UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

MEMORANDUM OPINION

Plaintiffs, members of the active duty and selected National Guardsmen components of the Armed Forces as well as civilian contract employees of the Department of Defense ("DoD") who have submitted or have been instructed to submit to anthrax vaccinations without their consent pursuant to the Anthrax Vaccine Immunization Program ("AVIP"), commenced this action against the Secretary of Defense (Donald Rumsfeld), the Secretary of Health and Human Services (Tommy Thompson), and the Commissioner of the Food and Drug Administration (Mark McClellan).

Because plaintiffs maintain that Anthrax Vaccine Adsorbed ("AVA") is an experimental drug unlicensed for its present use and that the AVIP violates federal law (10 U.S.C. § 1107), a Presidential Executive Order (Executive Order 13139), and the

DoD's own regulations (DoD Directive 6200.2), plaintiffs ask that in the absence of a presidential waiver the Court enjoin the DoD from inoculating them without their informed consent. Plaintiffs allege three causes of action against defendants: (1) violation of the Administrative Procedure Act ("APA") by defendant DoD based on the DoD's failure to follow federal law, a presidential executive order, and DoD directive with respect to its AVIP; (2) violation of the APA by defendant DoD for its intent to inoculate plaintiffs with an unlicensed drug that is unapproved for its intended use; and (3) violation of the APA by the defendants' alteration of the licensed Federal Drug Administration ("FDA")-approved schedule of vaccination which rendered AVA a drug unapproved for its intended use.[1]

Defendants DoD and FDA maintain that the issues plaintiffs present are non-justiciable and that plaintiffs fail to present an evidentiary basis sufficient to support standing at the preliminary injunction stage. With respect to the merits, they allege that, in seeking to prevent the DoD from inoculating them, plaintiffs seek to undermine a key component of military readiness and defense against battlefield use of biological weapons.

Pending before this Court is a Motion for a Preliminary

[1] None of the plaintiffs alleged that their vaccination schedule was altered, so the Court does not reach the third cause of action.

Injunction. The central question before this Court is whether AVA is an "investigational" drug or a drug unapproved for its use against inhalation anthrax. Upon consideration of plaintiffs' motion for a preliminary injunction, the opposition, the reply, and oral arguments, as well as the statutory and case law governing the issues, and for the following reasons, it is, by the Court, hereby **ORDERED** that the Motion for a Preliminary Injunction is **GRANTED**. In the absence of a presidential waiver, defendants are enjoined from inoculating service members without their consent.

I. Background

A. Factual Background

In 1970, the National Institutes of Health ("NIH"), the agency then charged with licensing biologic drugs, *see* 37 Fed. Reg. 4004, 4004-04 (Feb. 25, 1972), licensed AVA for use against anthrax. *See* 36 Fed. Reg. 8704, 8705 (May 11, 1971). Two years later, authority to approve biologic drugs was delegated to the FDA. 37 Fed. Reg. 4004, 4004-05 (Feb. 25, 1972).

After the authority to license biologic drugs was delegated to the FDA, the agency initiated a review of the safety, effectiveness, and labeling of all licensed biologics. 21 C.F.R. 601.25. The Federal Register published a proposed rule containing the results of AVA's review on December 13, 1985. In

that product review, the independent Biologics Review Panel recommended that the vaccine be classified as safe, effective, and not misbranded. In their recommendations the panel discussed the Brachman study[2] and stated 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." Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Reviews, 50 Fed Reg. 51,002 (Dec. 13, 1985)(to be codified at 21 C.F.R. pt. 610). To date the AVA label does not specify which method of anthrax exposure it protects against. The Proposed Rule published in the December 13, 1985, Federal Register has never been finalized.

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[2] According to the December 13, 1995, Federal Register:
The best evidence for the efficacy of anthrax vaccine comes from a placebo-controlled field trial conducted by Brachman covering four mills processing raw imported goat hair into garment interlining. The study involved approximately 1,200 mill employees of whom about 40 percent received the vaccine and the remainder received a placebo or nothing. The average yearly incidence of clinical anthrax in this population was 1 percent. During the evaluation period, 26 cases of anthrax occurred. Twenty-one had received no vaccines, four had incomplete immunization and one had complete immunization. Based on analysis of attack rates per 1,000 person-months, the vaccine was calculated to give 93 percent (lower 95 percent confidence limit = 65 percent) protection against cutaneous anthrax based on comparison with the control group. *Inhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease.* (emphasis added). Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Reviews, 50 Fed Reg. 51,002 (Dec. 13, 1985)(to be codified at 21 C.F.R. pt. 610).

On October 5, 1995, the U.S. Army Medical Research and Material Command wrote the Michigan Department of Public Health ("MDPH"), the vaccine's manufacturer, that they were enclosing a plan "to expand the indication for use to include projections from aerosol exposure to B. anthraces spores." Pls.' Compl. Ex. G, Letter from Anna Johnson-Winegar to Robert Myers of October 5, 1995. The plan specifically asserts that "[t]his vaccine is not licensed for aerosol exposure expected in a biological warfare environment." Pls.' Compl. Ex. G, Attachment to Letter from Anna Johnson-Winegar to Robert Myers of October 5, 1995. The plan proposed was to amend the anthrax vaccine license through an Investigational New Drug ("IND") application submission.

On October 20, 1995 (as reflected in a November 13, 1995, memorandum from the Department of the Army 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."[3] Pls.' Compl. Ex. H, Mem. Regarding: Minutes of the Meeting on Changing the Food and Drug Administration License for the Michigan Department of Public Health (MDPH) Anthrax Vaccine to Meet

[3] At this meeting, Colonel Arthur Friedlander, Chief of the Bacteriology Division of the U.S. Army Medical Research Institute for Infectious Diseases, briefed meeting participants on (1) evidence for a reduction in the number of doses of anthrax vaccine, (2) evidence for vaccine efficacy against an aerosol challenge, and (3) progress toward an in vitro correlate of immunity. SEALED.

Military Requirements from David L. Danley to Distribution List on November 13, 1995.

On July 2, 1996, the FDA held a meeting to consult with and provide guidance to the DoD and MDPH officials who were formulating the forthcoming September 1996 IND application. The Army "presented a plan in progress to develop correlates in immunity in animals and then in humans vaccinated with MAVA in order to obtain a specific indication for inhalation anthrax." Pls. Reply Ex. 1, Summary of the Michigan Anthrax Vaccine Adsorbed (MAVA) Pre-IND Meeting with the FDA: Specific Indication for Inhalation Anthrax; Change in Schedule and Route at ¶ 5.

In September 1996, AVA's manufacturer submitted an IND application to the FDA in an attempt to get FDA approval for a modification of the AVA license to demonstrate the drug's effectiveness against inhalation anthrax. The IND application is still pending and, to date, there is no indication for inhalation anthrax on the label or in the product insert.

In 1997, the Assistant Secretary of Defense "took...steps to confirm that AVA is approved for use against inhalation anthrax." Defs.' Opp'n at 10. For instance, the Assistant Secretary of Defense (Health Affairs) wrote to the FDA's Lead Deputy Commissioner, stating that the "DoD has long interpreted the scope of the license to include inhalation exposure, including that which would occur in a biological warfare context" and

inquiring "whether the FDA has any objection to our interpretation of the scope of the licensure for the anthrax vaccine." Defs. Opp'n. Ex. 3, Letter from Stephen Joseph to Mark Friedman of March 4, 1997. The Lead Deputy Commissioner responded "I believe your interpretation is not inconsistent with the current label." Defs. Opp'n. Ex. 2 Attach. 3, Letter from Mark Friedman to Stephen Joseph of March 13, 1997.

In a response to a citizen petition dated August 2002, the FDA's Associate Commissioner of Policy noted that the FDA still has yet to finalize the rule proposed in the December 13, 1985, Federal Register. But here, contradicting the panel's position regarding the Brachman study in the 1985 Federal Register, the FDA stated that the Brachman study included inhalation anthrax. Thus, the FDA concluded that "[t]he indication section of the labeling does not specify the route of exposure and thus includes both cutaneous and inhalation exposure." Pls.' Compl. Ex. D, Resp. to Citizen Pet. Dated October 12, 2001 from Margaret Dotzel to Russell Dingle on August 28, 2002.

The AVA product insert, which originally stated that the adverse reaction rate to the vaccine was 0.2 percent, was recently revised to reflect an adverse reaction rate between 5.0 percent and 35.0 percent. At least six deaths have been linked to the vaccine and the vaccine's pregnancy use risk has been upgraded from a Category C risk (risk cannot be ruled out) to a

Category D risk (positive evidence of risk.)

B. Legal Background

In 1998, in response to concerns about the use of investigational new drugs during the 1991 Gulf War that may have led to unexplained illnesses among veterans, Congress signed into law 10 U.S.C. § 1107. This provision prohibts the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. The consent requirement may be waived only by the President. In 1999, the President signed Executive Order 13139, pursuant to which the DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13139, 64 Fed. Reg. 54,175 (September 30, 1999). In August, 2000, the DoD formally adopted these requirements in DoD Directive 6200.2.

In 1998, the DoD began a mass inoculation program using AVA as a preventative measure against inhalation anthrax for service members and civilian employees. The program was administered without informed consent or a presidential waiver. Plaintiffs contend that because AVA is not licensed for inhalation anthrax, its use by the DoD is not only investigational but it is also a drug unapproved for its intended use in violation of 10 U.S.C. §

1107, Executive Order 13139, and DoD Directive 6200.2. Tr. at 7-8. Defendants maintain that they are not in violation of any law because AVA is not an investigational new drug and it is licensed for inhalation anthrax.

II. Standard of Review

When seeking a preliminary injunction, the movant must demonstrate to the Court that: (1) there is a substantial likelihood that plaintiff will succeed on the merits; (2) plaintiff will be irreparably injured if an injunction is not granted; (3) an injunction will not substantially injure the other party; and (4) the public interest will be furthered by an injunction. *Davenport v. Int'l Bhd. of Teamsters,* 166 F.3d 356, 361 (D.C. Cir. 1999).

III. Discussion

A. Justiciability

1. Jurisdiction in an Article III Court

The parties in this case dispute whether the threshold requirement of justiciability is met. While plaintiffs maintain that the DoD's use of AVA in the AVIP is justiciable, defendants contend that the Article III case or controversy requirement is not met because (1) plaintiffs' claims are non-justiciable and (2) plaintiffs fail to present an evidentiary basis sufficient to

support standing for purposes of a request for preliminary injunction. Whether or not this Court can exercise jurisdiction over plaintiffs' claims depends on whether those claims fall within the narrow category of demands for equitable relief that are not barred under the D.C. Circuit's jurisprudence.

Courts have traditionally been hesitant to intervene in the conduct of military affairs. *See, e.g., United States v. Stanley,* 483 U.S. 669, 683-84 (1987); *Chappell v. Wallace,* 462 U.S. 296, 300 (1983). The general concern that courts are "ill-equipped to determine the impact upon discipline that any particular intrusion upon military authority might have," *Chappell,* 462 U.S. at 305, is heightened when courts are called upon to intervene between soldiers and their military superiors. *See, e.g. Gilligan v. Morgan,* 413 U.S. 1, 10 (1973) (observing that the "complex subtle, and professional decisions as to the composition, training, equipping, and control of a military force are essentially professional military judgments...."). Based on concerns surrounding judicial competence, the Supreme Court has declined to entertain service-related damages claims under the Federal Tort Claims Act, *see, e.g., Feres v. United States,* 340 U.S. 135 (1950), and *Bivens* actions "whenever the injury arises out of activity 'incident to service.'" *Stanley,* 483 U.S. at 681.

While claims for damages are nonjusticiable, the circuits

are divided with respect to the viability of claims for *injunctive relief* against the military. The case of *Speigner v. Alexander,* 248 F.3d 1292, 1296 (11th Cir. 2001), *cert denied,* 543 U.S. 1056 (2001), held that cases brought by enlisted personnel against the military for injuries incident to service are nonjusticiable, whether those claims request monetary or injunctive relief. In its decision, the Eleventh Circuit surveyed the appellate decisions addressing the justiciability of claims seeking injunctions against the military. The court noted that the Second, Fifth, Seventh, and Eighth Circuits had all found suits by enlisted personnel against the military for an injury incident to service nonjusticiable for injunctive relief as well as for damages. The *Speigner* court observed that the minority of circuits have held that injunctive relief is attainable against the military. The First Circuit, for instance, explicitly held that, "*Chappell* and *Stanley* make it clear that intramilitary suits alleging constitutional violations but not seeking damages are justiciable." *Wiggington v. Centracchio,* 205 F.3d 504, 512 (1st Cir. 2000). In *Jorden v. Nat'l Guard Bureau*, the Third Circuit held that "*Chappell* itself suggests that it leaves open claims for injunctive relief against the military." 799 F.2d 99, 100 (3d Cir. 1986).

The United States Court of Appeals for the D.C. Circuit, however, has not interpreted *Chappell* or *Feres* as embracing

categorical rules. In a recent opinion addressing the justiciability of a service member's suit for equitable relief the D.C. Circuit stated that the "Supreme Court has made clear...that *Feres* does not bar all suits by service personnel...." *Braanum v. Lake,* 311 F.3d 1127, 1130 (D.C. Cir. 2002). The *Braanum* court rejected any distinction between facial challenges and as applied challenges and noted that "some as applied challenges are plainly permitted." *Id.* The court found that Braanum's assertions that his due process and other rights were violated by the military taking actions against him in excess of its jurisdiction under the Military Code fell squarely within the Supreme Court's decision in *Schlesinger v. Councilman. See Braanum,* 311 F.3d at 1130 (citing 420 U.S. 738, 740 (1975)). In *Schlesinger,* the Court held that Article III courts had jurisdiction to entertain an Army captain's suit seeking an injunction against pending court martial proceedings based on conduct he claimed was non "service-related" and therefore outside the court martial jurisdiction. *Id.*

Plaintiffs in this case argue that district courts called upon to review military decisions must employ the test adopted in *Mindes v. Seamen,* 453 F.2d 197 (5th Cir. 1971), *affirmed on appeal after remand,* 501 F.2d 175 (5th Cir. 1974). *See* Pls.' Mot. at 5; Pls.' Reply at 7. The *Mindes* court held that a court should only review internal military affairs if there is an

allegation that a constitutional right has been deprived or an allegation that the military has acted in violation of applicable statutes or regulations. *Mindes*, 453 F.2d at 201. The Fifth Circuit determined that there are four factors a court must analyze:

> (1) the nature and strength of the plaintiff's challenge to the military determination;
> (2) the potential injury to the plaintiff if review is refused;
> (3) the type and degree of anticipated interference with the military function;
> (4) the extent to which the exercise of military expertise or discretion is involved (courts should defer to superior knowledge and experience of professionals in matters such as military personnel decisions or other areas that relate to specific military functions.)

Id.

While plaintiffs concede that the D.C. Circuit has not expressly adopted the *Mindes* test, they point out that it has not rejected the test in circumstances such as those presented in the case at bar. The case of *Kreis v. Secretary of the Air Force*, 866 F.2d 1508, 1512 (D.C. Cir. 1989), however, suggests to this Court that the D.C. Circuit Court may not look particularly favorably upon the *Mindes* analysis. In the *Kreis* case, an Air Force major brought suit seeking retroactive promotion or, in the alternative, correction of military records. The Court of Appeals held that the major's claim for retroactive promotion was a nonjusticiable military personnel decision and that his

alternative claims for correction of military records were justiciable. In holding that appellant's second claim was justiciable as a request for review of agency action, the court held that

> In dismissing this case, the district court considered neither *Chappell* nor our decisions relying upon it. Instead, the court concluded that appellant's entire complaint is nonjusticiable based solely on *Mindes*...which, the district court noted, we cited in *Dilley v. Alexander,* 603 F.2d 914, 920 (D.C. Cir. 1979). Our reference to *Mindes*, however, was not intended to foreclose judicial review of decisions involving the correction of military records; indeed, in the same paragraph, we said that the federal courts may inquire whether the Secretary's action in this area is "arbitrary, capricious, or contrary to the statutes and regulations governing that agency." *Id.* Nor did we adopt the *Mindes* court's four factor analysis, which, as the Third Circuit has pointed out, erroneously "intertwines the concept of justiciability with the standards to be applied to the merits of the case." *Dillard v. Brown,* 652 F.2d 316, 323 (3d Cir. 1981).

Kreis, 866 F.2d at 1512.

As the above discussion highlights, there is no bright line rule in the D.C. Circuit when it comes to establishing justiciability. What can be said with certainty is that this Circuit has not ruled out the right of individuals to seek injunctive relief against the military in civilian courts in all cases. Therefore, to assess the question of justiciability, this Court examines: (1) whether a court martial was pending against any of the plaintiffs, s*ee, e.g., Schlesinger,* 420 U.S. 738; (2) the degree to which a ruling by this Court would interfere with

supervisory-subordinate relationships on the battlefield and/or personnel decisions, *see, e.g., Chappell*, 462 U.S. 296; and (3) the extent to which action by this Court would affect or disrupt the goals of discipline, obedience, and uniformity, *see, e.g., Goldman v. Weinberger*, 475 U.S. 503 (1986).

First, this lawsuit was not instigated in an attempt to thwart a pending court martial, as was the case in *Schlesinger*, 420 U.S. 738. Moreover, this Court has no reason to believe that any of the plaintiffs are currently facing a court martial. In fact, three of the plaintiffs have complied with the order to take the inoculation and are seeking review of the DoD's order in this Court. Tr. at 38. Further, two of the plaintiffs are civilian employees and could not be subjected to court martial proceedings. Tr. at 36. At most, only one plaintiff could potentially be facing a court martial and, in the event that the situation arose, the case could be permitted to proceed with regard to the other plaintiffs. Thus, there are no concerns that this lawsuit was an attempt to interfere with pending court martial proceedings or that a judgment in this case will interfere with a pending court martial against one of the plaintiffs.

Second, plaintiffs allege that the DoD acted arbitrarily and capriciously by failing to adhere to statutes and regulations governing its activities. Their claim is against the Secretary

of Defense about a decision made in headquarters, not about a tactical decision military supervisors made in the field. Tr. at 13. Similarly, because plaintiffs are a diverse class and include civilian individuals who are not in the employ of the military, the danger of disrupting discipline and/or supervisory-subordinate relationships is minimal at best. Thus, a judgment in this Court would not interfere with a supervisory-subordinate relationship on the battlefield.

Third, while the Court is cognizant of the fact that allowing some service members to refuse inoculations at this stage could threaten the uniformity of the military, this case is not analogous to *Goldman,* where plaintiff sued to enjoin application of an Air Force regulation that forbade officers from wearing a yarmulke while on duty. *Goldman*, 475 U.S. 503. In *Goldman*, the Court recognized that importance of the appearance of uniformity for a effective functioning military. *Id.* at 510 ("The Air Force has drawn the line essentially between religious apparel that is visible and that which is not, and we hold that those portions of the regulations challenged here reasonably and evenhandedly regulate dress in the interest of the military's perceived need for uniformity.") Rather, here there will be no visible differences between persons who choose to receive the vaccine and those who choose not to receive the vaccine. Thus, concerns about uniformity diminish and a judgment in this case

would not affect the uniformity of military personnel to any substantial degree.

2. Availability of APA Review

Defendants maintain that Section 10 of the APA precludes judicial review. Defs.' Opp'n at 20. Specifically, they point to 5 U.S.C. § 701(b)(1)(G), which renders the APA's judicial review provisions inapplicable to acts of "military authority exercised in the field in time of war or in occupied territory." In addition, they refer to 5 U.S.C. § 701(b)(1)(F), a provision barring judicial review of "court martial and military commissions." Finally, defendants aver that the APA "excludes from its waiver of immunity...claims for which an adequate remedy is available elsewhere." *Transhio Sav. Bank v. Director OTS,* 967 F.2d 598, 607 (D.C. Cir. 1992).

The Court finds 5 U.S.C. § 701(b)(1)(G) inapplicable to the present situation. As plaintiffs note, the AVIP was announced in December, 1997, implemented initially in March, 1998, and implemented force-wide in May of that year. Due to the vaccine shortages discussed above, few of the service members who fought in Afghanistan in 2001-2003 were vaccinated at all. The recommencement of the AVIP program was announced on June 29, 2002, – a date which predated Congressional authorization for the

use of force in Iraq by four months and the recent hostilities by almost eighteen months. The plaintiffs in the instant case are not challenging military authority exercised in the field in a time of war or in occupied territory. In fact, according to plaintiffs, "[n]one of the plaintiffs are presently in the 'field' or in 'occupied territory.'" Pls.' Reply at 9. Moreover, the order for the program at issue in this case was given by the Secretary of Defense, not by commanders in the field. Similarly, the Court finds 5 U.S.C. § 551(1)(F) inapplicable, as none of the plaintiffs in this case have asked this Court to review a court martial or military commission proceedings.

Finally, defendants submit that the proper forum for plaintiffs to raise their claims is in the military justice system *after* having refused orders to take the vaccine. They cite the case of *New v. Cohen,* 129 F.3d 639 (D.C. Cir. 1997), as the principal authority in support of their proposition. While this D.C. Circuit opinion does embrace comity principles and the exhaustion requirement, it explicitly states that, at the heart of the comity principle "is the general rule that a federal court must await the final outcome of court-martial proceedings in the military justice system before entertaining an action by a service member *who is the subject of the court-martial*." *New,* 129 F.3d at 642. (emphasis added.) Similarly, the decision

refers repeatedly to "pending" court martial proceedings, service members "charged" with crimes by military authorities, and the prohibition on "collateral review" of court-martials. *Id.* at 643. The language in *New* strongly suggests that its holding applies to cases in which alternative channels within the military justice system are already being pursued by, or against, the plaintiffs. The thrust of the *New* decision is clearly that Article III courts should not interfere with the proceedings of military tribunals. In the present case, the Court has no reason to believe that any of the plaintiffs are currently facing a court martial. Moreover, the civilian plaintiffs cannot be subjected to court martial proceedings. Thus, the Court finds no reason to stay its hand based on *New*.

Instead, this Court reads *New* for the proposition that the courts are another option for plaintiffs. As *New* stated:

> [u]pon receiving 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 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.

New, 129 F.3d at 647. At oral argument plaintiffs' counsel informed this Court that all six of the plaintiffs have been ordered to submit to the vaccine. Tr. at 38. Three of the

plaintiffs obeyed the order and now seek judicial review. *Id.* This Court finds that it is one of the proper forums for this claim.

3. Standing

A core element of Article III's case or controversy requirement is that a plaintiff must establish that he or she has standing to sue. *Lujan v. Defenders of Wildlife,* 504 U.S. 555, 561 (1992). The "question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues." *Allen v. Wright,* 486 U.S. 737, 750-51 (1984). A plaintiff must meet three requirements in order to establish Article III standing. *See, e.g., Friends of Earth, Inc. v. Laidlaw Environmental Serv. (TOC), Inc.,* 528 U.S. 167, 180-91 (2000). First, she must demonstrate "injury in fact" – a harm that is "concrete," "actual or imminent, not conjectural or hypothetical." *Whitmore v. Arkansas,* 495 U.S. 149, 155 (1990); *see also City of Los Angeles v. Lyons,* 461 U.S. 95, 101 (1983). Second, she must establish causation – a "fairly...trace(able) connection between the alleged injury in fact and the alleged conduct of the defendant." *Simon v. Eastern Ky. Welfare Rights Org.,* 426 U.S. 26, 41 (1976). Third, she must demonstrate redressability – a "substantial likelihood" that the requested

relief will remedy the alleged injury in fact. *Id.* at 45.

A plaintiff seeking injunctive relief demonstrates the first two standing requirements only by showing that the defendant is likely to injure the plaintiff. *Cone Corp. v. Florida Dep't of Transportation,* 921 F.2d 1190, 1205 (11th Cir. 1991). "Mere allegations will not support standing at the preliminary injunction stage." *Doe v. Nat'l Bd. Med. Exam'rs,* 199 F.3d 146, 152 (3rd Cir. 1999); *see also Nat'l Wildlife Fed. v. Burford,* 878 F.2d 422, 423 (D.C. Cir. 1989) *rev'd on other grounds sub non Lujan,* 497 U.S. 871 (burden of establishing standing at preliminary injunction stage is no less than for summary judgment).

In the present case, the government alleges that plaintiffs' claims of injury are purely speculative because adverse personnel actions against them for refusing inoculations may or may not occur. However, the Court agrees with plaintiffs that the defendants' argument ignores the fact that when challenging an investigational drug under 10 U.S.C. § 1107 an inoculation without informed consent or a presidential waiver is the injury. Tr. at 32. Because all six plaintiffs have been ordered to appear for the inoculation, and three of the six have already begun the series with more inoculations to follow, all plaintiffs have established that they will imminently suffer a harm that is actual, concrete, and inflicted at the hands of defendants unless

defendants are required to conform to 10 U.S.C. § 1107.

II. Likelihood of Success on the Merits

Having found that this claim is justiciable, the central question before the Court is whether AVA is being used as an investigational new drug or as a drug unapproved for its intended use. At bottom, this inquiry turns on whether the FDA has made a final decision on the investigational status of AVA; and if not (1) whether the 1996 IND application establishes the vaccine's status as an investigational drug and (2) whether the DoD is using AVA in a manner inconsistent with its license and intended use.[4]

As indicated previously, defendants' position is that 10 U.S.C. § 1107 is inapplicable because the AVA's license covers use against inhalation anthrax. Defs.' Opp'n Ex. 1, Goodman Decl. ¶ 11. They argue that the FDA has interpreted the lack of specificity concerning inhalation anthrax as permitting use of the vaccine against any route of exposure. While neither explaining the panel's finding in the December 15, 1985, Federal Register proposed rule stating that cases of inhalation anthrax

[4] In light of the fact that, as defendants concede, a vaccine can be licensed for one purpose and investigational for another, plaintiffs are correct in asserting that whether or not the vaccine in question is "licensed" is not, in itself, dispositive.

in the Brachman study were too infrequent to assess the vaccine against inhalation anthrax nor citing any additional studies of inhalation anthrax, defendants aver that agency officials have always considered the vaccine to include inhalation anthrax. Tr. at 92. They further allege that the 1996 IND application was submitted as a result of a dispute between underlings (Tr. at 92-93) and state that while the application is still technically pending, it is not longer being actively pursued. Tr. at 119. In addition, defendants point to a 1997 letter written by the Assistant Secretary of Defense stating that the IND application in no way suggests an official position that the DoD believed the approved label did not already encompass inhalation exposure. *See* Defs.' Opp'n at 31. Defendants note that such interpretations by an agency within its area of expertise are entitled to substantial deference. In support of their position, they cite several cases, including *Thomas Jefferson Univ. v. Shalala,* 513 U.S. 504, 512 (1994) and *Trinity Board of Fla., Inc. v. FCC,* 211 F.3d 618, 625 (D.C. Cir. 2000), standing for the proposition that an agency is entitled to deference with respect to the interpretation of the statutes it is tasked with administering.

While defendants' arguments concerning deference are correct, the dispute in this case has not focused on the language of a particular *DoD* statute. Rather, it is the *FDA's* term

"investigational" that is at the heart of the dispute. Title 10 U.S.C. § 1107 and the attendant DoD regulation apply only if the *FDA* determines that AVA is an investigational drug or a drug unapproved for its present purpose. As plaintiffs note, the letters and declarations defendants cite are not "formal FDA opinion(s)." *See* 21 C.F.R. § 10.85(k)(2000). Under 21 C.F.R. § 10.85(k)

> A statement made or advice provided by an FDA employee constitutes an advisory 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 bind or otherwise obligate or commit the agency to the views expressed.

Similarly, the personal opinions of FDA officials as expressed in a series of letters are not entitled to any particular deference. *See Christensen, et al v. Harris County, et al.,* 529 U.S. 576 (2000) (holding that an agency statutory interpretations contained in opinion letters are entitled to respect but only to the extent that interpretations have power to persuade.) The apparent change in position from the December 1985 proposed rule and the cryptic use of a double negative (i.e. "it is not inconsistent"), fail to persuade this Court that the view expressed in the 1997 letter is the FDA's formal opinion. Given that finding, the FDA has failed to provide any formal opinion *vis a vis* AVA's investigational status and the Court must

consider plaintiffs' arguments.[5]

In 1996, the manufacturer of the AVA, the Michigan Department of Public Health, filed an Investigational New Drug Application that remains open today. The manufacturer's stated purpose for filing the application was "to conduct clinical investigations designed to investigate changes in the approved labeling for the licensed product. The potential labeling would affect the specific clinical indication, route and vaccination schedule for AVA." Pls.' Compl. Ex. J, Letter from MDPH to Dr. Kathryn C. Zoon of October 20, 1996. The Introductory Statement to the 1996 IND application similarly provided that "[t]he ultimate purpose of this IND is to obtain a specific indication for inhalation anthrax and a reduced vaccination schedule." Pls.' Compl. Ex. K, Introductory Statement to the 1996 IND Application of September 20, 1996.

The source of the dispute concerns whether current use of the AVA for inhalation anthrax is licensed in light of the drug's present status and the IND application. Plaintiffs contend that,

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[5] At the oral argument, the government argued that the Citizen Petition states that the drug is licensed for inhalation anthrax and that is the agency's official position. Tr. at 86. However, the Court is persuaded by plaintiffs' arguments that the Citizen Petition addressed the licensing issue by merely relying on the 1997 Friedman letter and did not do the in-depth analysis as would be appropriate to make that kind of a determination or to contradict the opinion it expressed concerning the Bachman study in the 1985 Federal Register. *See* Tr. at 125.

as there has been insufficient study of the vaccine, its license does not incorporate inhalation anthrax. They rely on a 1985 panel that found that the license for anthrax was not broad enough to include inhalation anthrax. The panel findings were based partially on the Brachman Study, which noted that there were too few cases of inhalation anthrax to determine the efficacy of the vaccine. *See* Brachman and Friedlander, Vaccines 736 (eds. Plotkin and Mortimer)(1999). The Brachman Study observed that there have been "no controlled clinical trials in humans of the efficacy of the currently licensed U.S. vaccine." *Id.*[6] Plaintiffs correctly note that there have been no subsequent human studies on the efficacy of the vaccine against inhalation anthrax since that time. In addition, plaintiffs submit that defendants' own documents support their position that a vaccine is investigational if it is used in a manner, or for a purpose, identical to that set forth in the IND application. In this regard, plaintiffs cite a number of documents, including the October 5, 1995, letter by the U.S. Army Medical Research and Material Command, the November 13, 1995, memorandum from the Department of the Army's Joint Program Office for Biological Defense, and information provided by the Army at the July 2, 1996, FDA-sponsored meeting, chronicling the government's

[6] *See* Pls.' Reply at 13 n. 12 for relevant congressional testimony.

statements that the AVA lacked licensure for protection against inhalation anthrax.

Plaintiffs conclude that, because there is insufficient scientific evidence demonstrating that the anthrax vaccine protects against anthrax inhalation exposure, the government's claims violate fundamental precepts of drug law. Specifically, plaintiffs submit that the government claim violates 21 C.F.R. § 201.56(c), detailing general requirements on content and format of labeling for prescription drugs, which provides:

> 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.

Moreover, plaintiffs contend that 21 C.F.R. § 201.57 (c)(2) is violated. That section provides that "All indications shall be supported by substantial evidence of effectiveness based on adequate and well-controlled studies." *Id.* Plaintiffs assert that the government cannot identify "substantial evidence of effectiveness based on adequate and well-controlled studies" for the anthrax vaccine with respect to protection against inhalation anthrax.

While the issues presented to the Court are complex, and the

evidence somewhat contradictory, the Court is ultimately persuaded that plaintiffs enjoy a substantial likelihood of success on the merits for the following reasons. The FDA, the only agency that this Court could properly defer to in determining AVA's status as an investigational drug, has failed to provide a formal opinion as to AVA's investigational status. Having made that determination, the Court is required to make its own inquiry and determination regarding AVA's investigational status. The Court looked at the labeling requirement, 21 C.F.R. § 201.56, which mandates that "[n]o 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." In the case of AVA, the 1985 panel found insufficient data to license the drug for use against inhalation anthrax. To date, no additional studies have been performed and AVA's label does not specify use of the vaccine for this purpose. Moreover, the Court is persuaded that the 1996 IND application remains pending today. The introduction to the application expressly states that one objective of the application is to obtain a specific indication for use of AVA against inhalation anthrax. While the government states that the inhalation anthrax aspect of the IND is no longer active, the documents submitted to this Court under seal suggest otherwise.[7] Finally, statements made by DoD officials suggest

[7] SEALED.

that the agency itself has, at some point at least, considered AVA experimental with respect to inhalation anthrax. Given all these factors, the Court would be remiss to conclude that the original license included inhalation anthrax. Having reached that conclusion, the DoD's administration of the inoculation without consent of those vaccinated amounts to arbitrary action.

III. The Public Interest

Plaintiffs maintain that Executive Order 13139, Department of Defense Directive 6200.2, and especially 10 U.S.C. § 1107, were enacted to protect soldiers from involuntarily serving as "guinea pigs" in a mass use of investigational medicine. Pls.' Mot. at 23. In their view, defendants' disregard of the violations has already caused half a million members of the armed forces to be experimental subjects without their consent.

Defendants base their public policy argument on the idea that requiring compliance with informed consent would render it infeasible to continue the AVIP for current military operations in Iraq or in conjunction with the war on terrorism. Essentially, defendants argue that the harm to the public interest would include disrupting the smooth functioning of the military, hampering military readiness, and reducing the military's ability to protect its service members. Should those individuals who have refused anthrax vaccinations be injured by

anthrax, their injuries or deaths would have a detrimental effect on the military and its operation at large. Defs.' Opp'n at 37. Plaintiffs counter by observing that if the risks of anthrax injuries were so manifestly present, the State Department, as well as the coalition forces of Britain and Australia, would have taken similar steps to protect their employees. Plaintiffs refute the government's argument concerning the cumbersome administrative results that could ensue from the granting of a preliminary injunction by stating that the DoD was able to comply with similar administrative proceedings in only three weeks between adoption of the predecessor of 10 U.S.C. § 1107 and the start of the Gulf War in 1991. Plaintiffs conclude by remarking that "if the danger articulated by the government is so clear...there should be little difficulty in convincing the President...to sign off on the required paperwork to make the AVIP mandatory...which is all plaintiffs can ask." Pls.' Reply at 24.

The Court is persuaded that the right to bodily integrity and the importance of complying with legal requirements, even in the face of requirements that may potentially be inconvenient or burdensome, are among the highest public policy concerns one could articulate. Moreover, the Court is not convinced that requiring the DoD to obtain informed consent will interfere with the smooth functioning of the military. However, if obtaining

informed consent were to significantly interfere with military function, defendants are free to seek a presidential waiver. If the Executive branch determines that this is truly an exigent situation, then obtaining a presidential waiver would be an expeditious end to this controversy.

IV. Irreparable Harm

Plaintiffs argue that their injuries from non-consensual inoculations would be irreparable. They note that the informed consent documents provided to civilians as a result of the anthrax laden letters in the Fall of 2001 identify side effects such as Guillain-Barre Syndrome, multiple sclerosis, angiodema, aseptic meningitis, severe injection site inflammation, diabetes, and systemic lupus erythmatosis. In addition, the pregnancy risk assessment has, as noted above, been recently upgraded. Pls.' Mot. at 15. It is impossible to tell with any certainty what the long-term effects of the vaccination will be. Regardless, plaintiffs submit that no monetary award can adequately compensate individuals whose right to informed consent has been violated.

Defendants' position is that harm in the form of potential side effects is "hypothetical or, at best, unlikely to occur." Defs.' Opp'n at 40. Defendants refer to a *de minimis* risk of serious adverse reactions and report 105 serious adverse

reactions from AVA in over 830,000 recipients. *Id.* They stress that AVA has been used effectively in civilian industry for over 30 years.

Having found that AVA is an investigational drug under 10 U.S.C. § 1107, the Court is persuaded that requiring a person to submit to an inoculation without informed consent or the presidential waiver is an irreparable harm for which there is no monetary relief.

Conclusion

The Court has considered Plaintiff's Motion for a Preliminary Injunction, the Response and Reply thereto, counsel's representations at oral argument, and the relevant statutory and case law. In sum, because the record is devoid of an FDA decision on the investigational status of AVA, this Court must determine AVA's status for itself. This Court is persuaded that AVA is an investigational drug and a drug being used for an unapproved purpose. As a result of this status, the DoD is in violation of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2. Thus, because the plaintiffs are likely to prevail on the merits, defendants will not face substantial harm by the imposition of an injunction, the public interest is served, and plaintiffs face irreparable harm, the Court finds that the plaintiffs meet the requirements for a Preliminary Injunction.

The women and men of our armed forces put their lives on the line every day to preserve and safeguard the freedoms that all Americans cherish and enjoy. Absent an informed consent or presidential waiver, the United States cannot demand that members of the armed forces also serve as guinea pigs for experimental drugs.

An appropriate Order accompanies this Opinion.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1, *et al*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-707 (EGS)
DONALD H. RUMSFELD, *et al*	)	
Defendants.	)	

ORDER

Pursuant to Fed. R. Civ. P. 65 and for the reasons stated by the Court in its Memorandum Opinion docketed this same day, it is this 22nd day of December, 2003, hereby

ORDERED that the Motion for a Preliminary Injunction is **GRANTED.** In the absence of a presidential waiver, defendants are enjoined from inoculating service members without their consent; and it is

FURTHER ORDERED that defendants are directed to file responsive pleadings by January 30, 2004; and it is

FURTHER ORDERED that an Initial Scheduling Conference is scheduled for **March 9, 2004 at 10:00 a.m.** Pursuant to LCvR 16.3 of the Local Rules and Fed. R. Civ. P. 26(f) counsel shall meet and confer by no later than February 24, 2004 and submit their Report addressing all topics listed in LCvR 16.3(c) by no later than March 2, 2004.

Signed: Emmet G. Sullivan
United States District Judge
December 22, 2003