**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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

**DEFENDANTS' REPLY IN SUPPORT OF EMERGENCY MOTION TO MODIFY INJUNCTION**

On October 27, 2004, this Court issued an injunction prohibiting defendants' use of anthrax vaccine adsorbed ("AVA"), absent informed consent or a presidential waiver of the informed consent requirement, "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." On January 27, 2005, the Food and Drug Administration ("FDA") authorized the emergency use of AVA by the Department of Defense ("DoD") pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act ("FFDCA"). This emergency use authorization ("EUA") provided new and independent authority for the resumption of DoD's Anthrax Vaccine Immunization Program ("AVIP") pursuant to the specific terms of the EUA. Indeed, because section 564 of the FFDCA allows the authorization of an unapproved use of an approved product, and because 10 U.S.C. § 1107 expressly does not apply to the use of a product pursuant to an EUA, the entire basis for the Court's injunction is inapplicable in the EUA context. Nonetheless, because the injunction did not explicitly acknowledge the possibility that DoD could legally administer AVA pursuant to an EUA, defendants—out of an abundance of caution—filed an emergency motion to modify

the Court's injunction pursuant to Federal Rule of Civil Procedure 60(b).

Plaintiffs oppose defendants' emergency motion to modify the injunction on two primary grounds. First, plaintiffs argue that the tri-fold brochure which DoD plans to provide to potential vaccine recipients (and which was approved by FDA) meets some, but not all, of the informed consent requirements for an investigational new drug. Plaintiffs thus suggest a series of additional edits that they would like to be made to the tri-fold brochure. Second, plaintiffs claim that the Secretary of Defense improperly delegated his authority under section 564 of the FFDCA to the Deputy Secretary of Defense. Plaintiffs also make a few other miscellaneous contentions, including that the EUA was somehow improper because it was issued in response to the Court's injunction and that the requested modification of the injunction would be at odds with the terms of the injunction itself.

All of plaintiffs' arguments are without merit. As an initial matter, plaintiffs present no valid reason why the Court's injunction should not be modified in the narrow context of this proceeding. Instead, plaintiffs attempt to use the proceeding involving defendants' Rule 60(b) motion as a vehicle to present a series of new legal challenges to the issuance and implementation of the EUA. Such new challenges, however, are entirely improper because they are outside the scope of the narrow Rule 60(b) proceedings (particularly given that the case is currently closed and on appeal) and because plaintiffs have not raised any such claim in a valid complaint that demonstrates their standing or substantive basis to do so—either on their own behalf or on behalf of a putative class of all other personnel who will be offered the option of getting a vaccination. The Court thus should not even reach the substance of the arguments advanced by plaintiffs in their opposition.

Plaintiffs' contentions, in any event, can be easily dismissed. The information provided in the tri-fold brochure meets the specific requirements set forth for an EUA under the FFDCA. Plaintiffs attempt to confuse the EUA requirements with the informed consent requirements for an investigational new drug, but plaintiffs fail to mention that the investigational new drug requirements explicitly do not apply in the case of an EUA. Moreover, plaintiffs have no basis to propose revisions to the tri-fold brochure because the determination of the information to be provided in the brochure is expressly committed by statute to agency discretion. Furthermore, the delegation of authority from the Secretary of Defense to the Deputy Secretary of Defense was clearly proper under a federal statute that explicitly allows the Secretary to delegate any of his authority unless specifically prohibited by law.

Plaintiffs attempt to belittle the EUA because it was issued only after the Court's injunction, but that criticism is way off the mark. The potential for a military emergency due to a threat with anthrax attack obviously existed prior to the Court's injunction (and, indeed, underlay the AVIP), but—equally obviously—it was unnecessary to issue a separate declaration of emergency under the EUA procedures at that time because DoD was able to meet the emergent conditions by vaccinating personnel under the AVIP. Finally, the contention that the requested modification of the Court's injunction is inconsistent with the injunction itself warrants no detailed discussion. The very point of the motion for modification is, of course, to modify the terms of the injunction.

## I. THE ISSUES RAISED BY PLAINTIFFS ARE WELL BEYOND THE SCOPE OF THESE PROCEEDINGS

Plaintiffs' opposition to defendants' Rule 60(b) motion to modify the Court's injunction

consists of substantive challenges to the issuance and implementation of the EUA. As defendants have previously noted, however, the consideration of legal challenges to the EUA would be entirely improper in the narrow confines of the instant Rule 60(b) motion.[1] This is particularly so because (1) the Court has only very limited jurisdiction to proceed while this case is on appeal, and (2) plaintiffs have not filed any complaint that raises a proper challenge to the EUA or that demonstrates plaintiffs' standing to do so.

As previously explained, the filing of a notice of appeal "is an event of jurisdictional significance—it confers jurisdiction on the court of appeals and divests the district court of its control over those aspects of the case involved in the appeal." Griggs v. Provident Consumer Discount Co., 459 U.S. 56, 58 (1982); accord Princz v. Fed. Republic of Germany, 998 F.2d 1 (D.C. Cir. 1993) (per curiam). With certain exceptions, district courts thus have very limited jurisdiction to proceed in cases on appeal. See, e.g., Bradford-Scott Data Corp, Inc. v. Physical Computer Network, Inc., 128 F.3d 504, 505 (7th Cir. 1997) (while appeal is pending, a district court may award costs and attorneys' fees). One such exception recognized by the D.C. Circuit is that a district court may consider a Rule 60(b) motion for relief while an appeal is pending. See Haoi v. Vo, 935 F.2d 308, 312 (D.C. Cir. 1991); Reuber v. United States, 750 F.2d 1039, 1052 n.16 (D.C. Cir. 1985); Greater Boston Television Corp. v. F.C.C., 463 F.2d 268, 280 n.22 (D.C. Cir. 1979).

Here, defendants filed a notice of appeal of the Court's October 27, 2004 decision on December 23, 2004 and subsequently, upon issuance of the EUA, filed a Rule 60(b) motion

[1] See Defendants' Opposition to Petition for Leave of Court to File Amicus Curiae Brief at 3–5 (filed March 8, 2005).

seeking modification of the Court's injunction. Defendants' Rule 60(b) motion has thus opened a very narrow proceeding in this closed case: a proceeding merely to remedy any overbreadth in the terms of the Court's injunction due to the fact that—in enumerating the legally available options for administration of anthrax notwithstanding the injunction—the injunction omits the Government's extant statutory authority to invoke EUA procedures.[2] Defendants' motion, however, is not cause for swinging the door of this closed case wide open so that a brand-new legal challenge to DoD's and HHS's actual invocation of EUA procedures may be heard. Indeed, there is not even a complaint before the Court that sets forth any claim alleging the EUA to be improper. Such a claim could be appropriately raised, if at all, only in a fresh complaint by a party that demonstrates, inter alia, that party's requisite legal standing, a valid cause of action, and the source of the Court's jurisdiction.

This Court recognized as much in an analogous situation earlier in this case. On December 22, 2003, the Court issued a preliminary injunction enjoining inoculations under the AVIP in the absence of informed consent or a presidential waiver because the Court found that "the record was devoid of an FDA final decision on the investigational status of AVA." Memorandum Opinion at 10 (Oct. 27, 2004). When FDA subsequently issued a Final Rule and Order classifying AVA as a Category I drug, the Court granted defendants' emergency request to

[2] The limited nature of defendants' Rule 60(b) motion cannot be emphasized enough. As demonstrated by the attached proposed order, defendants do not seek a declaration from the Court validating in all respects the issuance and proposed implementation of the specific EUA at issue here. Rather, defendants merely seek a general modification to the injunction so that it recognizes that, just as AVA vaccinations may be administered by DoD pursuant to informed consent or a presidential waiver, vaccinations may also be administered pursuant to an EUA issued under the authority of section 564 of the FFDCA.

stay the Court's preliminary injunction.[3] See id. at 10. Significantly, the Court did not allow any potential challenges to the newly issued FDA Final Rule and Order to tie up the stay proceedings. Rather, plaintiffs were required, as any litigant would be, to present their challenges to the new FDA Final Rule and Order in a new complaint.

Although it should be plain that the same course should be followed here, especially given the limited nature of the Court's jurisdiction while this case is on appeal, plaintiffs are attempting to inject entirely new legal claims into these narrow Rule 60(b) proceedings. Plaintiffs, moreover, attempt to do so without demonstrating that they are at any risk of suffering any injury as a result of the EUA—an essential showing for purposes of establishing Article III standing. Indeed, the six Doe plaintiffs would be hard pressed to claim that they are at risk of suffering any injury as the result of the EUA, not only because it is unclear whether they currently are in a position where an anthrax vaccination would be offered, but also because they are undoubtedly on notice (at the very least, through their counsel) that they may refuse a vaccination under the EUA without penalty. Moreover, if plaintiffs attempted to bring a fresh complaint to challenge the EUA, they would be without a valid cause of action. The Administrative Procedure Act provisions upon which plaintiffs previously relied in this case for a cause of action and waiver of sovereign immunity would be unavailable in any challenge to actions taken under section 564 of the FFDCA, because those actions are expressly committed to agency discretion. See 21 U.S.C. § 360bbb-3(i); 5 U.S.C. § 701(a)(2).

In short, by using defendants' Rule 60(b) motion in this closed case as a vehicle to

[3] Pursuant to an agreement between the parties, the preliminary injunction was initially kept in place with respect to the six Doe plaintiffs, but the Court later vacated its injunction as to the six plaintiffs as well. See Memorandum Opinion at 13 n.4 (Oct. 27, 2004).

present new legal challenges to the EUA, plaintiffs are attempting an end-around the fundamental requirements for bringing a claim in federal court. Because plaintiffs have not identified a single case that would allow them to bypass those basic requirements, particularly in a closed case, their attempt to bootstrap new legal claims in the narrow confines of these Rule 60(b) proceedings should be rejected.

## II. THE TRI-FOLD BROCHURE MEETS THE APPLICABLE LEGAL REQUIREMENTS

Plaintiffs contend that the FDA-approved tri-fold brochure which DoD plans to provide to potential vaccine recipients under the EUA does not meet all of the requirements of informed consent as set forth in 21 U.S.C. § 355(i)(4) and 21 C.F.R. §§ 50.1–50.27. Specifically, plaintiffs argue that the brochure should include a signature line with text indicating that the service member has read and understands his or her rights under the terms of the EUA. See Plaintiffs' Opposition to Defendants' Emergency Motion to Modify Injunction ("Pls' Opp.") at 4. Plaintiffs also request that defendants be required to provide copies of the signed forms to service members who consent and that copies be filed in the medical records of those individuals. See id. at 5. Finally, plaintiffs suggest a series of additional edits that they would like DoD to make to the tri-fold brochure, including additional discussion of long-term side effects; the repositioning and boldfacing of a warning concerning the use of AVA for pregnant women; and the removal of a description of possible consequences of refusing anthrax vaccination, such as increased vulnerability to lethal anthrax infection and potential jeopardy to a mission or unit.[4]

[4] Plaintiffs seek deletion of this discussion "of the consequences, if any, of refusing administration of the product," even though such a discussion is required under certain circumstances under section 564(e)(1)(A) of the FFDCA. 21 U.S.C. § 360bbb-3(e)(1)(A).

For the reasons already discussed, the Court should not even reach the merits of these contentions because they are well beyond the scope of these proceedings and because plaintiffs have not demonstrated their standing to bring such challenges or even a proper cause of action. Because the six Doe plaintiffs themselves are unable to contend that they are at risk of blundering into acceptance of an anthrax inoculation under the EUA, their demands for additional information in the tri-fold brochure, and for supplemental procedures, represent improper attempts to advance the putative interests of third parties not before the Court. The absence of standing for the six Doe plaintiffs is only part of the problem, as the only proper way the Doe plaintiffs could purport to represent absent members of the Armed Forces who will receive offers of inoculation is to obtain certification of a class under Federal Rule of Civil Procedure 23—a procedure plaintiffs have failed to invoke in this litigation.[5] Moreover, as previously explained, in any proper class action complaint the plaintiffs would be without a valid cause of action, because the determination of the information to be provided under an EUA is expressly committed to agency discretion by statute. To recall, section 564(i) of the FFDCA explicitly states that actions taken under the authority of section 564 by the Secretary of HHS or the Secretary of Defense "are committed to agency discretion." 21 U.S.C. § 360bbb-3(i). And the establishment of conditions on an EUA, including the information to be provided to individual recipients, is plainly an authority committed to HHS under the statute. See § 360bbb-3(e). Given this clear textual commitment to agency discretion, there is no basis for plaintiffs to

[5] See Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Determine that Class Certification is Not Required for Program-Wide Injunctive Relief (filed Feb. 9, 2004).

invoke federal judicial review in order to propose their desired edits to the tri-fold brochure.[6]

In any event, the tri-fold brochure meets all of the applicable requirements, which are specifically enumerated in section 564(e) of the FFDCA. See 21 U.S.C. § 360bbb-3(e); see also Defendants' Emergency Motion to Modify Injunction at 4–8 (describing the conditions required by statute for an EUA and the conditions imposed on the EUA at issue). Instead of focusing their attention on the specific EUA requirements set forth in section 564(e), however, plaintiffs attempt to confuse those requirements with the separate and distinct requirements of informed consent for an investigational new drug under section 505(i) of the FFDCA (codified at 21 U.S.C. § 355(i)) and the regulations promulgated thereunder (21 C.F.R. §§ 50.1–50.27).

The investigational new drug provisions, however, clearly do not apply in the EUA context. Indeed, section 564(k) of the FFDCA expressly states that "the use of a product within the scope of [an EUA] *shall not be considered to constitute a clinical investigation for purposes of section 355(i) of this title*, section 360j(g) of this title, or any other provision of this chapter of section 262 of Title 42." 21 U.S.C. § 360bbb-3(k) (emphasis added). Moreover, the specific requirements for the administration of an investigational new drug to members of the armed forces also expressly do not apply in the case of an EUA. See 10 U.S.C. § 1107a (stating that, in the case of an EUA based on a determination of a military emergency by the Secretary of Defense, "subsections (a) through (f) of section 1107 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

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[6] See 5 U.S.C. § 701(a)(2) (judicial review provisions of the Administrative Procedure Act, as well as the Act's waiver of sovereign immunity, do not apply to the extent that the "agency action is committed to agency discretion by law"); see also, e.g., I.C.C. v. Bhd. of Locomotive Eng'rs, 482 U.S. 270, 282 (1987) (APA codifies "traditional principle" that judicial review is unavailable where action is committed to agency discretion).

authorization is effective"). Plaintiffs' failure to address, or even cite, section 564(k) or section 1107a is inexplicable.

Because the only applicable requirements regarding the information to be provided to individual recipients in the case of an EUA are set forth in section 564, because the tri-fold brochure meets those requirements, and because the determination of what information is to be provided is in any event committed to agency discretion by statute, all of plaintiffs' suggested revisions to the brochure must be rejected.

## III. THE DELEGATION OF AUTHORITY BY THE SECRETARY OF DEFENSE WAS PROPER

Plaintiffs argue that the EUA was improperly issued because the determination of "a significant potential for a military emergency" under section 564(b)(1)(B) was made by the Deputy Secretary of Defense instead of the Secretary of Defense. Pls' Opp. at 8–9. This argument is easily rejected. Section 113(d) of title 10 of the United States Code provides:

> *Unless specifically prohibited by law*, the Secretary [of Defense] may, without being relieved of his responsibility, perform any of his functions or duties, or exercise any of his powers through, or with the aid of, such persons in, or organizations of, the Department of Defense as he may designate.

10 U.S.C. § 113(d) (emphasis added). In addition, 10 U.S.C. § 132(b) provides that the Deputy Secretary of Defense "shall perform such duties and exercise such powers as the Secretary of Defense may prescribe." And in DoD Directive 5105.2 (dated March 2, 2001 and attached hereto as Exhibit 1), Secretary Rumsfeld directed that:

> Except as expressly prohibited by law, Deputy Secretary of Defense Paul D. Wolfowitz has full power and authority to act for the Secretary of Defense and to exercise the powers of the Secretary of Defense upon any and all matters concerning which the Secretary of Defense is authorized to act pursuant to law.

Plaintiffs contend that the Secretary of Defense cannot delegate his duties under section 564 of the FFDCA because the statute does not specifically provide for such delegation. See Pls' Opp. at 9. As expressly set forth in 10 U.S.C. § 113(d), however, the Secretary may delegate his authority to other persons in the Department of Defense unless the delegation is *specifically* prohibited by law—in other words, the presumption here is clearly in *favor* of delegation, not against it as plaintiffs suggest.[7] See, e.g., Touby v. United States, 500 U.S. 160, 169 (1991) (holding that the Attorney General's delegation of authority to the DEA was proper because the delegation was not specifically prohibited by statute). There is nothing in section 564 of the FFDCA that prohibits the Secretary of Defense from authorizing the Deputy Secretary of Defense

[7] In fact, when Congress wants to limit delegation authority, it does so expressly. Indeed, it did so in one provision of 10 U.S.C. § 1107. See § 1107(f)(3)(A) (stating that the Secretary of Defense "may not delegate to any other official the authority to request the President to waive the prior consent requirement for the Department of Defense"). Congress also expressly limited delegation authority at least seven times within five months of the enactment of the Project BioShield Act of 2004. See Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005, Pub. L. No. 108-375, § 3113, 118 Stat. 1811, 2160 (2004) ("The Administrator may not delegate the authority to approve projects under the preceding sentence."); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Div. A, Tit. III, 118 Stat. 2809, 2957 (2004) ("The Secretary may not delegate the authority to grant such a waiver."); Consolidated Appropriations Act, 2005, Pub. L. No.108-447, Div. I, Tit. II, 118 Stat. 2809, 2957 (2004) ("The Secretary may not delegate to any Department official other than the Deputy Secretary and the Assistant Secretary for Public and Indian Housing any authority under . . . ."); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Div. K, Tit. I, Subtit. C, 118 Stat. 2809, 3453 (2004) ("The Administrator may not delegate the authority described in this subsection except to the Deputy Administrator, an Associate Administrator, or an Assistant Administrator."); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Div. K, Tit. I, Subtit. E, 118 Stat. 2809, 3459 (2004) ("The Administrator may not delegate the authority granted under paragraph (1) except to an Associate Deputy Administrator."); Consolidated Appropriations Act, 2005, Pub. L. No. 108-447, Div. K, Tit. I, Subtit. F, 118 Stat. 2809, 3459 (2004) ("The Administrator may delegate the authority under the preceding sentence only to the Deputy Administrator and only if the Administrator is unavailable to take such action."); Intelligence Reform and Terrorism Prevention Act of 2004, Pub. L. No. 108-458, § 1011(a), 118 Stat. 3638, 3651 (2004) ("The Director may only delegate a duty or authority given the Director under this subsection to the Principal Deputy Director of National Intelligence.").

to exercise the Secretary's authority under that section. Thus, the delegation of that authority, which is provided for by DoD Directive 5105.2, was clearly proper.

Finally, plaintiffs contend that the emergency upon which the EUA is based is "illusory" and "manufacture[d]" because it was triggered by the Court's October 27, 2004 injunction. Pls' Opp. at 8, 10. This statement is apparently made simply for its imagined inflammatory effect, because plaintiffs do not further argue that the EUA should be deemed invalid as the result of a defective declaration of emergency.[8] Indeed, such an argument would surely fail because the determination of any emergency under section 564 of the FFDCA is expressly committed to agency discretion. See 21 U.S.C. § 360bbb-3(i).

In any event, plaintiffs' suggestion that the declared emergency is somehow defective is clearly without basis. In making his determination that there is a significant potential for a military emergency involving a heightened risk to United States military forces of attack with anthrax, Deputy Secretary of Defense Paul Wolfowitz considered a classified November 2004 intelligence assessment of the anthrax threat and noted that the heightened risk was "the basis for the DoD program of vaccinating personnel serving in the areas of the Central Command and Korea." Letter from Paul Wolfowitz, Deputy Secretary of Defense, to the Honorable Tommy G. Thompson, Secretary of Health and Human Services (Dec. 10, 2004) (attached as Ex. 4 to Defendants' Emergency Motion to Modify Injunction). The fact that the requisite emergency under the EUA was declared after the Court shut down the vaccination program does not at all

[8] Nor do plaintiffs present any evidence whatsoever to support their bald suggestions of impropriety. Indeed, under well-settled case law, government officials are presumed to act in good faith, and a plaintiff must present "well-nigh irrefragable proof" of bad faith in order to overcome that presumption. Adair v. England, 183 F. Supp. 2d 31, 60 (D.D.C. 2002) (internal quotation marks omitted).

suggest that an emergency did not exist. Rather, the heightened risk to United States military forces of attack with anthrax also existed prior to the injunction, which is why DoD was vaccinating its personnel. See, e.g., Memorandum by the Deputy Secretary of Defense, Re: Reintroduction of the Anthrax Vaccine Immunization Program (AVIP), June 28, 2002 (attached hereto as Exhibit 2) ("Current intelligence assessments indicate that the anthrax threat to Department of Defense (DoD) forces is real."). It was unnecessary, of course, to invoke the EUA procedures at that time, however, because DoD was able to administer the vaccinations pursuant to the AVIP.

## 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 an EUA issued under section 564 of the FFDCA. The language of the requested modification is attached hereto in the form of a proposed order.

Dated: March 10, 2005

Respectfully submitted,

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**ORDER**

Upon full consideration of Defendants' Emergency Motion to Modify the Court's Injunction, it is hereby

ORDERED that Defendants' Motion to Modify the Injunction is GRANTED, and

ORDERED that the Court's injunction shall be modified by the addition of the following language: "This injunction, however, shall not preclude defendants from administering AVA pursuant to the terms of an emergency use authorization issued under the authority of section 564 of the Federal Food, Drug, and Cosmetic Act."

DATED: _____

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HON. EMMET G. SULLIVAN