UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE # 1 et al.,	)	
	)	
Plaintiffs,	)	
	)	Civil Action No. 1:03CV00707
v.	)	
	)	
DONALD H. RUMSFELD et al.,	)	
	)	
Defendants.	)	

PLAINTIFFS' OPPOSITION TO DEFENDANTS' EMERGENCY MOTION TO MODIFY INJUNCTION

Plaintiffs John and Jane Does #1-6 oppose the granting of the Defendants' motion at this time because it is fundamentally at odds with the express terms of the Court's injunction. Moreover, the Defendants' motion, in its present form, effectively removes the careful lawful protections that the Court recognized existed specifically with relation to the use of the Anthrax Vaccine Adsorbed ("AVA").

FACTUAL POSTURE

This Court permanently enjoined the involuntary administration of anthrax vaccine absent a presidential waiver on October 27, 2004. The Court determined that the Defendant Department of Defense ("DoD") had for six years administered AVA as an investigational new drug to service members and DoD civilians in violation of 10 U.S.C. § 1107 (2004). Absent providing informed consent in a voluntary program, or without the required presidential waiver of informed consent, the Defendants were prohibited from continuing a mandatory vaccination program.

As described more fully in the Government's Motion and attachments, the Defendants responded to the Court's action by invoking the provisions of the Project Bioshield Act, 21 U.S.C. § 360bb-3, in an effort to restart the Anthrax Vaccine Immunization Program ("AVIP").[1] Following a hurried review of a DoD request, the Secretary of Health and Human Services ("HHS") authorized "emergency" use of the AVA under the terms of a specific use authorization. See 70 Fed. Reg. 5450, 5450-55. Among other things, this Emergency Use Authorization ("EUA") allegedly allows service members to refuse inoculation with no adverse consequences.

As part of the EUA requirements, the acting HHS Commissioner approved a so-called “tri-fold brochure” to be provided to each service member and civilian selected for vaccination by DoD. Although this Court's injunction required informed consent by service members prior to vaccination, the EUA does not provide for informed consent. Moreover, Defendants' counsel freely stated that the DoD does not believe informed consent is necessary, and that the information being provided via the tri-fold brochure falls short of an informed consent standard. See Transcript of Hearing of February 14, 2004, at 4-5 (“Tr.”), attached as Exhibit “1”; Tri-fold brochure, attached as Exhibit “2”.[2]

Pursuant to this new, improved and consensual AVIP, Defendants now seek an amendment of this Court's injunction to allow them to continue vaccinations with a vaccine that is unapproved for its intended use and still in investigational status. While

[1] In fact, Defendants' counsel admitted at the status conference on February 14, 2005, that the reason the Defendants sought the emergency use authorization at issue here was because of this Court's injunction. See Tr. at 19.

[2] Although the Acting HHS Secretary stated that the tri-fold brochure was "approved" by FDA on February 2, 2005, it was clear from the Defendants' attorney’s statements at the status hearing that this is not the case. In fact, final approval by FDA of the tri-fold brochure apparently did not occur until several days after the hearing on this matter.

Plaintiffs applaud Defendants' belated recognition that this program should be a voluntary one, the so-called "voluntary" aspect of the proposed AVIP falls well short of what is required under the terms of the injunction. The shortcomings are particularly troubling given DoD's admitted inability to comply with the original terms of the injunction in that an unknown number of service members continued to received AVA after October 27, 2004.[3]

ARGUMENT

I. THE TRI-FOLD BROCHURE DOES NOT MEET THE REQUIREMENTS OF INFORMED CONSENT UNDER THE LAW OR THE LANGUAGE OF THIS COURT'S PERMANENT INJUNCTION

In light of what Defendants propose regarding individual notice to service members affected by AVIP, the additional requirements for informed consent for the military, promulgated under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(i)(4)) and its supporting regulations, are not particularly onerous. See 21 CFR §§ 5.20-27. The notice requirements for a written informed consent form are contained in 21 CFR § 50.25 and include:

- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the subject or to others doing the research;
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to subject;

[3] Plaintiffs also ask the Court to note that the government represented from the very beginning of this litigation that a voluntary program was incompatible with the most basic requirements of military readiness. See Defendants' Opposition to Plaintiffs' Motion for a Temporary Injunction at 4, 35-36 (filed April 9, 2003). As recently as January 2004, Defendants' counsel continued with that sentiment. See Transcript of Hearing, January 14, 2004, at 30-31, attached as Exhibit "3". The Defendants' sudden conversion on this issue is, accordingly, suspect.

- Statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the FDA may inspect such records;

- Contact information for answers to pertinent questions about the research and the subject's rights and whom to contact in the event of research-related injury;

- A statement that the participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that subject may discontinue participation at any time without penalty.

In the current context, Plaintiffs note that the tri-fold brochure appears to comply with some of the regulatory requirements, but with several crucial exceptions. Chief among the omissions is a mechanism for tracking compliance with the education and information requirements of the EUA. Informed consent under the DoD regulations requires some form of documentation that the individual soldier or civilian who has been properly advised of the risks and benefits associated with the vaccination actually consents. Consent is documented by the individual's signing and dating a consent form. 21 CFR § 50.27.

There are no provisions in the tri-fold brochure for such documentation, nor have the Defendants proposed such an option.

Defendants plan on distributing the tri-fold brochures on an individual basis to every service member or civilian employee slated to take AVA. Under the circumstances, modifying the brochure to include a signature line with text indicating that the service member has read and understands her rights under the terms of the EUA does not seem particularly onerous.

Plaintiffs also request that Defendants be required to file copies of signed forms in the service member or civilian's medical records, as well as providing those who consent with a copy of the signed form for their own personal medical files. Again, given the relatively minimal administrative burden such a record-keeping requirement entails, this should not prove particularly onerous. Moreover, a signed record of consent would be of direct benefit both to the Defendants and the service members, given the apparent inability of the government to track shot records, shot sequences, or even shot administration for service members. See Defendants' Response to Court's Order of January 26, 2005 at 2-3; Tr. at 12-13.

A. Other Substantive Issues with the Tri-Fold Brochure.

Plaintiffs also note these additional shortcomings in the brochure and suggest the following modifications:

1. Although the brochure ostensibly raises the issue of long-term side-effects, there is no description of such effects anywhere in the brochure. In fact, long-term side effects are discussed in the product insert; and a similar description should be included in the brochure. Specifically, the AVA license insert, a document approved by the FDA, notes that approximately 6% of reported reactions to the vaccine were listed as "serious," which are defined as events resulting in death, hospitalization, permanent disability, or are life threatening. The license insert also contains an exhaustive list of "infrequently" reported adverse events including such things as asthma, aplastic anemia, lymphoma, collagen vascular disease, lupus, multiple sclerosis, renal failure and liver abscess. See Product insert, 31 Jan. 2002, at 5-6, attached as Exhibit "4". At a minimum, these long-

term effects should be provided to the service member to aid in later diagnosis should future health problems arise.

2. There should be a substantially stronger warning concerning the use of the vaccine for pregnant women. Specifically, the third paragraph under the "What if I'm Pregnant?" section should be moved so that it is the first paragraph in the sequence, and the sentence beginning, "Pregnant women should not be vaccinated against anthrax ...," should be boldfaced.

3. The front cover of the brochure should note that the vaccine is being used in an unapproved manner under the terms of an emergency use authorization.

4. The bullet point concerning a reported 92.5% effective rate is incorrect and misleading. In fact, the study cited in the brochure stated that inhalation anthrax (which is the focus of the entire AVIP) occurred too infrequently for the vaccine's effectiveness to be measured. See Brachman Study, FDA Administrative Record Concerning the AVA, at 3732-45; FDA Expert Panel Report, 50 Fed. Reg. at 51,058.

5. Given the identified risk of heart problems resulting from the vaccine, there should be a boldfaced warning prominently displayed in the brochure alerting soldiers of the need to respond immediately to certain symptoms associated with myocardiatis, cardiomyopathy, and atrial fibrillation.

6. The statement that the vaccine has been "FDA licensed to prevent anthrax since 1970," is misleading because it is quite clear from this Court's ruling that the vaccine has not been licensed to prevent inhalation (or gastrointestinal) anthrax. This statement should be corrected.

7. Notwithstanding the fact the vaccinations are to be voluntary and refusal is not to be punished, the brochure engages in both explicit and implicit coercion with its comments such as:

> *If you get infected with anthrax, your loss could endanger other people in your unit who depend on you.*
>
> *If you get infected with anthrax, it could endanger your mission.*
>
> *The consequences of refusing anthrax vaccine include that you will be more vulnerable to lethal anthrax infection. Your loss could threaten the lives of others in your unit who depend on you, and could jeopardize the success of your mission.*

These comments are incompatible with the requirements of informed consent. They demonstrate DoD's unwillingness to simply allow servicemembers the dignity of making an informed choice absent repeated implied threats and statements designed to minimize the potential for soldiers opting out of the vaccination program. The presence of these statements is positive proof that the need for a balanced assessment of the AVA's risks is more than theoretical.

Some or all of this information will not fit on the current tri-fold brochure. However, there is a substantial amount of redundant or incorrect information on the inside cover and center of the brochure which could be eliminated to provide for an acknowledgement, signature and date line, as well as product insert information. At a minimum, the brochure needs to provide more specific information concerning possible health side effects such as those listed in the product insert and provide an acknowledgement line so that it is possible to adequately determine who has consented to

vaccination. Without these relatively simple adjustments, the so-called "voluntary" nature of the program becomes meaningless.[4]

II. THE EMERGENCY USE AUTHORIZATION HAS BEEN IMPROPERLY ISSUED BY THE DEPARTMENT OF DEFENSE

It is undisputed that the triggering event for the EUA was not some escalated threat of anthrax use against U.S. forces, but rather this Court's issuance of a permanent injunction. See Tr. at 14. Thus, the very nature of the so-called "emergency" triggering the decision by the Secretary of HHS is, at best, illusory. Indeed, this concern has been raised by Members of Congress, including those who participated in the drafting of Project BioShield. See Exhibit "5".

In addition, the statute plainly requires the Secretary of Defense to determine that there is a military emergency, or a significant potential for a military emergency.

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[4] As touched upon earlier, the Court should note that the DoD's historic and continuing hostility to any kind of an informed consent requirement for service members involved in one of its vaccination programs is well documented. At the time of the Persian Gulf War, for example, DoD sought a waiver of requirements for informed consent for the use of Pyridostigmine Bromide ("PGB") and Botulinum Toxoid. Although representatives of FDA indicated that these drugs were clearly investigational, DoD representatives informed FDA that DoD leadership did not want to abide by informed consent regulations. DoD advised FDA that the secretary of the military departments could dictate the use of unapproved FDA-regulated products as needed. See Senate Report 103-97, Dec. 8, 1994, Notes 79 and 80. Although DoD later represented to FDA that the use of the investigational drugs in question would be voluntary, post-war interviews indicated that upwards of 80% to 90% of the soldiers who took the drugs were told at the time that they had no choice. Id., at Notes 84, 85. In addition, where there was an education and notice requirement in place, as with the use of PGB, it was clear that DoD failed to provide the required notice. See Friedman, M.A., Lead Deputy Commissioner, Food and Drug Administration, letter to E.D. Martin, Acting Assistant Secretary of Defense (Health Affairs), July 22, 1997, attached as Exhibit "6". Given this record of a previous voluntary program, it does not seem unwise for the Court to impose a signature and acknowledgement requirement for the voluntary AVIP. See also Declaration of Dr. Jonathan Moreno at ¶¶12-19, attached as Exhibit "7". Dr Moreno, a nationally recognized expert in bioethics, notes that the DoD brochure does not meet any commonly understood standard of informed consent, and is, in fact, coercive to an unacceptable degree. Id.

21 U.S.C. § 360bbb-3(b)(1)(B). However, in this case, the determination of such a military emergency, and the request to the Secretary of HHS was not made by the Secretary of Defense, but by a Deputy Secretary of Defense. See Defendants' Emergency Motion to Modify Injunction (filed February 4, 2005), at Exhibit 4.

It is undisputed that the provisions for issuing an EUA do not state that the Secretary of Defense *or his designee* can make the requisite determination and request, but only the "Secretary of Defense". While Defendants will presumably rely on the provisions of 10 U.S.C. § 113(d), which allows the Secretary of Defense to perform his functions through or with the aid of his designees unless specifically prohibited by law, it is clear from the nature of the Project Bioshield amendments that Congress expected EUA authority to remain with the cabinet secretaries. See e.g., Exhibit "5".

For example, it is the Secretary of Health and Human Services that issues the EUA with or without (under his discretion) consultation with other federal entities. Moreover, it appears from the language of the statute that the Secretary of HHS can waive the informed consent requirements for a drug unapproved for its unintended use. See 21 U.S.C. § 360bbb-3(e)(2)(A)("the secretary shall, *to the extent practicable given the circumstances of the emergency*" establish the requirements, including the option to accept or refuse administration of the product, relating to the EUA for the product).

Under these circumstances, it appears that Congress was providing substantial power to the Executive Branch to deal with a true national emergency, namely a biological warfare attack on the United States or its armed forces. The casual disregard of that requirement, especially under the circumstances present before the Court today,

argue strongly in favor of maintaining the determination and request authority at the secretary level.

CONCLUSION

In response to this Court's October 27, 2004 permanent injunction (which the government consistently refers to as nothing more than a "pause" in its AVIP literature), Defendants instituted a course of action that, in retrospect, can only be considered extraordinary. Defendants did nothing less than manufacture an emergency request under the cover of a statute designed to respond to a real or imminent biological attack on the United States, and now collude to end-run the Court's injunction. Given that Defendants have failed to comply with that injunction and in light of DoD's conduct, it seems only prudent and proper that Defendants be required to follow at least a minimum of procedural care in the administration of an investigational/unapproved vaccine on even a voluntary basis.

Plaintiffs urge the Court to deny Defendants' motion without prejudice so that they can return with a workable program that accommodates the rights and interests of service members and civilians, or that the Court grant the motion but with the modifications to the notice requirements as set forth above.

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Respectfully submitted,

/s/

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