JOHN DOE # 1, JOHN DOE # 2, JOHN DOE # 3, JOHN DOE # 4, JANE DOE # 1, JANE DOE # 2, c/o Mark S. Zaid, Esq., 1133 21<st> Street, N.W., Suite 800, Washington, D.C. 20036, and OTHER SIMILARLY SITUATED INDIVIDUALS, Plaintiffs, vs. DONALD H. RUMSFELD, SECRETARY OF DEFENSE, DEPARTMENT OF DEFENSE, 1000 Defense Pentagon, Washington, D.C. 20301, and TOMMY THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, 200 Independence Avenue, S.W., Washington, D.C. 20201, and MARK B. McCLELLAN, COMMISSIONER FOOD AND DRUG ADMINISTRATION, 5600 Fishers Lane, Rockville, Maryland 20857-0001, Defendants.

CASE NUMBER 1:03CV00707

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Motions 707; 2003 U.S. Dist. Ct. Motions LEXIS 11124

March 18, 2003

Motion for Temporary Restraining Order

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JUDGES: JUDGE: Emmet G. Sullivan

TITLE: MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

TEXT: Plaintiffs John Doe # 1, John Doe # 2, John Doe # 3, John Doe # 4, Jane Doe # 1 and Jane Doe # 2, on behalf of themselves and all similarly situated individuals, by their undersigned counsel, move this Court for a Temporary Restraining Order and Preliminary Injunction against defendants in this case to prevent Defendant DoD from inoculating plaintiffs with Anthrax Vaccine Adsorbed ("AVA"), in violation of federal law, a presidential executive order and DoD regulations.

Plaintiff's are entitled to this relief because:

a. This matter raises a justiciable claim that defendants are violating federal law, a presidential executive order, and DoD regulations by involuntarily inoculating members of the armed forces with an investigational, unapproved,

improperly licensed vaccine;

b. Plaintiff's will likely succeed [*2] on the merits of their case based on the undisputed evidence concerning the status of the AVA;

c. Plaintiff's face irreparable injury as a result of defendant's illegal inoculation program;

d. Defendants will not suffer comparable irreparable harm in that the AVA inoculation program can be continued under presidential waiver; and

e. Public interest militates in favor of granting the injunction.

For these and other reasons as set forth in the accompanying Memorandum in Support, and other reasons as may be developed at hearing, plaintiffs respectfully request this Court grant their motion enjoining the AVA inoculation program in its present form and directing defendants to comply with federal law, Presidential Executive Order and DoD regulations.

Date: March 18, 2003

Respectfully submitted,

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MEMORANDUM IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY [*3] **INJUNCTION**

Plaintiffs John Doe # 1, John Doe # 2, John Doe # 3, John Doe # 4, Jane Doe # 1 and Jane Doe # 2, on behalf of themselves and all similarly situated individuals, by their undersigned counsel, file this Memorandum in Support of a Motion for Temporary Restraining Order against defendants Donald Rumsfeld, Secretary of Defense, and Department of Defense ("DoD"), to prevent defendant DoD from inoculating plaintiffs with Anthrax Vaccine Adsorbed ("AVA"), under circumstances that violate federal law and federal regulations. As noted in their Complaint, plaintiffs are members of the active duty and selected National Guardsman components of the Armed Forces, and civilian contract employees of defendant DoD who have been or will be imminently or shortly instructed to submit to anthrax vaccination without their consent in violation of *10 U.S.C. § 1107*, Executive Order 13139, and DoD Directive 6200.

Plaintiffs seek this temporary restraining order to prevent irreparable harm to them as a result of being involuntarily inoculated with an experimental vaccine. This Court should grant the motion for a temporary restraining order as well as grant a preliminary [*4] injunction stopping the vaccine program because:

a. Plaintiffs raised a justiciable issue before this court in that the DoD's Anthrax Vaccine Immunization Program ("AVII") violates federal law, a Presidential Executive Order and DoD's own regulations.

b. There is a substantial likelihood plaintiffs will succeed on the merits of their case because there is no dispute that the vaccine is being used as an investigational new drug, and being used in a manner inconsistent with the AVA license, as well as being used in an unlicensed manner;

c. Plaintiff's face irreparable injury as a result of being forcibly and illegally inoculated with an experimental vaccine with substantial health risks;

d. The granting of the injunction will not prevent defendant DoD from continuing with its program in that DoD can require informed consent before administering the inoculation or can seek a presidential waiver of the informed consent requirement; and

e. Public interest will be furthered by granting the injunction because the public has an interest in the military's use of unlicensed and improperly administered vaccines that have already been used in response to public health crises.

FACTUAL [*5] **BACKGROUND**

Plaintiffs provided the Court with a detailed factual summary in their Complaint filed contemporaneously with this Motion. To summarize, plaintiffs are active duty and reserve members of the armed forces or civilian employees of defendant DoD. Because of their duties, they are being ordered to submit to inoculation with AVA. The plaintiffs must submit to these inoculations, they are not provided the opportunity to exercise informed consent, nor are they provided with product insert information concerning the vaccine.

In September 1996, the AVA manufacturer submitted an Investigational New Drug ("IND") application to defendant FDA seeking to get FDA approval for a modification of the AVA license to show that it was effective against inhalation anthrax. At the time of the IND application, neither defendant DoD nor defendant FDA believed that the AVA was licensed for inhalation anthrax; indeed, the FDA's own product review of AVA stated that the vaccine's efficacy against inhalation anthrax is not well documented and no meaningful assessment of its value against inhalation anthrax was possible due to the disease's low incidence. See Complaint, Attachment E. The IND [*6] application filed in September 1996 remains current and open. Although the AVA product insert has been amended several times since the vaccine was put on the market, there has never been an indication for inhalation anthrax on the label or in the product insert. See Complaint, PP 20-31. n1

n1 In fact, there is still no showing that AVA is effective in humans against inhalation anthrax. Animal studies have repeatedly failed to show a so-called "correlate of immunity" in vaccinated animals that translates into a similar correlate in humans. In other words, the vaccine does things to animals that have no equivalent in

human beings, and animal studies regarding the effectiveness of the vaccine cannot be used to validate a license change for AVA. See, Official Transcript, "Anthrax Vaccine efficacy Testing and Surrogate Markers of Immunity Workshop", FDA Center for Biologies Evaluation and Research, April 23, 2002.

In 1998, in response to concerns about the use of investigational new drugs during the Gulf War [*7] that may have led to unexplained illnesses among Gulf War veterans, Congress passed *10 U.S.C. § 1107*. This statute prohibits the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. Under special circumstances, the President may waive the informed consent requirement upon application by the Secretary of Defense. See *10 U.S.C. § 1107* (2000). In 1999, the President signed Executive Order 13139, which echoes the prohibitions against use of investigational new drugs or drugs unapproved for their intended use on service members without their informed consent. defendant DoD had formally adopted these requirements in DoD Directive 6200.2 on August 1, 2000.

Notwithstanding these requirements, in 1998 defendant DoD initiated and has maintained a mass inoculation program using AVA as a preventative against inhalation anthrax for its service members and civilian employees without informed consent or a presidential waiver. See Complaint, PP 33-35. In addition, defendant DoD has unilaterally altered the shot timing sequence for AVA from its FDA approved [*8] sequence. See Complaint, PP 43-49. Under these circumstances, the vaccine becomes a drug unapproved for its intended use within the meaning of *10 U.S.C. § 1107*, Executive Order 13139, and DoD Directive 6200.2 and may not be administered without informed consent or a presidential waiver.

Finally, FDA recently admitted in a response to a citizen petition that it has never finalized the licensing review for AVA undertaken during the 1970s and reported out in 1985. Specifically, the FDA admits that it failed to issue a final rule or labeling status for AVA following the recommendation of its Biologies Review Panel. This failure by the FDA to finalize the proposed rule means that the vaccine is not properly licensed and, therefore, unapproved for its intended use, again, within the meaning of *10 U.S.C. § 1107*, the Executive Order and the DoD Directive. See Complaint, PP 13-14.

Although *10 U.S.C. § 1107* itself seeks to prevent harm that may not develop for years as a result of experimental drugs or vaccines, there are already indications that AVA is creating irreparable health effects. For example, the AVA [*9] product insert, which originally stated that the adverse reaction rate to the vaccine was .2%, was recently revised (based on the adverse medical reactions to AVA in the U.S. military force) to reflect an adverse reaction rate of between 5% and 35%. 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 cannot be ruled out) to Category D (positive evidence of risk).

In other words, service men and women receiving involuntary inoculations with AVA face substantial health risks at a rate at least twice the rate of projected fatalities or serious reactions from another bioweapon vaccine, smallpox.

Because of the way DoD is using the vaccine, and because it is under a current Investigational New Drug application for inhalation anthrax, the vaccine is clearly investigational and unapproved for its intended use. Its continued involuntary administration by DoD violates *10 U.S.C. § 1107*, the Presidential Executive Order and DoD's own Directive. For these reasons, the Court should grant the temporary restraining order and grant preliminary injunctive relief.

ANALYSIS

I. THE DEFENSE [*10] **DEPARTMENT'S USE OF AVA IN THE AVIP IS JUSTICIABLE**

Given the traditional deference accorded to military affairs, courts are required to balance several competing interests in reviewing internal military determinations. *McVeigh v. Cohen, 986 F. Supp. 59, 60 (D.D.C. 1998)*. However, where the military violates a constitutional right, a federal statute, or its own regulations, the military and its

decisions are subject to judicial review. Id.; *Shaw v. Gwatney, 795 F.2d 1351, 1357 (8th Cir. 1986)*.

A district court called on to examine or review military decisions must analyze and weigh several factors. These factors are enumerated in the seminal case *Mindes v. Seamen, 453 F.2d 197 (5th Cir. 1971)*, affirmed on appeal after remand, *501 F.2d 175 (5th Cir. 1974)*. The Mindes court determined that a court should not review internal military affairs in the absence of (a) an allegation of the deprivation of a constitutional right or an allegation that the military has acted in violation of applicable statutes or its own regulations, and (b) exhaustion of available intra-service corrective measures. *Mindes, 453 F.2d at 201*. [*11]

If a plaintiff seeking review of a military decision sufficiently alleges the appropriate violation, and exhaustion of administrative remedies, or if no such remedies are available, the court must then examine the substance of the allegations in light of the policy reasons that militate in favor of not reviewing military decisions. Id. The Mindes court determined there were four factors that a court must analyze:

> (1) The nature and strength of the plaintiff's challenge to the military determination. An obviously tenuous claim of any sort must be weighted in favor of declining review.
>
> (2) The potential injury to the plaintiff if review is refused.
>
> (3) The type and degree of anticipated interference with the military function. Interference that would "seriously impede the military in the performance of vital duties" militates strongly against relief.
>
> (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.

Plaintiffs in this case [*12] have no difficulty meeting all of the Mindes factors. Accordingly, this Court should exercise its jurisdiction over plaintiffs' claims and grant their motion for a temporary restraining order and preliminary injunction as requested.

As a threshold matter, plaintiffs allege not only a violation of a statute, but a Presidential Executive Order and the military's own service regulations. Any single one of these allegations is sufficient to meet the initial requirement under Mindes. See, e.g., *McVeigh, 996 F. Supp. at 60*.

With regard to the second preliminary inquiry, that plaintiffs show that they have exhausted applicable administrative remedies prior to bringing their action, it is well settled that federal courts cannot require a plaintiff to exhaust available administrative remedies before seeking judicial review under the Administrative Procedures Act. See e.g., *Darby v. Cisneros, 509 U.S. 137, 153-4 (1993)*.

In addition, neither the statute in question, the Administrative Order, nor the DoD Directive require an aggrieved service member to appeal an order to subject themselves to involuntary inoculation to a higher authority. Indeed, in its [*13] rush to inoculate the Armed Forces, defendant DoD has summarily and rapidly disciplined soldiers, sailors and airmen who have refused to take the shot. See, e.g., *Ponder v. Stone, 54 M.J. 613* (N-M Ct. Crim. App. 2000); *Perry v. Wesley, No. NMCM 200001397, 2000 WL 1775249* (N-M Ct. Crim. App. Nov. 29, 2000).

Moreover, this is not a situation where a service member can simply request her disciplinary records be expunged, that she receive appropriate back pay and allowances, or have a bad performance report removed from her permanent record. The harm resulting from DoD's violation of the statute and regulations in question is immediate and permanent, resulting from inoculation with an untested vaccine. In short, there are no administrative remedies to exhaust for a

service member faced with what is palpably an illegal order. Accordingly, plaintiffs readily satisfy the second prong of the Mindes analysis.

Having determined that the initial allegations are sufficient, this Court must then turn to the four-factor analysis delineated in Mindes. These factors, comparable to a test for a preliminary injunction, readily show that this case is appropriate [*14] for judicial intervention and remedy.

A. The AVIP is being administered in violation of federal law, a presidential executive order, and a DoD directive

The first factor is the nature and strength of the plaintiffs' challenge to the military program or determination. It would be difficult to imagine a more conclusively established case than the one plaintiffs present in their Complaint. plaintiffs provide this Court with fact after undisputed fact, substantiated by the government's own documents and declarations, that the vaccine is being used in an investigational status, that it is being used in a manner that is inconsistent and unapproved by its current labeling, and that the vaccine is not properly licensed by the FDA.

1. The AVA is being used as an investigational new drug

The vaccine's status as an investigational new drug is conclusively established by the Investigational New Drug Application filed by the manufacturer in September, 1996. See Complaint, PP 21-25.

The purpose of the application is undisputed -- it is to conduct experiments to make up for a previously identified deficiency in the vaccine licensing, namely that there is insufficient evidence [*15] that the vaccine works against inhalation anthrax. See Complaint, PP 13-15.

Once the Investigational New Drug Application is filed, there is no dispute that the vaccine is not considered licensed if it is used in a manner consistent with the IND application. The FDA itself advised the Army of this in a December 13, 1996 letter. The Army published an advertisement in the Washington Post on October 15, 1996, seeking experimental test subjects as part of the AVA IND application. The Army noted in the advertisement that the AVA was fully licensed. The FDA's letter to the Army strongly criticizes the Army for describing the vaccine as fully licensed and advises the Army that the vaccine is not licensed for the indication for which the IND application was filed, namely as a preventative against inhalation anthrax.

The undisputed status of the AVA as an investigational new drug, based on the application and the FDA's contemporaneous interpretation of the application, make a substantial likelihood that plaintiffs will succeed on the merits of proving a violation of *10 U.S.C. § 1107*, Executive Order 13139 and DoD Directive 6200.2.

2. The AVA is a drug unapproved [*16] **for its intended use**

The AVIP has had a rocky road from its inception. The program itself was virtually shut down in July of 2000, after the FDA effectively closed down the BioPort manufacturing facility, preventing additional lots of vaccine from being produced. The resulting shortage caused DoD to suspend the mass inoculation program it began in 1998. For many of the vaccine recipients, this meant stopping the vaccine administration in mid-sequence. Rather than reinitiate the sequence in accordance with the FDA approved license, defendant DoD has elected to start the sequence of shots as if no hiatus occurred. Service members who received their last vaccination more than two years ago will pick up the sequence of shots as if they were still meeting the labeled requirements.

FDA representatives warned DoD that deviation from the shot schedule was not approved. See Complaint, P 43 and attachment.

Accordingly, there is a substantial likelihood that plaintiffs will succeed in showing that DoD is currently using AVA in a manner unapproved by its license and its intended usage and, therefore, is in violation of *10 U.S.C. § 1107*,

Executive Order 13139 and [*17] DoD Directive 6200.2.

3. AVA is not properly licensed

In a response to a citizen petition, the FDA admitted in August 2002 that it had not completed its licensing review of AVA. Incredibly, the failure of the FDA to properly complete the licensing for the vaccine goes back more than 30 years. In 1972, Congress directed that the FDA be given authority to regulate biological products, i.e., vaccines, from the National Institute of Health (Public Health Service). As part of this new responsibility, in 1973 FDA initiated a comprehensive review of the safety, effectiveness and labeling of all licensed biologics. Biologics review panels recommended to FDA that the agency classify individual biological products as either safe, effective and not misbranded (so-called Category I); safe, ineffective or misbranded (Category II); or insufficient information to classify, further testing required (Category III). After reviewing each panel's recommendations and conclusions, FDA published a proposed order to classify the biological products under review. After providing an opportunity for public comment, FDA then issued a final order with final product classifications. See generally, Complaint, [*18] P 13, and attachment.

Failure to complete this process essentially means that the FDA failed to complete its review of the product license. In 1985, the panel reviewing AVA concluded the vaccine was safe, effective and not misbranded, although it also noted that there was no basis for determining that the vaccine worked against inhalation anthrax. n2 Although the proposed rule issued on December 13, 1985, FDA failed to issue a final rule for the AVA. It has yet to do so. See generally, Complaint Attachment D, August 28, 2002 letter to Russ Dingle, Citizen Petition Response.

n2 The panel also noted that there was a disparity between the number of shots required for effective vaccination. Apparently, one source noted that three shots were the prescribed dose, while another source stated that six shots, the current licensed dosage, was effective treatment.

The failure of the FDA to finalize its proposed rule making and properly certify AVA is undisputed proof that, unlike other commercially available biologics, [*19] the vaccine is not properly vetted and, therefore, not fully licensed by the FDA. The AVA has not completed the FDA's certification process and, therefore, cannot be approved for the mass inoculation program undertaken by defendant DoD without compliance with *10 U.S.C. § 1107*, Executive Order 13139 and DoD Directive 6200.2.

B. Plaintiffs Will Suffer Irreparable Harm in Violation of Federal Law

The second factor to be weighed by the Court is the potential injury to the plaintiff if the Court refuses to review the military action. It cannot be emphasized enough that the harm in this case to plaintiffs, and to those similarly situated to them, is irreparable.

10 U.S.C. § 1107 was enacted in response to the use of investigational new drugs on service members during the Gulf War. n3 The medical implications and issues concerning the involuntary inoculation of service members with investigational drugs during the Gulf War are still being heavily debated by the medical community. Recognizing that harm from use of investigational medications might not be immediately apparent, *10 U.S.C. § 1107* was passed and signed [*20] into law to prevent the military from using experimental or untested medications on service members, except with informed consent by the service member or in cases where such use was required by military necessity. In those limited cases, of military necessity, a Presidential waiver is required to involuntarily inoculate service members. The loss of the right to informed consent, granted specifically by the statute, is irreparable harm in and of itself and suffices to satisfy the standard for a preliminary injunction.

n3 See generally, Rand Report on Interim Rule and Byrd Amendment located at *www.Rand.org/publications/MR/MR1018.9/*.

In addition, service members are now faced with the prospect of being injected with an improperly licensed, untested and unapproved vaccine with ramifications that are completely unknown in both the near and far term. This risk of harm is not speculative; the informed consent documents provided to civilian employees as a result of anthrax mailings in the Fall of 2001 clearly [*21] identify side effects such as Guillain-Barre Syndrome, multiple sclerosis, angioedema, aseptic meningitis, severe injection site inflammation, diabetes, and systemic lupus erythmatosis. In addition, the pregnancy risk assessment for AVA has recently been upgraded from Category C to Category D, indicating a definitive risk for servicewomen who are pregnant at the time of the inoculation.

Finally, the Court should not be deterred from a finding of irreparable harm based on a lack of conclusive medical evidence that the vaccine causes debilitating illness, fertility problems, and even death. The prohibitions contained in *10 U.S.C. § 1107*, Executive Order 13139 and DoD Directive 6200.2 were put in place to obviate precisely this issue. Congress, knowing that the epidemiology of the effects of experimental medications is often difficult, time consuming and may not be resolved for years after administration of the subject drug, enacted *10 U.S.C. § 1107* to prevent this problem from arising in the first place. The irreparable harm suffered by service members subjected to this vaccine is the loss of their statutory rights to informed consent, [*22] or to at least have the President make a formal determination that the use of the vaccine trumps those informed consent rights. Once the soldiers are injected with the vaccine without their consent, and without a presidential waiver, the irreparable harm has occurred.

C. There will be virtually no interference with the military's ability to vaccinate service members if the court grants Plaintiffs' motions

The third factor under Mendes for the Court to consider is the type and degree of anticipated interference with the military function resulting from the requested action. In fact, the granting of the requested injunctive relief does not bar defendant DoD from administering the vaccine to U.S. troops. If DoD believes that anthrax vaccination is militarily necessary for its forces, the Secretary of Defense can formally request a waiver of the informed consent requirement by the President. Such a request could be made and granted within a matter of hours, and the program will continue. The Court should give no consideration to any arguments by defendants that granting an injunction will somehow affect military readiness or troop protection. defendant can remedy that situation [*23] easily if it is willing to follow the requirements of the statute and its own directives.

D. Virtually no military discretion is involved in the determination necessary to grant Plaintiffs' motion

The final factor to be considered is the extent to which the exercise of military expertise or discretion is involved in the matter at issue. *Mindes, 453 F.2d at 201.*

Although courts generally should defer to the superior knowledge and expertise of military members in matters directly related to specific military functions, in this case, Congress has preempted the deference normally given to military decisions about inoculations and use of medications on troops with the passage of *10 U.S.C. § 1107*. In fact, there is very little military expertise or discretion in the determination the Court is being asked to make. The military does not have any particular expertise regarding investigational medications, drugs unapproved for their intended use, or unlicensed medications. In fact, the expertise in these areas lies solely with the Food and Drug Administration which has remained virtually silent on this entire issue over the last five years. [*24]

Given the fact that the military can easily maintain its vaccination program by Presidential waiver of informed consent, there would appear to be little impact on the exercise of military discretion, particularly since Congress has seen fit to insert itself into the matter through legislation reinforced by a Presidential Executive Order and DoD's own directive.

II. PLAINTIFFS MEET THE REQUIREMENTS FOR THE GRANTING OF A TEMPORARY

RESTRAINING ORDER AND PRELIMINARY INJUNCTION

The legal standard plaintiffs must meet in moving for a Temporary Restraining Order or preliminary injunction is not in dispute. "A court considering a plaintiff's request for a preliminary injunction must examine whether: (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 the injunction." *Serono Lab v. Shalala, 158 F.3d 1313, 1317-18 (D.C.Cir 1998)*. See *Sea Containers Ltd. v. Stena AB, 890 F.2d 1205, 1208 (D.C.Cir. 1989); Washington Metro Area Transit Comm'n v. Holiday Tours, Inc., 559 F.2d 841, 843 (D.C.Cir. 1977)*. [*25] The court "must balance the strengths of the requesting party's arguments in each of the four required areas." *CityFed Fin. v. Office of Thrift Supervision, 58 F.3d 738, 747 (D.C.Cir. 1995)*. An injunction may be issued if the arguments in favor of one particular factor are particularly strong "even if the arguments in other areas are rather weak." Id. Therefore, "[a]n injunction may be justified, for example, where there is a particularly strong likelihood of success on the merits even if there is a relatively slight showing of irreparable injury." Id.

The Plaintiffs' arguments relating to the first three requirements for a preliminary injunction are virtually identical to the Mindes factors discussed at length above and plaintiffs will not recount them here. Because plaintiffs make such a strong showing of a likelihood of success on the merits, and irreparable harm, inquiry into the remaining factors should be minimal. The only factor that is not discussed in the Mindes analysis relates to the effect of the proposed action on public policy, plaintiffs discuss this remaining aspect below.

A. Public policy concerns argue in favor of granting the [*26] **requested restraining order and injunction**

10 U.S.C. § 1107 and its progeny -- Executive Order 13139 and Department of Defense Directive 6200.2 -- were enacted to protect soldiers from involuntarily serving as "guinea pigs" in a mass use of investigational medicine. In fact, defendants' flagrant disregard of statutory and regulatory requirements have already caused over half a million members of the armed forces to be experimental subjects without their consent. The Center for Disease Control informed consent form and recent changes in the licensing inserts for AVA reflect, to a large degree, the experience the manufacturer has gained from DoD inoculating hundreds of thousands of active duty service members over the last five years.

The public policy of the United States, as codified in the Food, Drug and Cosmetic Act, its associated regulations, the establishment of the Food and Drug Administration and its regulatory framework for monitoring drugs and biologic products, and the policies behind *10 U.S.C. § 1107* argue for enjoining a program that ignores the rights of American service members.

DoD's actions are contrary to public [*27] policy as indicated in the above-referenced statutes and regulations. The Court should grant the injunctive relief to insure compliance by the federal government with the laws Congress enacts. Accordingly, there is no basis for opposing the granting of an injunction on public policy grounds; in fact, public policy demands that this program, conducted in violation of federal law, be brought into consonance with that law.

CONCLUSION

Because there is no issue of material fact concerning the status of the vaccine, this Court should grant injunctive relief to plaintiffs and order defendant DoD and FDA to suspend the AVIP as it is currently constituted. AVA's manufacturer placed the vaccine in investigational status for inhalation anthrax in September 1996. Six and a half years later, that status has not been changed. In addition, DoD is willfully deviating from the vaccine's shot regimen, using the vaccine in a manner completely unapproved by FDA. Finally, the FDA itself has failed to finalize the licensing and approval for the vaccine for almost twenty years. As a result, the vaccine cannot be considered a drug approved for its use, because its licensing has not been finalized. [*28] Under all or any of these bases, AVIP should be suspended. The Court should grant plaintiffs' motion for a restraining order and injunction and set a final trial date to resolve these issues.

Date: March 18, 2003

Respectfully submitted,

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[SEE APPENDIX IN ORIGINAL]

CERTIFICATE OF COUNSEL

Pursuant to Local Rule 65.1, the undersigned counsel for the plaintiffs hereby certifies as follows:

1. Notice of plaintiffs' intention to file a Motion for Temporary Restraining Order ("TRO") and Preliminary Injunction was given to Madelyn Johnson, Deputy Chief, United States Attorney's Office for the District of Columbia, on the afternoon of March 17, 2003.

2. Courtesy copies of all pleadings and papers filed in this action, or to be presented to the Court in support of plaintiffs' Motion, were furnished to Ms. Johnson via e-mail and hand delivery on March 18, 2003.

3. Ms. [*29] Johnson's telephone number is 202-514-7135.

Dated: March 18, 2003

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