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JOHN DOE # 1, et al., Plaintiffs, v. DONALD H. RUMSFELD, SECRETARY OF DEFENSE, et al., Defendants.

1:03-cv-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 8166

March 18, 2003

Motion for Preliminary Injunction

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TITLE: [**1]

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

TEXT: INTRODUCTION

With our military forces currently engaged in armed hostilities in which the threat of biological and chemical weapons is a constant and substantial reality, plaintiffs ask this Court to grant extraordinary and unprecedented relief. They seek to undermine a key component of military readiness and defense against battlefield use of biological weapons -- the Department of Defense's Anthrax Vaccination Immunization Program ("AVIP"). In implementing AVIP, the Secretary of Defense has determined that mandatory inoculation of military personnel deployed in the Persian Gulf region with Anthrax Vaccine Adsorbed ("AVA") -- the only known effective vaccine against exposure to anthrax -- is necessary to shield our military against a possible biological attack using anthrax. Nevertheless, plaintiffs ask this Court to enjoin defendants from inoculating certain military service members and civilian employees with AVA, arguing that the anthrax vaccination program violates *10 U.S.C. § 1107*, a statute requiring the Department of Defense to comply with the "prior consent [**2] requirement imposed under section 505(i)(4) of the Federal Food, Drug and Cosmetic Act" ("FFDCA") anytime it seeks to administer "an [*2] investigational new drug or a drug unapproved for its applied use" to a member of the armed forces. *10 U.S.C. § 1107(f)*.

The legal predicate for plaintiffs' suit and for their assertion of irreparable harm is their mistaken understanding that the vaccine has not been approved for the treatment of inhalation anthrax. To the contrary, as the relevant history and attached declaration from the Food and Drug Administration ("FDA") make clear, the FDA has indeed approved the vaccine for treatment of inhalation anthrax. Accordingly, use of the vaccine for that approved purpose plainly does not trigger the applicability of the informed consent requirements of *10 U.S.C. § 1107*. For similar reasons, the balance of harms also tips decidedly against injunctive relief. The military has a strong interest in administering an anthrax vaccine that has been approved as safe and effective, and the receipt of such an approved vaccine will cause plaintiffs no

irreparable injury. By contrast, enjoining the administration [**3] of that vaccine as plaintiffs request would interfere with the ability of the military to conduct its crucial operations during wartime, a result that underscores the impropriety of such relief as a matter of equitable discretion for much the same reasons that it also demonstrates the lack of a justiciable controversy.

For a number of reasons, plaintiffs' request for preliminary injunctive relief should be denied. As an initial matter, plaintiffs cannot demonstrate a likelihood of success on the merits -- the touchstone of injunctive relief -- both because this Court lacks jurisdiction over their claims and because their claim to relief under section 1107 is legally erroneous. First, this Court lacks jurisdiction to hear plaintiffs' claims, which are nothing short of an attack on decisions of the military chain-of-command regarding military readiness and the conduct of battle. As the [*3] Supreme Court has held: "Civilian courts must, at the very least, hesitate long before entertaining a suit which asks the court to tamper with the established relationship between enlisted military personnel and their superior officers," because "that relationship is at the heart of the necessarily [**4] unique structure of the Military Establishment." *Chappell v. Wallace, 462 U.S. 296, 300 (1983)*. Indeed, the Administrative Procedure Act ("APA") itself recognizes that this unique relationship inherent in the military chain-of-command is especially outside the ken of judicial expertise during times, such as these, of military conflict, expressly excepting from APA review all "military authority exercised in the field in time of war or in occupied territory." *5 U.S.C. § 701(b)(1)(G)*. Instead, the military justice system affords the military plaintiffs their proper remedy for claims that an order to submit to inoculation is unlawful. see *New v. Cohen, 129 F.3d 639, 643 (D.C. Cir. 1997)*. Given this important and unique disciplinary structure, this Court should not entertain plaintiffs' claims here.

Plaintiffs' request for preliminary injunctive relief is especially inappropriate on the record now before the Court. The anonymous plaintiffs have failed to present this Court with anything other than speculative and unsupported allegations that they may be harmed. But because preliminary injunctive relief alters the relations between [**5] the parties, a much more substantial evidentiary showing is required to support court intervention. See *Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985)*.

Second, notwithstanding these jurisdictional defects, plaintiffs would not prevail were this Court to reach the merits of their claims. Defendants simply did not violate the informed consent/waiver provisions of section 505(i)(4) of the FFDCA and section 1107 because AVA is, [*4] and always has been, approved for anthrax generally, including inhalation anthrax. While plaintiffs suggest that the vaccine is only approved for cutaneous (or skin) exposure, they are simply mistaken. The license and label for AVA are silent as to the route of exposure by the victim, and that silence means AVA is approved for exposure to anthrax bacterium *regardless of how the victim became infected*. This interpretation has been consistently applied to the vaccine by both the Department of Defense ("DoD") and the FDA, an interpretation confirmed by the only published opinion to have reached the issue. *O'Neil v. Secretary of the Navy, 76 F. Supp. 2d 641, 645 (W.D. Pa. 1999)* (holding that AVA is [**6] not subject to Executive Order 13139). AVA is not an "investigational new drug" or a drug that is not approved for the use for which the military has required it, i.e., to protect against inhalation anthrax. Accordingly, section 1107 does not apply here.

Not only are plaintiffs unable to demonstrate a likelihood of success on the merits, but they also cannot satisfy any of the remaining factors necessary for preliminary injunctive relief. The balance of harms tips decidedly in favor of the government in this case. Any order now compelling informed consent under section 505(i)(4) of the FFDCA unless there is a Presidential waiver under section 1107 would have the effect of halting the military's use of the vaccine during wartime and would have potentially devastating effects on military preparedness on the battlefield. At the very least, even if relief were limited to these particular plaintiffs (as plaintiffs themselves, at the initial status conference, indicated might be appropriate), judicial relief would impact severely on the combat readiness of plaintiffs' particular military units. Moreover, any success in this action would embolden further suits by others seeking to avoid [**7] the vaccination. [*5] The collective second-guessing of military orders that these suits would engender, even if ultimately unsuccessful, would seriously compromise military discipline and readiness.

Moreover, the harm to the nation's fighting strength from fielding combat or support units in which some members are susceptible to an anthrax attack significantly outweighs the de minimis potential harm plaintiffs could face if they

proceed with the vaccination. AVA is a safe vaccine that has been used for over 30 years in the civilian world with minor side effects comparable to other common vaccines. Within the AVIP itself, the rate of serious adverse reactions is only 0.013%.

Finally, the public policy underlying the judiciary's usual deference to military decisions is all the more appropriate in this time of actual combat both in Iraq and in the global war on terrorism. The public interest is best served by fielding a combat force that is protected to the greatest feasible extent against potential theater threats. Such protection will lower casualties and, possibly, shorten any conflict. The Secretary of Defense's decision to require AVA for the combat forces of the [**8] United States furthers that interest.

For all of these reasons, as set forth more fully below, the plaintiffs' requested relief should be denied.

BACKGROUND

I. Plaintiffs' Claims

Plaintiffs are an anonymous group of six military members and civilians either employed by DoD or by private companies under contract with DoD, n1 purportedly under orders to receive [*6] AVA. Plaintiffs' claims for relief are based upon the so-called "informed consent" provisions of *10 U.S.C. § 1107* as well as the section-1107-implementing Executive Order and DoD regulation. Under section 1107, whenever the DoD intends to provide an "investigational new drug or a drug unapproved for its applied use" to a member of the armed forces, the "prior consent requirement imposed under" the FFDCA -- which requires that the Secretary give certain information to a person required to receive such a drug and obtain each person's consent prior to use of the drug -- "may be waived only by the President." See *10 U.S.C. § 1107(f)*. While plaintiffs suggest that AVA is approved for cutaneous (skin contact) anthrax, they argue here that the military [**9] violates the informed-consent provision of section 1107 because AVA is not currently approved for inhalation anthrax -- that is, exposure through breathing in the spores -- and because no Presidential waiver has been obtained. Plaintiffs also allege that the defendants have failed to adhere to the vaccine's approved dosage schedule.

n1 The complaint alleges that the six plaintiffs are military members or "DoD civilian contract employees." Complaint, P 1. But at the March 27, 2003 status conference, plaintiffs' counsel asserted that the six unnamed plaintiffs include one DoD civilian employee.

II. The Anthrax Threat

Anthrax is a deadly disease caused by spores of the bacterium *Bacillus anthracis*. Ex. 1, Grabenstein Decl. P 4. Human infection may occur by three routes of exposure to the spores: by skin contact (cutaneous), by ingestion (gastrointestinal), and by inhalation (pulmonary). Id. Fatality rates from anthrax vary depending on the exposure route: cutaneous anthrax without antibiotics [**10] -- approximately 20%; gastrointestinal anthrax -- 25 to 75%; pulmonary anthrax -- 45 to 80% or higher. Id.

U.S. military forces now in combat against Iraq or stationed elsewhere in Southwest Asia [*7] fighting the global war on terrorism face a very significant threat from anthrax as a biological weapon. Id. P 3; see also H.J. Res. 114, Pub. L. 107-243, 107th Cong., *116 Stat. 1498* (Oct. 16, 2002) (declaring that "Iraq both poses a continuing threat to the national security of the United States and international peace and security in the Persian Gulf region and remains in material and unacceptable breach of its international obligations by, among other things, continuing to possess and develop a significant chemical and biological weapons capability, actively seeking a nuclear weapons capability, and supporting and harboring terrorist organizations"). As President Bush stated in his 2003 State of the Union Address.

> The United Nations concluded in 1999 that Saddam Hussein had biological weapons material sufficient to produce over 25,000 liters of anthrax -- enough doses to kill several million people. He has not accounted for that material. He has given [**11] no evidence that he has destroyed it.

149 Cong. Rec. H214 (Daily ed. Jan. 28, 2003) (also available at http://www.whitehouse.gov /news/releases/ 2003/01/20030128-19.html). Accordingly, the Secretary of Defense determined that the highest threat area of the world for anthrax attack is the geographical area near Iraq, and he directed that military personnel and certain civilians who perform emergency-essential functions n2 with the force deployed to this region must be vaccinated against anthrax. Ex. 1, Grabenstein Decl. P 3.

> n2 Emergency-essential civilians occupy positions that perform duties of "immediate and continuing support for combat operations or to support maintenance and repair of combat essential systems" and do so "in a combat zone." *10 U.S.C. § 1580*, see also DoD Dir. 1404.10, encl. 2, P E2.1.5. Similarly, "contractors providing services designated as essential by a DoD Component are expected to use all means at their disposal to continue to provide such services, in accordance with the terms and conditions of the contract during periods of crisis, until appropriately released or evacuated by military authorities." DoD Inst. 3020. *37 P 4*.2.

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[*8] **III. Regulatory History of AVA**

A. AVA's License

The only known, effective prevention against anthrax is the vaccine referred to as Anthrax Vaccine Adsorbed. Ex. 1, Grabenstein Decl. P 5. Prior to AVA being licensed, a well-controlled field trial using a similar precursor vaccine n3 was conducted using mill workers who processed animal hair. Id. During this trial, 26 cases of anthrax were reported at the mills -- 21 cutaneous and 5 inhalation. Id. Of the five inhalation cases, two individuals had received the placebo, while three individuals (in the observational group) had received no injections. Id. Four of the five people who developed inhalation anthrax died. Id. No cases of inhalation anthrax occurred in any of the individuals who had received the anthrax vaccine. Id. Based upon a comparison between the anthrax vaccine and placebo recipients, the authors calculated a vaccine efficacy level of 92.5 percent. Id.

> n3 As the FDA has determined, the differences between the precursor vaccine and AVA are minor changes in the manufacturing process and in the formulation of the drug. Ex. 2, Goodman Decl. Attach. 2, Citizen Pet. Resp. to R. Dingle, Docket No. 01P-0471 (Aug. 28, 2002) p. 8. The comparability of the two vaccines has been verified using potency data and safety/immunogenicity tests. *Id. p. 9*.

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Largely on the basis of this field study, in 1970, the National Institutes of Health, the agency then charged with licensing biologic drugs, see *37 Fed. Reg. 4004, 4004-05* (Feb. 25, 1972), licensed AVA for use against anthrax. See *36 Fed. Reg. 8704, 8705* (May 11, 1971). In 1972, authority to approve biologic drugs such as AVA was delegated to the FDA. *37 Fed. Reg. 4004, 4004-05* (Feb. 25, 1972). Despite this change in licensing authority, AVA, like all other biologic drugs, remains licensed unless the FDA takes formal action to suspend or revoke its [*9] license. *21 C.F.R. § 601.4(a)*. AVA's license has never been suspended or revoked. See Ex. 2, Goodman Decl. P 9.

B. FDA License Review of AVA

After authority to license biologic drugs like AVA was delegated to the FDA, it initiated a comprehensive review of the safety, effectiveness, and labeling of all licensed biologies. *21 C.F.R. § 601.25*; Ex. 2, Goodman Decl. P 6. In this

review, independent advisory panels of scientific experts from outside the government examined each biologic. *21 C.F.R. § 601.25(a)*; Ex. 2, Goodman Decl. P 6. Based on their examination, the panels [**14] were to recommend to the FDA that the agency classify each individual biologic in one of the following ways: (1) safe, effective, and not misbranded; (2) unsafe, ineffective, or misbranded; or (3) insufficient information to classify, further testing required. *21 C.F.R. § 601.25(e)*; Ex. 2, Goodman Decl. P 6.

AVA underwent this review in the mid-1980s, and the panel recommended that the vaccine be classified as safe, effective, and not misbranded. *50 Fed. Reg. 51002* (Dec. 13, 1985); Ex. 2, Goodman Decl. P 9. Pursuant to the governing regulation, the FDA then published a proposed order adopting the panel's classification. Id. In its order, the FDA did not propose revoking the license for AVA, an action that it would have taken if FDA had determined that AVA was unsafe. *21 C.F.R. § 601.25(f)*; see Ex. 2, Goodman Decl. P 9. Thus, notwithstanding that the FDA has not issued a final order on AVA's classification, see *21 C.F.R. § 601.25(g)*, AVA's license remains valid because the FDA has never sought to revoke or suspend it, *21 C.F.R. § 601.4(a)*; Ex. 2, Goodman Decl. P 9.

[*10] **C. AVA's Approved Uses**

For any licensed product, the approved uses are derived [**15] from the FDA-approved label. See *21 C.F.R. § 201.100*. The approved labeling for AVA states that it is indicated for individuals who may come in contact with animal products that may be contaminated with *Bacillus anthracis* spores and for individuals engaged in diagnostic or investigational activities which may bring them in contact with *Bacillus anthracis* spores. Ex. 1, Grabenstein Decl. P 5; Ex. 2, Goodman Decl. P 10. It is also recommended for persons at high risk of exposure, such as veterinarians, lab workers, and others whose occupation may involve exposure to contaminated materials. Id.; Complaint, Ex. B (AVA product insert). This non-exhaustive list of high-risk persons has been interpreted by DoD to encompass military personnel serving in areas where there is a significant threat of a biological attack from anthrax. Ex. 1, Grabenstein Decl. P 5.

Importantly, AVA's label does not limit its use to any particular route of anthrax exposure. Id. P 7; Ex. 2, Goodman Decl. P 11. The label does not distinguish among individuals who may be infected by spores entering the body through skin contact, ingestion, or inhalation. Id. DoD and FDA have thus consistently [**16] interpreted the label as encompassing inhalation exposure. Id.; Ex. 2, Goodman Decl. P 11 & Attach. 2 (Pet. Resp.) p. 6.

Prior to commencing the current anthrax vaccination program, and prior to passage of section 1107, DoD took appropriate steps to confirm that AVA is approved for use against inhalation anthrax. On March 4, 1997, the Assistant Secretary of Defense (Health Affairs) wrote to the Lead Deputy Commissioner for the FDA, stating "DoD has long interpreted the scope of the license to include inhalation exposure, including that which would occur in a biological [*11] warfare context," and asking "whether the FDA has any objection to our interpretation of the scope of the licensure for the anthrax vaccine." Ex. 3, Letter from Stephen C. Joseph, M.D., Asst. Sec'y of Defense, Health Affairs to Michael A. Friedman, M.D., Lead Dep. Comm'r, FDA (Mar. 4, 1997). The Lead Deputy Commissioner for the FDA responded on March 13, 1997: "I believe your interpretation is not inconsistent with the current label." Ex. 2, Attach. 3, Letter from Michael A. Friedman, M.D., Lead Dep. Comm'r, FDA to Stephen C. Joseph, M.D., Asst. Sec'y of Defense, Health Affairs (Mar. 13, 1997).

The FDA [**17] recently reiterated its determination that AVA is licensed against inhalation anthrax. In an August 28, 2002 response to a citizen petition filed by an opponent of the DOD AVIP, the FDA's Associate Commissioner for Policy stated: "The indication section of the labeling does not specify the route of exposure and thus includes both cutaneous and inhalation exposure." Ex. 2, Goodman Decl. P 11 & Attach. 2 p. 6.

D. AVA's Approved Dosing Schedule

AVA's label currently recommends six doses administered subcutaneously. Ex. 1, Grabenstein Decl. P 16; Ex. 2, Goodman Decl. P 12. After the first dose, the label recommends that the remaining doses be injected at 2 weeks, 4

weeks, 6 months, 12 months, and 18 months. Id. DoD currently adheres to this schedule. Ex. 1, Grabenstein Decl. P 16.

Beginning in July 2000, a shortage of AVA required the DoD to suspend inoculations for many individuals. Ex. 1, Grabenstein Decl. P 16. Thus, some individuals who had received one or more of the first five doses had their remaining doses deferred. Id. When the shortage of AVA abated last year, DoD resumed inoculating those individuals who had doses deferred and [*12] who remained in units [**18] or positions subject to combat duty in Iraq or duty elsewhere in Southwest Asia. Id. This reinitiating of the dosing schedule at the point where it was interrupted is consistent with sound vaccination practice and the recommendation of the United States Centers for Disease Control and Prevention, id., and it is routinely followed for other, more common, vaccines. Id.; Ex. 2, Goodman Decl. P 13. In this particular case, FDA has stated that

> The resumption of a multi-dose vaccine series unavoidably interrupted by a vaccine shortage is not a clinical investigation' that requires the filing of an Investigational New Drug application. See 21 C.F.R. Part 312. The resumption of the anthrax vaccine series under these circumstances is not inconsistent with the product labeling, in that the labeling does not specifically address closing in the event of unavoidable vaccine shortages, and resumption of the dosing series at the point at which it was interrupted is consistent with the principles of safety and efficacy underlying the dosing regimen in the anthrax vaccine labeling.

Ex. 2, Goodman Decl. P 14.

As for individuals who began the inoculation series after the shortage [**19] abated, DoD is adhering to the schedule recommended on the label. Ex. 1, Grabenstein Decl. P 16. Significantly, plaintiffs have not alleged that any of their dosing schedules were ever interrupted by the AVA shortage.

ARGUMENT

Plaintiffs Are Not Entitled To Injunctive Relief

Injunctive relief is an extraordinary remedy, and the party seeking it has a substantial burden of proof. See *American Coastal Line Joint Venture v. United States Lines, Inc., 580 F. Supp. 932, 935 (D.D.C. 1983)*. Because of the extraordinary nature of this form of judicial relief, courts should grant preliminary injunctions sparingly. *Barton v. District of Columbia, 131 F. Supp. 2d 236, 242 (D.D.C. 2001)* (citing *Moore v. Summers, 113 F. Supp. 2d 5, 17 (D.D.C.* [*13] *2000))*. Moreover, when plaintiffs seek to intrude into areas reserved to the Executive Branch -- such as the protection of our armed forces during a time of war -- they must make an especially strong showing that they are entitled to relief. *Adams v. Vance, 570 F.2d 950, 956 (D.C. Cir. 1978); Palestine Info. Office v. Schultz, 674 F. Supp. 910, 918 (D.D.C. 1987)*. [**20] Plaintiffs fail to do that and, thus, are not able to meet the basic requirements for obtaining a preliminary injunction.

When seeking a preliminary injunction, the movant must demonstrate to the Court that: (1) there is a substantial likelihood 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)*. Although this is a flexible standard, both the elements of likelihood of success on the merits and irreparable harm must be shown to prevail. *District 50, United Mine Workers of Am. v. International Union, United Mine Workers of Am., 412 F.2d 165, 167 (D.C. Cir. 1969)*. n4 Here, plaintiffs cannot satisfy any of the standards for preliminary injunctive relief; thus, the Court must deny plaintiffs' motion.

> n4 Where the plaintiff makes a particularly weak showing on one factor, the other factors may not be enough to compensate. *Taylor v. RTC, 56 F.3d 1497, 1506* (D.C. Cir.), amended on other grounds on reh'g *66*

F.3d 1226 (D.C. Cir. 1995). Therefore, for example, if the plaintiff fails to make a strong showing of likelihood of success on the merits, "it would take a very strong showing with respect to the other preliminary injunction factors to turn the tide in plaintiff's favor." *Davenport, 166 F.3d at 367*.

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[*14] **I. Plaintiffs Cannot Demonstrate A Likelihood Of Success On The Merits**

A. The Court Lacks Jurisdiction

Plaintiffs' prayer for injunctive relief founders on the most basic requirement -- that this Court has jurisdiction over the asserted claims. Article III of the Constitution restricts the jurisdiction of the federal courts to "Cases" and "Controversies." U.S. Const, art. III, § 2; *Flast v. Cohen, 392 U.S. 83, 94 (1968); Allen v. Wright, 468 U.S. 737, 750 (1984)*. Indeed, "no principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases and controversies. *Simon v. Eastern Ky. Welfare Rights Org., 426 U.S. 26, 37 (1976); Valley Forge Christian Coll. v. Americans United for Separation of Church & State, Inc., 454 U.S. 464, 471 (1982)* (noting the "bedrock requirement" that courts hear only "cases or controversies"). For two independent reasons, the case or controversy jurisdictional requirement is lacking here. First, the issues that plaintiffs present are non-justiciable. Second, [**22] plaintiffs fail to present an evidentiary basis sufficient to support standing at the preliminary injunction stage.

1. Plaintiffs' Challenge To The Decisions Of The Military Chain-of-Command Presents a Non-Justiciable Question

The plaintiffs' challenge to orders requiring their inoculation with the anthrax vaccine is an extraordinary one. It represents an attempt by military servicemen and emergency-essential civilians during wartime to judicially countermand decisions by their superiors about military preparedness and conduct of the war. It thus seeks relief which, if granted, may imperil the lives of military personnel and civilians and jeopardize the prosecution of ongoing military operations. [*15] Plaintiffs' attempt to interpose the federal courts between themselves and their superiors in a theater of active military operations is foreclosed by established principles of judicial restraint and by the explicit text of the Administrative Procedure Act.

Traditional principles of judicial deference to military decisions counsel strongly against judicial intervention here. Although framed as a garden-variety APA challenge to agency action, the relief that is sought would [**23] require this Court to engage in review of military decisions regarding the battlefield activities of troops engaged in combat. While their complaint names as defendants the Secretary of Health and Human Services ("HHS") and the Commissioner of the Food and Drug Administration, plaintiffs do not complain of any agency action by either HHS or the FDA, and they do not seek any relief against those defendants. Rather this case focuses solely on the decision by the Secretary of Defense to prepare his combat forces for battle by vaccinating them against anthrax, a known biological weapon. We know of no precedent for entertaining such a suit, and there are compelling reasons why it should not be.

Courts traditionally have been reluctant to intervene in the conduct of military affairs. See, e.g., *United States v. Stanley, 483 U.S. 669, 684 (1987); Chappell v. Wallace, 462 U.S. 296, 300 (1983); Schlesinger v. Councilman, 420 U.S. 738, 757-58 (1975); Gilligan v. Morgan, 413 U.S. 1, 10 (1973); Orloff v. Willoughby, 345 U.S. 83, 93-94 (1953)*. This reluctance rests on the fundamental and highly salutary [**24] principle that judges "are not given the task of running [the military]," *Orloff, 345 U.S. at 93,* and that they are "ill-equipped" to determine the impact of judicial intrusion on military authority, *Chappell, 462 U.S. at 305*.

These general concerns take on an added dimension when courts are called on to [*16] interpose themselves between soldiers and their military superiors. In the words of the Supreme Court, "no military organization can function without strict discipline and regulation that would be unacceptable in a civilian setting." *Chappell, 462 U.S. at 300*.

Judicial intervention risks disrupting the "the inescapable demands of military discipline and obedience to orders," id., that are integral to the military's performance. See also *Gilligan, 413 U.S. at 10* (noting inappropriateness of judicial intervention in "the complex, subtle, and professional decisions as to the composition, training, equipping, and control of a military force").

Judicial reluctance to interfere with military decisions has been manifest in a wide range of cases and has drawn on a variety of judicial doctrines. In some instances, [**25] concerns about judicial competence in military matters have implicated the tenets of the political question doctrine. See, e.g., *Gilligan, 413 U.S. at 5-12*. Similar concerns have been viewed in other cases as "special factors counseling hesitation" in the recognition of remedies for constitutional violations. See, e.g., *Chappell, 462 U.S. at 298-304* (citations omitted). And in still other cases, these concerns have influenced the course of statutory interpretation, leading courts to give narrow compass to broadly written statutory provisions. See, e.g., *Feres v. United States, 340 U.S. 135 (1950)*.

Relying on these concerns, the Supreme Court has declined to entertain service-related damages claims by military personnel, even in peacetime and even concerning claims for which no explicit "military exception" exists. Thus, in Feres and its progeny, the Supreme Court disallowed claims by servicemen against the United States under the Federal Tort Claims Act ("FTCA") for service-related injuries, despite the absence of any explicit exception for such [*17] claims in the text of the FTCA and regardless [**26] of whether the claims related to an actual military undertaking. See *Chappell, 462 U.S. at 298-99* (discussing Feres). Similarly, the Court has refused to entertain Bivens actions by servicemen against their superiors "whenever the injury arises out of activity "incident to service." *Stanley, 483 U.S. at 681*. Stanley is particularly noteworthy because the specific claim before the Court there was a claim of unlawful medical experimentation on members of the military.

The same principles apply to injunctive claims. At least five courts of appeals have held that Chappell and Stanley categorically preclude soldiers from seeking injunctive relief against their commanding officers, see *Speigner v. Alexander, 248 F.3d 1292, 1296-98* (11th Cir.), cert. denied, *534 U.S. 1056 (2001)* (collecting cases), n5 on the ground that "the potential for [*18] disruption of the hierarchical structure [of the military] exists each time a soldier hales his superior into court . . . regardless of the remedy the soldier seeks," *Watson v. Arkansas Nat'l Guard, 886 F.2d 1004, 1008 (8th Cir. 1989)*. [**27]

n5 *Meister v. Texas Adjutant General's Dept., 233 F.3d 332 (5th Cir. 2000)* (court has little competence in military discipline and management), cert. denied, *532 U.S. 1052 (2001); Jones v. New York State Div. of Military & Naval Affairs, 166 F.3d 45 (2d Cir. 1999)* (injuctive relief would compromise military discipline and readiness for combat); *Knutson v. Wisconsin Air Nat'l Guard, 995 F.2d 765 (7th Cir. 1993)* (military reinstatement cases are nonjusticiable because their review would undermine military discipline and decision-making or impair training programs and operational readiness); *Watson v. Arkansas Nat'l Guard, 886 F.2d 1004 (8th Cir. 1989)* (Feres doctrine bars both damages and injunctive relief; to do otherwise would be to exalt form over substance); *Crawford v. Texas Army Nat'l Guard, 794 F.2d 1034 (5th Cir. 1986)* (suits for injunctive relief must be restricted to prevent intrusion of courts into the military structure). One of these courts even went so far as to hold that military decisions concerning civilian employees were also non-justiciable for the same reasons, *Meister, 233 F.3d at 340,* a position also adopted by at least one district court, *Mann v. Heigh, 891 F. Supp. 256, 263 (E.D.N.C. 1995),* aff'd on other grounds, *120 F.3d 34 (4th Cir. 1997)*

The recent decision in *Brannum v. Lake, 311 F.3d 1127 (D.C. Cir. 2002),* is not to the contrary. There the court applied the well-established, narrow exception that federal courts may entertain equitable suits that challenge the military's jurisdiction over a citizen. *Id. at 1130;* see also *Reid v. Covert, 354 U.S. 1, 30 (1957); New v. Cohen, 129 F.3d 639, 644 (D.C. Cir. 1997)*. Simply put, the military cannot court martial civilians. *Reid, 354 U.S. at 30; New, 129 F.3d at 644*. Brannum is inapplicable here because the plaintiffs do not claim that the military is improperly asserting jurisdiction over any of them.

[**28]

The case against judicial intervention is at its most compelling here. Unlike Stanley and Feres, which involved damages claims arising out of peacetime controversies, this suit is brought during ongoing hostilities and seeks to have this Court second-guess and overturn a military decision relating to military preparedness and conduct on the battlefield. The demands of military discipline are at their zenith during armed combat. See *Chappell, 462 U.S. at 300* (the requirement that servicemen "meet certain overriding demands of discipline and duty' . . . becomes imperative in combat"). 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). n6

n6 The deference that defendants ask this Court to exercise is very narrow. This Court need not consider whether all prospective injunctive relief is precluded by Chappell. Rather, this Court need only rule that it should defer in cases such as this, where military orders relating to ongoing hostilities are at issue. This Court need not define the further contours of this doctrine in this case.

[**29]

For this very reason, the decision of the Court of Appeals for the District of Columbia in *Doe v. Sullivan, 938 F.2d 1370 (1991),* is inapposite to this case. In Sullivan, the court emphasized that "deference is owed to the political branches in military matters," but nevertheless permitted the plaintiffs to bring a facial challenge to the FDA's issuance of a regulation relating to the military's use of vaccines. *Id. at 1380*. Notably, Sullivan was decided [*19] after hostilities had ended, yet the Court still refused to question the military's decisions, focusing solely on the straightforward APA-appeal of the FDA's rulemaking. Here, plaintiffs have not made any such facial challenge to an FDA regulation but, instead, have asserted claims against their superior officers and the Department of Defense. This distinction was not lost on the court in Sullivan, which was careful to narrowly limit its holding to the facial challenge made and to note specifically that the dispute was not one between soldiers and their superiors. Id. ("His claim, as now advanced, entails no judicial interference with the relationship between soldiers [**30] and their military superiors. . . . We confront at this time not a dispute over military strategy or discipline, not one between soldiers and their superiors, but one over the scope of authority Congress has entrusted to the FDA.") (citations omitted) (emphasis added). Sullivan permits, at most, only ordinary APA review of typical, non-DoD agency activities during peacetime. n7 The case before this Court differs because plaintiffs challenge, in the midst of ongoing combat, military orders by commanding officers regarding how to prepare for battle. If Chappell is to have any meaning, it is surely in a case such as presented now in which plaintiffs seek relief from decisions regarding military preparedness and combat readiness during the middle of an ongoing military conflict. n8

n7 Unlike Sullivan, plaintiffs here are not alleging any improper agency action by either of the non-DoD defendants. Plaintiffs did not petition HHS or FDA for review of AVA, nor have they ever attempted to appeal a denial of a petition for review submitted by others. Rather plaintiffs' claims focus on one decision: that of the Secretary of Defense to inoculate his forces. Accordingly, the non-DoD defendants are not proper parties to this case.

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n8 The FDA waiver provisions that were challenged in Sullivan are no longer applicable to DoD's decision to inoculate military personnel as a result of *10 U.S.C. § 1107*, enacted after Sullivan. Thus, the relevant factual context in which Sullivan was decided -- and the key regulatory factor at issue in Sullivan, i.e., an independent decision by the FDA challenged by the plaintiffs -- is simply not the same in this case.

[*20] If Congress were to desire to grant plaintiffs a judicial remedy in these circumstances, it would have to say so in explicit terms. But tellingly, Congress did not grant an express cause of action in enacting section 1107. See *Alexander v. Sandoval, 532 U.S. 275, 286-87 (2001)* (in the absence of clear congressional intent, courts may not infer private rights of action from statutes). Thus, plaintiffs may not rely on the text of that statute to seek relief before this Court.

Nor may plaintiffs seek relief under the APA because that statute contains an explicit statutory bar against judicial review. [**32] Section 10 of the APA expressly makes the APA's judicial review provisions inapplicable to acts of "military authority exercised in the field in time of war or in occupied territory." *5 U.S.C. § 701(b)(1)(G)*. n9 The APA thus recognizes and incorporates the traditional judicial deference to military decisionmaking and avoids judicial interference with that authority in critical times of war.

n9 *5 U.S.C. § 701(b)(1)(G)* excludes "military authority exercised in the field in time of war or in occupied territory" from the definition of "agency." It thereby places such actions outside the scope of *5 U.S.C. § 702*, which waives the sovereign immunity of the United States for claims ("other than ones for money damages") by persons "suffering legal wrong" or "adversely affected or aggrieved" by "agency action." See also *5 U.S.C. § 551(1)(G)*.

Here, plaintiffs are seeking to enjoin their superiors from requiring them and others [**33] similarly situated to take AVA before entering duty in Iraq or elsewhere in Southwest Asia. Plaintiffs' claims thus ask the Court to countermand acts of "military authority exercised in the field." And given the level of armed hostilities, the requirement that the decision relate to "time of war" is obviously met. See, e.g., *Rasul v. Bush, 215 F. Supp. 2d 55, 64 (D.D.C. 2002)* [*21] (holding that APA review unavailable under "military authority" exception for claims by alien detainees captured during military action against A1 Qaeda and Taliban in Afghanistan), aff'd, *321 F.3d 1134 (D.C. Cir. 2003)*. Accordingly, Section 10's prohibition against judicial review is squarely applicable. n10

n10 For the same reasons already explained, Sullivan does not foreclose reliance on the APA's "military authority" exception. As explained, supra at 18, that case involved the review of an independent decision of the FDA, separate and apart from the military chain of command. Here, however, the FDA has no role in the decision to require inoculations and thus plaintiffs' attack is directly on the decisions of "military authority exercised in the field in time of war or in occupied territory." *5 U.S.C. § 701(b)(1)(G)*.

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As to the military plaintiffs, another section of the APA bars judicial review of "courts martial and military commissions." *5 U.S.C. § 701(b)(1)(F)*. n11 As set out below, should the military plaintiffs refuse to receive the vaccine, they may be charged with violations of the Uniform Code of Military Justice. Such charges could be heard, at their option, by courts martial, potentially subject to at least five levels of post-trial review. See *10 U.S.C. §§ 860-869*. Congress established this military justice system to handle claims just like this that require a court to balance the needs of military preparedness with fairness to the individual military member. *Schlesinger v. Councilman, 420 U.S. 738, 758 (1975)*. The military plaintiffs here are, in essence, attempting to bypass that system and have this Court predetermine the outcome of their military cases. Such forum-shopping is expressly barred by the APA and should not be [*22] countenanced here.

n11 This exception for courts martial and the exception for military authority exercised in the field in time of war not only bar judicial review, but have several distinct, independently dispositive consequences. Section

701 actually excludes these two categories from the definition of "agency" under the APA. Accordingly, these categories of decisions are excluded from any right of review under section 702, any waiver of sovereign immunity under section 702, any review under section 704, and any scope of review under section 706.

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Finally, the APA "excludes from its waiver of sovereign 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)*. n12 As discussed below, both service members and civilian employees have adequate alternative remedies.

n12 Defendants note that, other than the APA, there is no basis for a waiver of sovereign immunity. Section 1107, the statute under which plaintiffs seek relief, contains no waiver of sovereign immunity. And it is well-settled that the general federal question provision, *28 U.S.C. § 1331*, is not a waiver of sovereign immunity. See, e.g., *Clopton v. Department of the Navy, 1996 WL 680189 (D.C. Cir. 1996)* (per curiam). It is similarly well-established that the Declaratory Judgment Act, *28 U.S.C. § 2201*, does not grant jurisdiction or waive sovereign immunity; it simply provides a remedy. See *Skelly Oil Co. v. Phillips Petroleum Co., 339 U.S. 667 (1950)*. And the Little Tucker Act, *28 U.S.C. § 1346*, is only relevant with respect to claims for money damages, not for the injunctive or declaratory relief that plaintiffs seek. See *28 U.S.C. § 1346* (providing district court jurisdiction over claims against the United States not exceeding $ 10,000). That plaintiffs have requested the Court to award them costs and attorneys' fees does not alter this conclusion. See *Sharp v. Weinberger, 798 F.2d 1521, 1524 (D.C. Cir. 1986)*. Accordingly, the lack of a waiver of sovereign immunity also bars this suit.

[**36]

(a) Service Members Have An Adequate Remedy In The Military Justice System

The proper forum for the military plaintiffs to raise their claims is in the military justice system after having refused an order to take the vaccine. This action improperly seeks to preempt that military system from considering the issues presented. But under principles of comity recognized in this Circuit, this Court should not become entangled in matters that are better left to that process. See *New v. Cohen, 129 F.3d 639, 643 (D.C. Cir. 1997)*.

The military plaintiffs' refusal or pending refusal to take AVA will result in one of three possible outcomes. First, no action may be taken against them. Second, they may be charged with a violation of the Uniform Code of Military Justice for refusing to obey a lawful order. And [*23] third, they may be processed for administrative separation from the service. The first option obviously entails no harm to the plaintiffs and is not at issue here. Plaintiffs have filed this action as a defense to preempt the second and third possibilities. But the resolution of that defense is more appropriately handled within the military justice [**37] system.

To balance military preparedness and fairness, Congress created the military court system. *New v. Cohen, 129 F.3d 639, 643 (D.C. Cir. 1997)*. This military system includes such procedural safeguards as the rights to counsel; to present evidence; to assert defenses (including their claims here); to be tried by a jury or by a judge at their option; and to have their case considered by up to five levels of review, including two neutral appellate panels. See *10 U.S.C. §§ 860-869*. Via a petition for certiorari, ultimate review by the Supreme Court may also be available. *10 U.S.C. § 867a*. In creating this system, Congress recognized that the military is a specialized society separate from civilian society with laws and traditions of its own, a society whose need to prepare for and fight wars requires a respect for duty far beyond that required in the civilian world. *Schlesinger v. Councilman, 420 U.S. 738, 757 (1975)*.

Honoring Congress's concerns in this regard, federal courts have invoked the doctrine of comity and followed a general rule that they must await the final outcome of a court martial [**38] before entertaining a military member's claim for relief. *New, 129 F.3d at 642*. Indeed, New explained the options available to military members, like plaintiffs,

who seek to challenge the orders of their superiors. There, plaintiff sought judicial relief against pending court martial proceedings for failure to follow an order requiring the wearing of the United Nations insignia by U.S. troops stationed in Macedonia as part of a peacekeeping mission. Rejecting the judicial [*24] challenge, the D.C. Circuit explained that plaintiffs had adequate remedies in the military justice system:

> 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. . . . Or he could follow the path that he took: disobey the orders and challenge their validity in the subsequent disciplinary proceedings. Having chosen the latter course of action, New might yet obtain vindication through court-martial proceedings. . . . However, any option contemplating an exception to the exhaustion requirement is foreclosed by the doctrine of comity. . . .

Id. at 647 [**39] (citations omitted).

Plaintiffs are no differently situated here. As set out in more detail below, plaintiffs are asking this Court -- with the country now at war -- essentially to stop the anthrax vaccination program. If they wish to challenge the decisions of their superiors to impose the inoculation requirement, however, they must do so in the context of the military justice system. The "need for duty and discipline in the armed forces makes clear that, absent a clearly defined right enforceable in proceedings other than a court martial . . . the federal courts normally should not interfere with the day-to-day operations of the military services." Id. (emphasis added). Consequently, federal courts have routinely deferred to the military justice system on matters that will have significantly less impact on the military's preparedness for war. See, e.g., *Councilman, 420 U.S. at 740* (drug crimes); *New, 129 F.3d at 641* (refusal to wear a United Nations beret); *Noyd v. Boyd, 395 U.S. 683 (1969)* (refusal to serve as an instructor pilot); *Gusik v. Schilder, 340 U.S. 128 (1950)* (murder). Given this precedent, [**40] an order depriving the services of their best defense against a devastating enemy weapon best comes from the institution expressly set up to balance the combat needs of the nation against the fairness due to each service member.

[*25] **(b) Civilian Employees Have Adequate Remedies For Adverse Employment Decisions**

Like their military counterparts, certain civilian employees, n13 both of the DoD and of private companies with DoD contracts, are essential to the conduct of military operations. Also like their military counterparts, civilian employees have adequate remedies for adverse personnel actions. Civilian employees of DoD, for example, have a right to appeal to the Merit Systems Protection Board (MSPB) and obtain relief if "the agency decision was not in accordance with law." *5 U.S.C. §§ 7701(a)* & (c)(2)(C). Further, any employee "adversely affected or aggrieved by a final order or decision of the Merit Systems Protection Board may obtain judicial review of the order or decision," generally in the United States Court of Appeals for the Federal Circuit. *5 U.S.C. § 7703*. In *Mazares v. Department of the Navy, 302 F.3d 1382 (Fed. Cir. 2002),* [**41] cert. denied, No. 02-846, (U.S. Apr. 7, 2003), two DoD civilian employees who refused anthrax vaccinations had the opportunity to present their contention that the agency order to them to receive the vaccine was improper. In that case, the MSPB and the Court of Appeals ruled specifically on the merits of the employees' arguments (both upholding the DoD decision).

> n13 Plaintiffs filed this action anonymously, though plaintiffs' counsel has now disclosed the identity of one of them, a DoD civilian employee, to forestall adverse action before this Court can hear this motion. By filing this opposition, the government does not acquiesce in the plaintiffs' wish to remain anonymous. Should this matter proceed further, the government reserves its right to seek to require the identities of the remaining five plaintiffs.

With respect to employees of private companies under contract with the DoD, they have no employer-employee relationship with DoD, and DoD cannot take any personnel action, favorable or unfavorable, [**42] affecting them.

However, they likely have some grievance procedures with their employers, or their employers could address these issues in dispute with the DoD [*26] components with which they contract. In any event, plaintiffs have failed to establish for purposes of APA jurisdiction that there is not an adequate remedy available elsewhere. It is well-settled that they have adequate remedies in damages actions for any adverse employment decisions. See *Sampson v. Murray, 415 U.S. 61, 91-92 (1974)* (adequate legal remedies exist for loss of income and damaged reputation; such injuries are not irreparable). Thus the civilian plaintiffs, too, fall outside the APA.

2. Plaintiffs Have Failed To Provide Evidentiary Support Sufficient To Confer Standing For Purposes Of Preliminary Injunctive Relief

Not only do plaintiffs present nonjusticiable claims, but they fail to present evidence sufficient to establish standing. One core element of Article Ill'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)*. Hence, "the question [**43] 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, 468 U.S. at 750-51*.

"Mere allegations will not support standing at the preliminary injunction stage." *Doe v. National Bd. of Medical Examiners, 199 F.3d 146, 152 (3d Cir. 1999);* see also *National Wildlife Fed. v. Burford, 878 F.2d 422, 432 (D.C. Cir. 1989)*(burden of establishing standing at preliminary injunction stage is no less than for summary judgment), rev'd on other grounds sub nom. *Lujan v. National Wildlife Fed., 497 U.S. 871 (1996)*. Moreover, bare allegations of harm will not suffice to justify equitable relief. *Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985)*.

[*27] Here, to preserve their anonymity, plaintiffs have chosen not to submit evidence that they are subject to imminent orders to take the vaccine or any adverse personnel action for refusing. Their very standing to pursue these claims is at issue, and yet the Court and defendants have nothing more on which to analyze that claim than their allegations. Plaintiffs' [**44] allegations alone do not suffice to permit the exercise of jurisdiction at the preliminary injunction stage.

With respect to the anonymous civilian plaintiffs, they would be unable to establish standing to sue here, even if they had provided factual support. The most fundamental constitutional prerequisite for standing is that of an injury-in-fact, one that is actual and imminent, not conjectural or hypothetical. *Lujan, 504 U.S. at 560-61*. Here, the injury that the civilian plaintiffs plead is wholly speculative; simply put, adverse employment actions against them for refusal to be inoculated may or may not occur. And as to the DoD civilians, DoD's own policy is to transfer them to other duties, if available, if they refuse to agree to the requirements for serving in an emergency-essential position. DoD Dir. 1404. *10 P 6*.5.3. As to the contractor personnel, their employers may be able to use them on other projects or in other geographic areas. The potential actions of these third-party employers are far removed from the decision of the DoD to protect military and other personnel deployed to high threat areas from a biological warfare attack with anthrax [**45] and, thus, not a basis to find irreparable injury. *Lujan, 504 U.S. 562* (When the future action of a third party not before the court is needed to establish standing, "it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such a manner as to produce causation and redressability of injury.") (citation omitted), *Simon v. Eastern Ky. Welfare Rights Org., 426 U.S. 26, 43-46 (1976)* (action by third [*28] parties needed to redress harm too speculative to support standing). In summary, while an adverse personnel action may result for either the civilian DoD or contractor employees, that prospect is far from likely and, for the moment, wholly speculative.

B. Plaintiffs Cannot Prevail On The Merits Of Their Claims

Even were this Court to reach the merits of this dispute, plaintiffs cannot prevail. AVA is a licensed vaccine, and one for which the label includes protecting against inhalation anthrax. Defendants, moreover, have complied with the vaccine's dosage schedule. Consequently, there is no "prior consent requirement imposed under section 505(i)(4)" of the FFDCA and no need for a Presidential [**46] waiver under *10 U.S.C. § 1107(f)*, either with respect to plaintiffs' claim

that use for inhalation anthrax is not an "approved use" (or renders the vaccine an investigational new drug) or with respect to plaintiffs' challenge to the resumed dosing schedule for persons whose doses were interrupted by a temporary vaccine shortage.

1. The AVA License Covers Use Against Inhalation Anthrax

Section 1107, upon which plaintiffs' base their entire claim for relief, is inapplicable here because AVA's license covers use against inhalation anthrax. n14 Since its licensing in 1970, see Ex. 2, Goodman Decl. P 9, AVA's label has not specified an exposure route. The FDA, as the government agency responsible for approving drugs, has interpreted this lack of specificity [*29] concerning the route of exposure to mean that the AVA license permits use of the vaccine against any route of exposure. Ex. 2, Goodman Decl. P 11. Such an interpretation by an agency within its area of expertise is entitled to substantial deference. *Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994); Trinity Broad. of Fla., Inc. v. FCC, 211 F.3d 618, 625 (D.C. Cir. 2000);* [**47] cf. *NLRB v. Bell Aerospace Co., 416 U.S. 267, 274-75* ("a court may accord great weight to the long-standing interpretation placed on a statute by the agency charged with its administration"); *Massachusetts Trs. of E. Gas & Fuel Assocs. v. United States, 377 U.S. 235, 241 (1964)* (some weight is due to the consistent interpretation of the agency entrusted with the administration of the statute). This interpretation is eminently reasonable as it pertains to AVA. In the initial field study, no one vaccinated with the anthrax vaccine contracted inhalation anthrax. Additionally, from 1962 through 1974, the United States Centers for Disease Control and Prevention continued to collect epidemiological data on the vaccine's efficacy. Ex. 2, p. 9. Those data show that no cases of anthrax, including inhalation anthrax, were detected in persons who had received the full vaccine. Id. Thus, the FDA's clearly and repeatedly stated conclusion that AVA's label includes inhalation anthrax is proper. n15

n14 The informed consent requirements of section 1107 arise from and are those required by section 505(i)(4) of the FFDCA. Section 1107 simply does two things: (1) prescribes the form of notice required for military members; and (2) restricts authority to waive these requirements to the President.
[**48]

n15 Although the reviewing panel's report on AVA noted that inhalation anthrax occurs too infrequently to assess the protective effect of the vaccine, the initial field study's calculated overall effectiveness rate was 92.5%, a calculation that applied to both the cutaneous and inhalation cases in the study. Ex.2, Attach. 2 (Pet. Resp.) n. 9. Thus, the FDA concluded that because the indication section of the labeling does not specify the route of exposure, it includes both inhalation and cutaneous exposure. Id. p. 6.

The FDA's position on AVA predates the passage of section 1107. The exchange of letters between the Assistant Secretary of Defense for Health Affairs and the Lead Deputy Commissioner occurred in March 1997, see Ex. 2, Attach. 3; Ex. 3, over six months before the [*30] statute passed. Importantly, the FDA has been consistent in its assessment about AVA's applicability to inhalation anthrax, confirming it in a non-litigation context as recently as last year in a response to a citizen petition. Ex. 2, Attach. 2 (Pet. Resp.) p. 3. n16 Thus, DoD is not using AVA as an investigational [**49] new drug or in an unapproved manner. Absent such uses, the informed consent requirements of the FFDCA do not apply, thereby rendering *10 U.S.C. § 1107*, Executive Order 13139, and DOD Directive 6200.2 inapplicable.

n16 FDA's citizen petition procedures are set forth in *21 C.F.R. §§ 10.25*, *10.30*, & *10.45(d)*. Final decisions issued by the FDA pursuant to these procedures, if subject to judicial review, are accorded deference by the courts. See, e.g., *Henley v. FDA. 77 F.3d 616, 620-21 (2d Cir. 1996)*.

Plaintiff's reliance on the DoD-initiated 1996 investigational new drug (IND) application for AVA is misplaced.

That application does not establish that DoD considers use of AVA for inhalation anthrax to be an unlicensed use. Subsequent to the first Gulf War, as part of the effort to refine medical countermeasures to chemical and biological weapons, DoD began research to determine whether the same level of protection against anthrax could be achieved with a shorter shot [**50] schedule -- specifically, two shots with annual boosters, instead of the current requirement of six shots over 18 months -- and by administering the vaccine through intramuscular, rather than subcutaneous, injections (to reduce inflammation at the shot site). Ex. 1, Grabenstein Decl. P 8. This led to the 1996 IND application. Id. The IND application included a proposed study of the effectiveness of the vaccine against inhalation exposure (using an animal model) under the investigational, two intramuscular shot schedule. Id. If this study were successful, a by-product would have been an explicit statement that AVA is approved for inhalation anthrax. But as the Assistant Secretary's subsequent March 1997 letter establishes, see Ex. 3, the IND application in [*31] no way suggests an official position that DoD believed the approved label did not already encompass inhalation exposure. n17

n17 Nor does the fact that FDA has not issued a final order in its license review change this analysis. That review found AVA to be safe, effective, and not misbranded. *50 Fed. Reg. 51002* (Dec. 13, 1985). The FDA issued a proposed rule adopting the panel's finding in 1985. Id. At no time has the FDA initiated proceedings to revoke or suspend the AVA license. Ex. 2, Goodman Decl. P 9. Accordingly, the lack of a final order endorsing the panel's review is irrelevant. By regulation, AVA has remained licensed. *21 C.F.R. § 601.4(a)*.

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The only opinion published to date on this issue holds that Executive Order 13139 (and thus section 1107), is not applicable to AVA as it is being used by the military. In *O'Neil v. Secretary of the Navy, 76 F. Supp. 2d 641 (W.D. Pa. 1999),* a service member sought a hardship discharge based in part on having to take part in DoD's anthrax inoculation program. Chief Judge Ziegler disposed of the very issue in this case, ruling that "Executive Order No. 13139 is irrelevant to the instant dispute because the anthrax vaccine has been licensed by the FDA since 1970, and the vaccine is not an experimental drug." *Id. at 645*. As in O'Neil, nothing here supports plaintiffs' contention that AVA is either an investigational new drug or a drug unapproved for its use.

Congressional action subsequent to the military's adoption of the AVIP confirms the correctness of DoD's interpretation of section 1107 as excluding the anthrax vaccine. Fully aware that DoD had long taken the position that AVA was not covered by section 1107, Congress addressed the AVIP program by statute in 2000, requiring only that DoD keep a count of the number of service members separated [**52] as a result of "a refusal to participate in the anthrax vaccination program" and annually to report that number to Congress. *10 U.S.C. § 1178*. Similarly, Congress required DoD to have regulations to ensure that any civilian emergency-essential [*32] employees required to participate in the AVIP are "notified of the requirement to participate and the consequences of a decision not to participate." *10 U.S.C. § 1580a*. n18 By addressing the existing program without changing DoD's interpretation of the "informed consent" requirement, Congress has effectively acquiesced in DoD's mandatory vaccination program, deferring to the considered judgment of military leaders as to how best to ready their troops for combat. n19 See *Utah v. Evans, 536 U.S. 452, 472 (2002)* (Utah has failed to overcome the fact that the Bureau has long and consistently interpreted § 195 as permitting imputation, while Congress, aware of this interpretation, has enacted related legislation without changing the statute); *North Haven Board of Ed. v. Bell, 456 U.S. 512, 535 (1982)* (when Congress is aware of an agency's interpretation [**53] of a statute but then fails to alter that interpretation when amending the statute, then presumably the agency correctly inferred Congress's intent).

n18 In addition, the Court of Appeals for the Federal Circuit recently held that "there is ample authority in the appropriate Navy regulations" to "require all civilian employees, including those not designated emergency essential' to receive the anthrax vaccine when the Navy determines that such action is necessary and appropriate to protect the health of such employees." *Mazares v. Department of the Navy, 302 F.3d 1382, 1385 (Fed. Cir. 2002),* cert. denied, No. 02-846 (U.S. Apr. 7, 2003).

n19 The Constitution having delegated authority for and oversight of military decisions to the political branches, this Court should not supplant their judgment with its own. Thus, the suit also implicates the principles underlying the political question doctrine, for there plainly is "an unusual need for unquestioning [judicial] adherence to a political decision already made" regarding the means of prosecuting the war, and there is a "textually demonstrable commitment" of military governance to the political branches of the federal government. *Baker v. Carr, 369 U.S. 186, 217 (1962).*

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2. Defendants Are Adhering To The Approved Dosing Schedule

Plaintiffs cannot base their claim on the altered dosing schedule prompted by a shortage of the vaccine. First, based on the limited allegations of the complaint, plaintiffs lack standing to [*33] challenge this dosing schedule. None of the plaintiffs allege that his or her dosing schedule was interrupted by prior suspensions of production of the vaccine. Rather, they allege that they are concerned with starting the inoculation series. Complaint P 1. Because they cannot assert that they are "injured in fact" by the continuation of an approved dosing schedule, they cannot establish standing to challenge this practice before this Court. See, e.g., *Lujan v. Defenders of Wildlife, 504 U.S. 555, 563 (1992)* ("'injury in fact'" requirement of standing "requires that the party seeking review be himself among the injured"). n20

n20 As to all prospective recipients who have never received a dose of the vaccine prior to now, DoD is currently adhering to the label's requirement of six doses over an 18 month schedule. Ex. 1, Grabenstein Decl. P 16. Thus, plaintiffs, who do not allege that they have received any prior dose, cannot be heard to complain that the inoculation schedule applied to them is unlawful.

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Even assuming that plaintiffs have standing to challenge the interruption and resumption of the normal dosing schedule, that practice is medically appropriate. Beginning in July 2000, an unexpected shortage of the vaccine forced DoD to defer scheduled doses for some individuals who were not assigned to high-risk locales. Ex. 1, Grabenstein Decl. P 16. When vaccine supplies were restored, DoD recommenced the interrupted dosing schedules for those members still assigned to high-risk areas. Id. Consistent with the well-established and prevailing practice of vaccination and the recommendation of the U.S. Centers for Disease Control and Prevention, DoD resumed these dosing series at the points at which they were interrupted, directing the administration of all subsequent doses consistent with the intervals recommended in the approved labeling. Id. Restarting of a vaccine series such as AVA at the first dose is medically inappropriate. Id. As the FDA explicitly states, "resumption of a multi-dose vaccine series [*34] unavoidably interrupted by a vaccine shortage is not a clinical investigation that requires the filing of an Investigational New Drug application." Ex. 2, [**56] Goodman Decl. P 14. Moreover, such resumption "is not inconsistent with the product labeling, in that the labeling does not specifically address dosing in the event of unavoidable shortages." Id. Thus, the interrupted dosing schedule for individuals not before this Court provides no basis for subjecting AVA to the requirements of section 505(i)(4) of the FFDCA, nor are *10 U.S.C. § 1107* or its implementing regulations at all relevant.

II. The Requested Relief Will Severely Harm Defendants And Is Contrary To the Public Interest

The harm to defendants and the public interest both counsel strongly against any form of injunctive relief, whether such relief is limited to the individually named Plaintiffs or is broadly applied to those similarly situated to them. n21

n21 It is not clear whether plaintiffs seek relief only as to themselves or also as to those similarly situated to them. In their Complaint, Plaintiffs seek to "enjoin Defendant from inoculating Plaintiffs and those similarly

situated to them. . . ." Compl. Relief at P F. At the initial status conference, however, plaintiffs' counsel indicated that plaintiffs would identify themselves in the event this Court determines to permit preliminary injunctive relief. Thus, according to plaintiffs' counsel, interim relief could be limited to the individual plaintiffs. For the reasons set forth herein, see Argument § II, both the public interest and the harm to defendants weigh against the granting of injunctive relief whether the relief is broadly applied to all those similarly situated to plaintiffs or is applied only to the named plaintiffs.

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Armed combat with Iraq has begun and the global war on terrorism continues. Iraq is believed to have stockpiled great quantities of anthrax. See 149 Cong. Rec. H214 (daily ed. Jan. 28, 2003). 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 [*35] caused by the unnecessary loss of comrades. Indeed, DoD believes that the mere existence of an anthrax vaccination program may deter an opponent from using the pathogen in an attack. Ex. 1, Grabenstein Decl. P 14.

Moreover, requiring compliance with the informed consent requirements of the FFDCA or the waiver requirements of *10 U.S.C. § 1107* would render it infeasible to continue the program for the current military operations against Iraq or the global war on terrorism. DoD has experience complying with the informed consent requirements for investigational new drugs for force health protection, including several in relation to current events. Ex. 1, Grabenstein Decl. P 17. The process requires the development of a detailed protocol, approval through necessary channels, [**58] approval by an Institutional Review Board, submission and discussions with the FDA, a 30-day review period, training of principal and associate investigators, education of recipients of the drug, execution of consent forms, and the other steps required by 21 C.F.R. Part 312. Id. Experience has demonstrated that this is a several month undertaking, even with a generous allotment of personnel to implement it. Id. Thus, if the Court ordered the defendants to comply with section 505(i)(4) of the FFDCA or obtain a Presidential waiver under section 1107 before administering AVA, the AVIP would have to halt for a period of months.

The ability to seek a presidential waiver of these requirements does not lessen the impact. Were the Secretary of Defense to request a waiver from the President, the procedure outlined in Executive Order 13139 requires further layers of review and compliance beyond those above and, so, would take at least as much time if not more to obtain. Id. Compliance with either the informed consent or waiver provisions would be onerous, effectively shutting down the [*36] inoculation program for months. Thus, should this Court enjoin the Secretary as requested [**59] by plaintiffs, the inoculation program would effectively grind to a halt. Id. The war in Iraq and the global war on terrorism would proceed (as would other military missions), but some troops would not be protected against anthrax. Id.

The harm to military readiness resulting from judicial intrusion in military affairs weighs heavily against plaintiffs' request for an injunction. If a program-wide injunction is issued, n22 the President and his military commanders will have to cease inoculating the replacement troops currently slated to reinforce the combat forces, as well as to interrupt the shot series for many other personnel. Id. Many military members will have to carry out duties in the combat zone -- or occupied territory, where the threat will remain until all stores of anthrax are discovered and destroyed -- without being as protected. Id. The effect of an injunction thus would be to alter military strategy decisions in the midst of ongoing combat hostilities. Article III courts have traditionally shied away from interfering with military affairs. E.g., *Kries v. Secretary of the Air Force, 866 F.2d 1508, 1513-14 (D.C. Cir. 1989);* see discussion [**60] supra at Section I(A)(1). Second-guessing military orders such as those in this case would be extremely disruptive to the military chain of command. The requested preliminary injunction seeks to interfere with affairs peculiarly within the jurisdiction of the military authorities. *Orloff, 345 U.S. at 95.* As the long line of deferential precedent establishes, because such interference is not in the public interest, the federal judiciary generally shuns intervention in the management and control of the military, [*37] areas constitutionally reserved to the executive and legislative branches of government. *Chappell, 462 U.S. at 301; Gilligan, 413 U.S. at 7; Cargill v. Marsh, 902 F.2d 1006, 1007 (D.C. Cir. 1990).* This well-settled prudential rule has even more force today, as our troops are in combat and this action seeks to affect their

means of defending themselves from a potential threat.

> n22 Plaintiffs sued on behalf of themselves and others "similarly situated." Complaint P 1. No other class allegations have been made, nor have they sought class certification. See *Fed. R. Civ. P. 23(c)*. Absent class certification, this Court should not issue a program-wide injunction.

[**61]

The impact is severe and detrimental to the public interest even if injunctive relief is limited only to the named plaintiffs. Particularly with respect to matters involving military readiness, an injunction only as to one or a few individuals would be disruptive, others similarly situated to those obtaining injunctive relief would then seek similar relief. The Court thus cannot focus narrowly on the individually named plaintiffs in this case:

> The harm to the Army is greater than it first appears. If we upheld the injunction granted under the facts before us, injunctions would routinely be sought in drug discharge cases. The result would be judicial second-guessing of a kind that courts have been reluctant to engage in. . . . To start second-guessing the military under these circumstances "would be a disruptive force as to affairs peculiarly within the jurisdiction of the military authorities. . . ." We conclude that the harm to the Army would be substantial if we upheld this injunction.

Guerra v. Scruggs, 942 F.2d 270, 275 (4th Cir. 1991) (citations omitted). Collective second-guessing of military orders by the judiciary would frustrate the dual [**62] objectives of fairness to the member and ensuring military readiness that Congress sought to achieve in creating the military justice system. *Schlesinger v. Councilman, 420 U.S. at 758*. Individual relief as to multiple claimants seeking similarly to avoid participation in the vaccine program could then result in the same degree of harm to defendants and to the public interest as if the Court were to order [*38] systemic injunctive relief.

Moreover, even if the relief were somehow limited only to some who wish not to be inoculated, their refusal to take AVA could have a serious impact on the overall success of the military mission and on the ultimate resolution of the conflict. Ex. 1, Grabenstein Decl. P 14. Should a soldier or essential civilian member contract anthrax in combat, the consequences could be devastating; in the event members are subjected to an anthrax attack, any who declined the AVA inoculation would be more likely to become a casualty and, probably, a fatality. Id. Attention would be diverted from the immediate task at hand -- fighting the battle -- to assisting the injured member. Id. Such assistance would in many combat situations [**63] increase the peril faced by those rendering the aid. Id. In addition, medical resources would be diverted from other casualties to care for such a member, all because the member refused to be inoculated. Id. Moreover, the loss of the member would reduce the fighting strength of the member's unit, lessening its effectiveness and possibly its chances of survival on the battlefield. Id. On a large scale, unnecessary reductions in combat effectiveness would greatly affect the conduct of the battle and, possibly, determine its outcome.

For all of these reasons, whether injunctive relief is given as to all similarly situated to plaintiffs or merely to plaintiffs, the consequences are detrimental to defendants and contrary to the public interest.

[*39] **III. Plaintiffs Have Not Established Irreparable Injury If Injunctive Relief Is Denied**

Though plaintiffs couch their potential irreparable harm in terms of job loss or military punishment, neither of these events are irreparable harm. As noted above, civilian contractor employees may not necessarily be compelled by defendants to take the vaccine. Were they to refuse to take the vaccine and suffer adverse employment [**64] consequences as a result, they would have an adequate remedy and thus would not suffer irreparable harm. See *Sampson v. Murray, 415 U.S. 61, 91-92 (1974)* (loss of income and damaged reputation are not irreparable injury); *Veitch v. Danzig, 135 F. Supp. 2d 32 (D.D.C. 2001)*(same). Moreover, as to them, it is entirely speculative that they

would have their employment adversely affected. For example, efforts would be made to find other DoD employment, if available, for those employees who refuse the vaccine and therefore disqualify themselves from serving in an emergency-essential position. See DoD Dir. 1404. *10 P 6.5*. Similarly, a contractor's employees serving in DoD maybe able to find other positions (with the same employers) that do not require the vaccine.

As for the military members, they have the full panoply of legal rights available to them under the Uniform Code of Military Justice, including the right to be represented by counsel and to present defenses (such as their claims here) to any charges brought against them. Thus, they will not be legally prejudiced by the denial of an injunction. *Sampson, 415 U.S. at 91-92*. [**65]

The only remaining possible harm stems from a potential adverse reaction from the vaccine. But such harm is hypothetical or, at best, very unlikely to occur. AVA's adverse events profile is similar to that for other vaccines. 30% of men and 60% of women report soreness, redness, itching, and swelling at the injection site. Ex. 1, Grabenstein Decl. P 13. These minor [*40] reactions typically go away on their own after a few days. Id. Commonly, a lump occurs at the site, usually lasting for a few weeks before going away on its own. Id. Systemic reaction beyond the injection site -- muscle or joint aches, headaches, rashes, chills, low-grade fever, nausea -- are reported by 5 to 35% of those vaccinated. Id. There have been no deaths attributed to AVA by the CDC. Id. AVA has been administered to over 830,000 military members since March 1998. Id. Of this group, representing over 2.8 million inoculations, there have been only 1,857 formal reports of adverse events reported under the HHS Vaccine Adverse Events Reporting System. Id. Only 64 of those inoculated were hospitalized, and only 11 of those hospitalizations were found to have been probably caused by [**66] AVA. Id. All 11 of those hospitalizations involved allergic or inflammation reactions at the injection site. Id. An additional 172 of the military personnel inoculated were absent from duty for more than 24 hours, and only 94 of those were absences that were certainly or probably caused by AVA. Id. In summary, DoD has recorded 105 serious adverse events from AVA in over 830,000 recipients. The Institute of Medicine, which reviewed AVA in a Congressionally mandated report, also found AVA to be a safe and effective vaccine. Id. PP 12, 13. CDC, which tracks data on adverse effects from all vaccines, has found AVA to be a safe and effective vaccine. Id.

In short, plaintiffs will be subject to a de minimis risk of a serious adverse reaction if required to take the inoculation. AVA has been used effectively in civilian industry for over 30 years, being voluntarily taken by those working with animals to guard against anthrax. The potential for an adverse reaction to plaintiffs from taking the inoculation is virtually non-existent. It provides no basis for the relief that they seek.

[*41] **CONCLUSION**

Plaintiffs cannot demonstrate a substantial likelihood [**67] of success on the merits and have failed to demonstrate any significant harm to outweigh the palpable damage that an injunction would cause to the defendants and the public at large. Plaintiffs' application for injunctive relief should be denied.

Respectfully submitted,

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