

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

ORDER

On October 27, 2004, this Court issued an order permanently enjoining the military's anthrax vaccine program. Specifically, the Court held, "Unless and until FDA classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccine program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver."

Defendants have now filed an Emergency Motion to Modify the Injunction, seeking clarification that there exists a third option - an alternative to informed consent or a Presidential waiver - by which defendants can administer AVA to service members even in the absence of FDA approval of the drug: that is, pursuant to an Emergency Use Authorization ("EUA") under the

Project BioShield Act of 2004, 21 U.S.C.A. § 360bbb-3.

In enacting the EUA provision, Congress appears to have authorized the use of unapproved drugs or the unapproved use of approved drugs based on a declaration of emergency by the Secretary of Health and Human Services, which in turn is based on "a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a specified biological, chemical, radiological or nuclear agent or agents." 21 U.S.C.A. § 360bbb-3(b)(1)(B).

Without ruling on the lawfulness or merits of any EUA, upon consideration of the defendants' motion, the opposition and replies thereto, the *amicus curiae* brief, the arguments heard in open court on March 21, 2005, and the draft language jointly submitted by the parties in this case, it is hereby

ORDERED that the defendants' Motion to Modify the Injunction is **GRANTED**; it is further

ORDERED that the Court's injunction of October 27, 2004, is modified by the addition of the following language: "This injunction, however, shall not preclude defendants from administering AVA, on a voluntary basis, pursuant to the terms of a lawful emergency use authorization ("EUA") pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act, without prejudice to a future challenge to the validity of any such EUA.

The Court expressly makes no finding as to the lawfulness of any specific EUA that has been or may be approved by the Department of Health and Human Services."

Signed: Emmet G. Sullivan
United States District Judge
April 6, 2005