IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' EMERGENCY MOTION TO MODIFY INJUNCTION

On January 27, 2005, the Food and Drug Administration ("FDA") authorized the emergency use of anthrax vaccine adsorbed ("AVA") for the prevention of inhalation anthrax for individuals deemed by the Department of Defense ("DoD") to be at heightened risk of exposure due to attack with anthrax. See Letter from Dr. Lester M. Crawford, D.V.M., Ph.D., FDA, to Dr. William Winkenwerder, Assistant Secretary of Defense for Health Affairs (Jan. 27, 2005) (Exhibit 1), published at 70 Fed. Reg. 5452, 5453–56 (Feb. 2, 2005) (Exhibit 2). This emergency use authorization ("EUA") was issued pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") (codified at 21 U.S.C. § 360bbb-3), following a declaration of emergency by the Secretary of Health and Human Services ("HHS"), which in turn was based on a determination by the Deputy Secretary of Defense that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax. See Declaration of Emergency Pursuant to 21 U.S.C. § 360bbb-3(b), Tommy G. Thompson, Secretary of Health and Human Services (Jan. 14, 2005) (Exhibit 3); Letter from Paul Wolfowitz, Deputy Secretary of Defense, to the Honorable Tommy G. Thompson, Secretary of Health and Human Services (Dec. 10, 2004) ("Wolfowitz Letter") (Exhibit 4); see also

Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax, 70 Fed. Reg. 5450, 5450–51 (Feb. 2, 2005) (Exhibit 5). Among other conditions, the EUA requires DoD to revise its Anthrax Vaccine Immunization Program ("AVIP") to give personnel the option to refuse vaccination. See 70 Fed. Reg. at 5455.

As a result of this new development, DoD now has express authority to begin voluntary AVA vaccinations in accordance with the terms of the EUA. The resumption of AVIP as a voluntary vaccination program, moreover, would be consistent with the apparent intent of the Court's October 27, 2004 Order, which struck down on procedural grounds "the *involuntary* anthrax vaccination program . . . absent informed consent or a Presidential waiver." Order at 1 (emphasis added). However, the EUA authority was not previously an issue in this litigation, and the Court thus had no reason to address it in its prior rulings. Accordingly, the Court's October 27, 2004 Order does not expressly contemplate the possibility that an EUA could be issued by HHS to authorize the use of AVA for inhalation exposure, even in the absence of a final FDA order addressing the use of AVA for inhalation anthrax. Nor does it contemplate that the requirements of 10 U.S.C. § 1107 explicitly do not apply where an EUA has been granted. See 10 U.S.C. § 1107a(c). Nonetheless, out of an abundance of caution, defendants respectfully request that the Court modify its injunction to expressly acknowledge the legality of DoD's use of AVA pursuant to the EUA.[1]

[1] Defendants do not intend to resume AVA vaccinations under the EUA until the Court rules on this motion. Defendants thus seek modification of the Court's injunction on an emergency basis, and in so doing, hope to avoid the need to seek any stay from the injunction.

BACKGROUND

A. Statutory Authority

Section 564(a)(1) of the FFDCA provides that the Secretary of Health and Human Services ("HHS") may "authorize the introduction into interstate commerce . . . of a drug, device, or biological product intended for use in an actual or potential emergency," notwithstanding the licensure requirements of, inter alia, section 351 of the Public Health Service Act (codified at 42 U.S.C. § 262). 21 U.S.C. § 360bbb-3(a)(1). In issuing such an EUA, the Secretary of HHS may authorize the use of an unapproved product or the unapproved use of an approved product. See id. at § 360bbb-3(a)(2).

An EUA must be based on a declaration of emergency made under section 564(b). See id. at § 360bbb-3(b). The Secretary of HHS may declare such an emergency on the basis of, inter alia, "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." Id. at § 360bbb-3(b)(1)(B). The declaration of the emergency shall expire after one year, if not terminated earlier by the Secretary of HHS. Id. at § 360bbb-3(b)(2)(A). The Secretary may, however, renew the declaration at any time. Id. at § 360bbb-3(b)(2)(B).

In addition to the declaration of emergency, there are various other criteria for the issuance of an EUA under the FFDCA. For example, under section 564(c), the Secretary of HHS may issue an EUA "only if, after consultation with the Director of the National Institutes of Health and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the circumstances of the emergency involved)," the Secretary concludes

that (1) an agent specified in the emergency declaration "can cause a serious or life-threatening disease or condition"; (2) based on the totality of scientific evidence available to the Secretary, it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition, and the known and potential benefits of the product when used to diagnose, treat, or prevent such disease or condition outweigh the known and potential risks; (3) there is "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition"; and (4) "such other criteria as the Secretary may by regulation prescribe are satisfied." Id. at § 360bbb-3(c).[2]

Section 564(e) also imposes certain conditions upon the issuance of an EUA. These conditions differ depending upon whether the EUA authorizes the use of an unapproved product or an unapproved use of an approved product. With respect to the emergency use of an unapproved product, the Secretary of HHS, "to the extent practicable given the circumstances of the emergency, shall, for a person who carries out any activity for which the authorization is issued," establish conditions the Secretary finds necessary or appropriate to protect the public health, including conditions designed to ensure that individuals to whom the product is administered are informed (1) that the Secretary has authorized the emergency use of the product, (2) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown, and (3) "of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of

[2] These statutory criteria governing the issuance of an EUA are separate and distinct from the standards of licensure for biological products under section 351 of the Public Health Service Act, which requires, inter alia, that FDA find a biologic product to be "safe, pure, and potent." 42 U.S.C. § 262(a).

the product, and of the alternatives to the product that are available and of their benefits and risks." Id. § 360bbb-3(e)(1)(A); see also id. § 360bbb-3(e)(1)(B) (providing that the Secretary may establish additional conditions necessary or appropriate to protect the public health, including conditions on distribution and administration of the product).

With respect to the unapproved use of an approved product, "the Secretary shall, to the extent practicable given the circumstances of the emergency," establish certain conditions also required for the emergency use of an unapproved product, including the condition designed to ensure that individuals to whom the product is administered are adequately informed of, inter alia, the option to accept or refuse administration of the product. Id. § 360bbb-3(e)(2)(A). However, the Secretary is only required to impose such conditions, including the option-to-refuse condition, "[f]or a manufacturer of the product who carries out any activity for which the authorization is issued." Id.

Significantly, section 564(i) expressly provides that actions taken under the authority of section 564 by the Secretary of HHS or the Secretary of Defense "are committed to agency discretion." Id. § 360bbb-3(i). The statute also makes clear that "[n]othing in [section 564] impairs the "authority of the United States to use or manage quantities of a product that are owned or controlled by the United States." Id. § 360bbb-3(j)(3).[3]

Finally, section 564(k) states that a use of a product pursuant to an EUA "shall not be considered to constitute a clinical investigation for purposes of section 355(i) of this title, section

[3] See also 21 U.S.C. § 360bbb-3(j)(1)–(2) (stating that nothing in section 564 impairs the "authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution," or "the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law").

360j(g) of this title, or any other provision of this chapter or section 262 of Title 42." Id. § 360bbb-3(k). Consistent with this command, section 1107a of title 10 defines the interrelation of the EUA regime and the requirements regarding the use of an investigational new drug in the armed forces under section 1107 of title 10. In the event that an EUA is issued under section 564(a)(1) of the FFDCA based on a determination by the Secretary of Defense under section 564(b)(1)(B), "subsections (a) through (f) of section 1107 [of title 10] shall not apply to the use of a product that is the subject of such authorization, within the scope of such authorization and while such authorization is effective." 10 U.S.C. § 1107a(c). To the extent that the issuance of an EUA requires that individuals be informed of an option to refuse administration of the product, that condition may be waived "only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security." Id. § 1107a(a).

B. The January 27, 2005 EUA

On December 10, 2004, the Deputy Secretary of Defense, pursuant to authority assigned by the Secretary of Defense, determined that there is a significant potential for a military emergency involving a heightened risk to U.S. forces of attack with anthrax. See Wolfowitz Letter (Ex. 4); 70 Fed. Reg. at 5451, 5453 & n.1. On January 14, 2005, the Secretary of HHS, on the basis of that determination, declared an emergency justifying the authorization of the emergency use of AVA. See Declaration of Emergency Pursuant to 21 U.S.C. § 360bbb-3(b) (Ex. 3); 70 Fed. Reg. at 5451, 5453. On January 27, 2005, after consulting with the NIH and CDC and concluding that the criteria for the EUA were met, FDA authorized the emergency use of AVA subject to certain established conditions. See 70 Fed. Reg. at 5452–56; see also id. at

5453 n.2 (stating that the Secretary of HHS "has delegated his authority to issue an EUA under section 564 to the FDA Commissioner").

Among the conditions contained in the EUA is the requirement that DoD conduct an educational and informational program to ensure that each potential AVA recipient is informed, prior to vaccination, that FDA has authorized the emergency use of AVA for preventing inhalation anthrax; of the significant known and potential benefits and risks of the emergency use of AVA, and of the extent to which such benefits and risks are unknown; of the option to accept or refuse administration of AVA, and of the consequences, if any, of refusing administration of the product; and of the alternatives to AVA that are available, and of their benefits and risks. See id. at 5455. With respect to the option to refuse, the EUA requires that the AVIP be revised to give personnel the option to refuse anthrax vaccination and that individuals who refuse will not be punished. See id. Specifically, potential vaccine recipients will be given a brochure that states, inter alia:

> You may refuse anthrax vaccination under the EUA, and you will not be punished. No disciplinary action or adverse personnel action will be taken. You will not be processed for separation, and you will still be deployable. There will be no penalty or loss of entitlement for refusing anthrax vaccination.

Id.[4]

In addition, the scope of the EUA is limited to the use of AVA for the prevention of

[4] The EUA also states that other information may be provided by DoD to potential AVA recipients, including "[t]hat unvaccinated people are more vulnerable to lethal anthrax infection; morbidity or mortality due to anthrax could threaten the lives of others in the unit who depend on each other; and anthrax infections could jeopardize the success of the mission." 70 Fed. Reg. at 5455. Individuals subject to vaccination may also be informed "that their military and civilian leaders strongly recommend anthrax vaccination, but such individuals may not be forced to be vaccinated." Id.

inhalation anthrax for individuals between 18 and 65 years of age who are deemed by DoD to be at heightened risk of exposure due to attack with anthrax. See id. The EUA is effective for six months from the date of issuance, although it may be extended within the duration of the declaration of emergency if the statutory criteria are met. See id. 5455–56. In cases where the risk status of individuals initially eligible for vaccination may change during the duration of the EUA (e.g., due to changes in deployment or other circumstances), DoD must determine whether such individuals continue to be at a heightened risk of exposure due to attack with anthrax, and therefore, whether they continue to be eligible for vaccination with AVA under the EUA. See id. at 5455.

C. The Current Injunction

On October 27, 2004, the Court ruled that FDA's Final Rule and Final Order, which had classified AVA as safe and effective against the anthrax bacterium regardless of the route of exposure, was procedurally invalid to the extent that the Order addressed AVA's use for the prevention of inhalation anthrax. The procedural flaw, according to the Court, resulted because FDA did not provide a sufficient opportunity for public comment on the classification of AVA as safe and effective as it pertains to inhalation anthrax. As a remedy, the Court vacated and remanded the Final Rule and Final Order to FDA for reconsideration following an appropriate notice-and-comment period in accordance with the Administrative Procedure Act and FDA regulations. See Memorandum Opinion at 33 (Oct. 27, 2004).

Having "vacated and remanded FDA's Final Rule and Order," the Court held that AVA could not, under 10 U.S.C. § 1107, be administered by DoD absent informed consent or a Presidential waiver of the informed consent requirement. See id. The Court thus issued an

injunction, which is to remain in effect "[u]nless and until FDA classifies AVA as a safe and effective drug for its intended use." Order at 1 (Oct. 27, 2004). The injunction prohibits "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." Id.[5] The Court's order further states that "the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver." Id.

ARGUMENT

I. THE INJUNCTION SHOULD BE MODIFIED IN LIGHT OF THE EUA

Because the recently issued EUA is conditioned on providing individuals with an option to refuse administration of AVA, the EUA is consistent with the apparent intent of the Court's Order, which struck down the "*involuntary* anthrax vaccination program." Id. (emphasis added). However, in light of the fact that the Court's ruling focused on the requirements of 10 U.S.C. § 1107, and that the EUA authority was not previously an issue before the Court, the injunction could be read narrowly to allow voluntary AVA vaccinations only pursuant to the specific informed consent procedures set forth in § 1107. Accordingly, out of an abundance of caution, defendants respectfully request that the Court modify its injunction to allow DoD to administer vaccinations pursuant to the EUA.

A. Federal Rule of Civil Procedure 60(b)

Federal Rule of Civil Procedure 60(b) provides that, "[o]n motion and upon such terms as are just, the court may relieve a party . . . from a final judgment, order, or proceeding," for

[5] In deference to the procedural ruling of this Court, the EUA specifies that the use of AVA for prevention of inhalation anthrax is an unapproved use of an approved product. See 70 Fed. Reg. at 5454.

various reasons, including "(5) the judgment has been satisfied, released, or discharged, or a prior judgment upon which it is based has been reversed or otherwise vacated, or it is no longer equitable that the judgment should have prospective application; or (6) any other reason justifying relief from the operation of the judgment." Fed. R. Civ. P. 60(b).

Rule 60(b)(5), as the Supreme Court recently noted, "encompasses the traditional power of a court of equity to modify its decree in light of changed circumstances." Frew ex rel. Frew v. Hawkins, 124 S. Ct. 899, 906 (2004); see also Rufo v. Inmates of Suffolk County Jail, 502 U.S. 367, 393 (1992) (in context of institutional reform litigation, applying "flexible standard" under Rule 60(b)(5) to the modification of consent decrees and finding modification appropriate when parties "establish that a significant change in fact or law warrants revision of the decree and that the proposed modification is suitably tailored to the changed circumstance"); United States v. Western Elec. Co., Inc., 46 F.3d 1198, 1202, 1203 (D.C. Cir. 1995) (extending flexible standard of Rufo to "all types of injunctive relief" and recognizing that Rule 60(b)(5) codified the universal principle that "[t]he power of a court of equity to modify a decree of injunctive relief . . . is long-established, broad, and flexible") (quoting New York State Ass'n for Retarded Children, Inc. v. Carey, 706 F.2d 956, 967 (2d Cir. 1983)). In addition, Rule 60(b)(6) is a "catchall" provision that covers reasons for modification other than those specified in Rule 60(b)(1)-(5). E.g., Balta Air Lines, Inc. v. Transaction Management, Inc., 98 F.3d 640, 642 (D.C. Cir. 1996); Twelve John Does v. District of Columbia, 841 F.2d 1133, 1140 (D.C. Cir. 1988).

B. The EUA Provides a Clear Basis for Modification

The January 27, 2005 EUA clearly constitutes the type of changed circumstance that justifies modification of the Court's October 27, 2004 injunction. As set forth above, the

injunction prohibits 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." Order at 1 (Oct. 27, 2004). With the issuance of the EUA, however, the FFDCA provides express statutory authority for the administration of AVA to prevent inhalation anthrax, even in light of the Court's ruling that AVA is unapproved for such use. See 21 U.S.C. § 360bbb-3(a)(2). This is so because section 564(a) of the FFDCA provides an independent source of authority for FDA to permit distribution of drugs, devices, and biological products in interstate commerce that is distinct from, inter alia, section 351 of the Public Health Service Act. Moreover, the requirements of 10 U.S.C. § 1107 are rendered inapplicable to the use of AVA under the EUA. See 10 U.S.C. § 1107a(c). Therefore, the resumption of AVIP pursuant to the terms of the EUA is expressly authorized by statute, and such authorization is independent from the basis of the Court's injunction and plaintiffs' complaint.

The basis for modification, moreover, is particularly strong because the resumption of AVIP as a voluntary program is consistent with the spirit of the Court's prohibition of AVA inoculations in the absence of informed consent or a Presidential waiver of the informed consent requirement. As described above, the EUA requires DoD to conduct an educational and informational program to ensure that potential AVA recipients are informed, prior to vaccination, that they may refuse vaccination without penalty. See 70 Fed. Reg. at 5455. DoD is also required to inform such individuals, prior to vaccination, that FDA has authorized the emergency use of AVA for preventing inhalation anthrax; of the significant known and potential benefits and risks of the emergency use of AVA, and of the extent to which such benefits and risks are unknown; and of the alternatives to AVA that are available, and of their benefits and risks. See

id. Similar to the informed consent requirement of 10 U.S.C. § 1107, the EUA's requirement of an option to refuse may be waived "only by the President only if the President determines, in writing, that complying with such requirement is not in the interests of national security." 10 U.S.C. § 1107a(a)(A).

In light of the express statutory authority for the EUA, there is no basis to prohibit the resumption of AVIP pursuant to the conditions of the EUA. Accordingly, the injunction should be modified to allow DoD to resume AVIP as a voluntary program, as set forth in the EUA.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court modify the injunction issued on October 27, 2004 to expressly acknowledge the legality of DoD's resumption of AVIP pursuant to the EUA and section 564 of the FFDCA.

Dated: February 4, 2005

Respectfully submitted,

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