the global war against terrorism continues." See Defs' Memo at 34. Therefore, the "public interest will not be served by depriving the troops of the vaccine, thereby subjecting them to increased risk either from anthrax itself or from the increased battlefield risk caused by the unnecessary loss of comrades." Id. While the government's interest in protecting our troops is admirable and important (though highly suspect given its apparent disregard of continuing vaccinations in the "battlefield" region), the underlying claims are nothing more than exaggerated rhetoric.

If the concern and risks were so manifestly present, then why does the Department of State, whose employees are in the same regions as that of the plaintiffs and tens of thousands of military troops, not mandate the anthrax vaccine for its personnel? Instead, it offers them a supply of antibiotics. Surely, the defendants would not argue that the State Department cares less about its employees than does the Defense Department? Indeed, why are both British and Australian troops [**42] -- the other coalition nations with significant [*23] forces participating in the present Iraqi military conflict -- being offered an anthrax vaccine on a voluntary basis? n18

n18 See Ministry of Defence, "The Voluntary Immunisation Programme (VIP) Against Anthrax", June 13, 2002, at *http://www.guardian.co.uk/military/story/0,11816,893825,00.html* (United Kingdom); Australian Chief of Navy Vice Admiral Chris Ritchie message to all Naval personnel, February 13, 2003, SUBJ: ANTHRAX

VACCINATIONS AND WELL BEING OF NAVY PEOPLE, at *http://www.defence.gov.au/media/2003/16020303.htm* (Australia). The Canadian military also offers the anthrax vaccine on a voluntary basis. In fact, the highest ranking judge in the Canadian military ruled that use of AVA was a "violation of the Canadian Charter of Human Rights." The Christian Science Monitor, "*Canada: Soldiers have right to refuse anthrax vaccine*", May 9, 2000. It is noteworthy to add that the Canadian military judge reached his conclusion after hearing extensive testimony by the U.S. Army's top anthrax vaccine researcher, Colonel Arthur Friedlander, M.D. (ret), whose testimony the judge characterized in his ruling as "somewhat contradictory." See *http://www.majorbates.com/ law/canadatranscript.htm #* (transcript of Military Judge Colonel G.L. Brais' ruling, May 5, 2000). Although the ruling was overturned on appeal, it was done on the basis that dismissal of the court martial charges should not have occurred during the pre-trial phase. Despite this apparent victory, the Canadian military chose not to retry the case, nor has it reinstituted a mandatory anthrax vaccine program

[**43] .

The defendants also claim that the public interest favors denial of the plaintiffs' request because of administrative inconvenience over a process they control. It is alleged that an injunction would require layers of administrative review that would derail the program for months. See Defs' Memo at 35. n19 However, DoD was able to comply with similar administrative provisions in only three weeks between the adoption of the Interim Rule (predecessor of *10 U.S.C. § 1107*) on December 20, 1990, and the start of Gulf War combat operations on January 16, 1991. Moreover, DoD and FDA have had over four years since the passage of *10 U.S.C. § 1107* to comply with the law. The Court cannot [*24] now allow the defendants to jointly violate the law simply because they have chosen to ignore its requirements.

n19 Plaintiffs are at a loss to understand what onerous administrative requirements defendants refer to with regard to Executive Order 13139 ("E.O."). The E.O. requires certification from the FDA that the IND is safe and effective relative to the risk to troops without the IND, a recommendation from the Secretary of Defense that the waiver is necessary, and notice to the troops concerning the side effects of the IND. See E.O. 13139, PP 3(b)-(i). Such documentation is already in place following the civilian anthrax attacks. In fact the Center for Disease Controls provided a far more detailed assessment of the risks of the AVA than has ever been given to military members. See Exhibit "4".

[**44]

Surely, if the danger articulated by the government is so clear and immediate, there should be little difficulty in convincing the President and other necessary agencies to sign off on the required paperwork to make the AVIP mandatory and in compliance with the law, which is all the plaintiffs can ask.

E. Plaintiffs Face Irreparable Injury Because They Cannot Be Compensated For The Loss Of A Statutorily Guaranteed Right To Informed Consent Before Being Inoculated With An Investigational New Drug Or A Drug Unapproved For Its Use

If the Court does not grant this injunction, no monetary award can adequately compensate individuals whose right to informed consent has been violated as a result of the AVIP program. Although the defendants argue that the vaccine is safe and effective, the FDA itself has stated that the Army's so-called safety studies of AVA have "significant methodological limitations" because they were "not randomized or well-controlled." See FDA letter to Mark S. Zaid, Esq., dated January 7, 2002, at *http://www.fda.gov/ohrms/ dockets/dailys/02/Jan02/012302/00p-0653_ans0001_voll.pdf*. It is also undisputed that the vaccine label has recently been dramatically [**45] modified with respect to the systemic reaction rate (which went from 2% in the 1999 and preceding labels to between 5% and 35% in the January 2002 revised label; an increase of 175 fold) and in the variety of chronic illnesses that are associated with the vaccine (notably, the Pregnancy Rating was changed to Category D, which denotes "positive evidence of risk").

Moreover, it is impossible to tell with any certainty what the long-term effects of the vaccination will be. Establishing the etiology of vaccine-related illnesses or medical conditions is a costly and time-consuming process. It is for precisely this reason that *10 U.S.C. § 1107* was passed, so that drugs undergoing investigational studies would not [*25] be used on soldiers absent their informed consent of the risks, or a presidential waiver determination that the benefits outweigh the risks.

Accordingly, the plaintiffs can establish irreparable injury if their vaccinations are allowed to go forward because the AVIP will violate their statutory rights established by Congress and because there is no adequate remedy at law for the loss of these rights and for the potential medical injury that may [**46] result.

CONCLUSION

Based on the foregoing, this Court should declare that the anthrax vaccine is either an investigational new drug or a drug unapproved for its use, with respect to inhalation exposure, and grant the plaintiffs' Motion for a Preliminary Injunction.

Date: April 25, 2003

Respectfully submitted,

/s/

John J. Michels, Jr., Esq.

D.C. Bar # 457575

McGUIREWOODS LLP

77 W. Wacker, Suite 4400

Chicago, Illinois 60601

(312)849-8150

/s/

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