LEXSEE 2005 U.S. DIST. LEXIS 5573

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

Civil Action No. 03-707 (EGS)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2005 U.S. Dist. LEXIS 5573

April 6, 2005, Decided

SUBSEQUENT HISTORY: Later proceeding at *Doe v. Rumsfeld, 2005 U.S. App. LEXIS 25276 (D.C. Cir., Nov. 21, 2005)*

PRIOR HISTORY: *Doe v. Rumsfeld, 2005 U.S. Dist. LEXIS 1989 (D.D.C., Feb. 14, 2005)*

COUNSEL: For JOHN DOE, JANE DOE, Plaintiffs: Mark S. Zaid, KRIEGER & ZAID, PLLC, Washington, DC; John J. Michels, MCGUIRE WOODS, LLP, Chicago, IL.

For DONALD H. RUMSFELD Secretary of Defense, TOMMY THOMPSON Secretary of Health and Human Services, MARK B. MCCLELLAN, Defendants: Ronald James Wiltsie, U.S. DEPARTMENT OF JUSTICE, Washington, DC; Andrew H. Tannenbaum, U.S. DEPARTMENT OF JUSTICE, Civil Division, Federal Programs Branch, Washington, DC; Craig M. Blackwell, US DEPT OF JUSTICE-CIVIL DIVISION, Washington, DC.

For MILITARY VACCINE EDUCATION CENTER, NATIONAL GULF WAR RESOURCE CENTER, Movants: Martin Henry Karo, NELSON LEVINE DELUCA & HORST, Blue Bell, PA.

For NATIONAL VACCINE INFORMATION CENTER, Movant: Martin Henry Karo, Kenneth T. Levine , NELSON LEVINE DELUCA & HORST, Blue Bell, PA.

JUDGES: [*1] Emmet G. Sullivan, United States District Judge.

OPINION BY: Emmet G. Sullivan

OPINION

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, [*2] 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 [*3] 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