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

1:03-cv-00707-EGS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Motions 40715; 2004 U.S. Dist. Ct. Motions LEXIS 19977

January 2, 2004

Motion to Stay

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TITLE: DEFENDANTS' EMERGENCY MOTION FOR IMMEDIATE ADMINISTRATIVE STAY PENDING DISPOSITION OF DEFENDANTS' MOTIONS

TEXT: For the reasons stated in the accompanying memorandum, Defendants Donald H. Rumsfeld, Tommy Thompson, and Mark B. McClellan hereby move the Court on an emergency basis for an immediate administrative stay of it preliminary injunction entered on December 22, 2003 as to all service members but the six Doe. Plaintiffs in this matter while the Court considers Defendants' pending motions. Defendants ask the Court to issue a decision with respect to this motion on or before January 6, 2004 so that Defendants can seek an immediate administrative stay or other relief in the D.C. Circuit, if necessary.

Pursuant to Local Civil Rule 7.1(m), counsel for Plaintiffs was contacted concerning the motion [**2] and has indicated that Plaintiffs do not consent to the requested relief. A proposed Order accompanies this motion.

Respectfully submitted,

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January 2, 2004

MEMORANDUM IN SUPPORT OF DEFENDANTS' EMERGENCY MOTION FOR IMMEDIATE ADMINISTRATIVE STAY PENDING DISPOSITION OF DEFENDANTS' MOTIONS

Defendants respectfully request that the Court enter an immediate administrative stay of its injunction - except insofar as the six Doe Plaintiffs are concerned - pending disposition by this Court of Defendants' Emergency Motion To Vacate Preliminary Injunction And For Stay ("Emergency Motion") and Defendants' related Motion For Clarification Or In The Alternative For Reconsideration ("Motion For Clarification"). Defendants ask the Court to issue a decision with respect to [**3] this motion on or before January 6, 2004 so that Defendants can seek an immediate administrative stay or other relief in the D.C. Circuit, if necessary, on January 7, 2004. n1

n1 By the relief they have requested since the Court entered its preliminary injunction order, Defendants have consistently maintained that immediate review in the D.C. Circuit would not be necessary if the Court would clarify that its injunction applies only insofar as the six Doe Plaintiffs are concerned or if the Court would issue a stay of the injunction with respect to all but the six Doe Plaintiffs during the Court's consideration of Defendants' pending emergency motions.

[*2] The relief sought in this motion is both exceedingly narrow and exceedingly urgent. We do not seek, at this stage, to affect the preliminary injunction at all insofar as it concerns the six Doe plaintiffs who filed this lawsuit and who wish to avoid exposure to the anthrax vaccine. We also do not seek to affect the Court's current scheduling order, which [**4] contemplates a hearing on the pending emergency motions on January 14 and a decision at some unspecified date thereafter. And we do not seek an immediate determination that defendants are likely to prevail on the merits of the case, or even on their pending emergency motions, although (as explained below), we believe they will. Instead, we seek only a brief administrative stay, limited in its scope to non-parties and limited in time until this Court decides our pending motions. See *In re Rice, 2003 WL 2287627* (D.C. Cir. Dec. 3, 2003) (purpose of administrative stay is "to give the court sufficient time to consider the merits of the motion for stay, and should not be construed in any way

as a ruling on the merits of that motion").

An administrative stay will allow the court, before effectively shutting down the military's ongoing anthrax vaccination program on a worldwide basis, to consider the merits of our pending arguments that (i) the preliminary injunction cannot properly be applied to non-parties, many of whom are soldiers who may desire the vaccine not only for combat readiness, but also for their own personal protection; and (2) intervening FDA action has foreclosed [**5] any basis for the preliminary injunction. Because of the significant legal issues raised by these arguments and the substantial likelihood that the government will succeed on either or both, the default rule in the interim (i.e., prior to this Court's January 14th hearing and subsequent decision), should be that the injunction issued by this Court should be limited to the six Doe plaintiffs currently before the Court. Even in the civilian context, there is no basis for a court to issue an injunction with [*3] respect to persons not before the court. A fortiori that is so in the military context of this case, in which a military-wide injunction would broadly affect the protection of the Nation's military personnel against attack, their combat readiness, and matters of military judgment and command. See *Department of Defense v. Meinhold, 510 U.S. 939, 939 (1993)* (staying military-wide injunction issued against Department of Defense to extent it related to any person other than named plaintiff); *Lever Brothers Co. v. United States, 981 F.2d 1330, 1338 (1993),* (vacating injunction to the extent it barred government from enforcing a regulation as to [**6] all foreign goods, and not merely those of the plaintiff's own foreign affiliates). Accordingly, a stay should be granted until the Court has ruled on the government's motion to clarify that the preliminary injunction is limited to the six plaintiffs before the Court (or, in the alternative, to modify the injunction insofar as it might be read to extend beyond those six plaintiffs).

The Court Should Grant An Immediate Stay

On December 31, 2003, the Court issued a Minute Order granting Plaintiffs' Motion for Extension of Time and setting a hearing on Defendants' pending emergency motions for January 14, 2004 ("Minute Order"). The Defendants appreciate that the Court, while granting Plaintiffs' Motion for Extension of Time, also granted Defendants' request to expedite consideration of Defendants' pending emergency motions, thereby recognizing some measure of immediacy associated with those motions. In their pending Emergency Motion, however, Defendants asked not only that the Court vacate its preliminary injunction order, but also that the Court grant an immediate stay of its injunction with respect to all but the six Doe Plaintiffs pending disposition of the Emergency Motion [**7] and pending disposition of the related Motion For Clarification. Because of the urgent nature of these requests, Defendants asked that the Court rule on that [*4] motion and the related Motion For Clarification by January 6, 2004 so that Defendants would have a timely opportunity to seek review in the D.C. Circuit if necessary. Mem. in Support of Emergency Motion at 4 n.4. n2

> n2 Defendants did not repeat this request for a decision on these motions by January 6th in the text of the motion itself or in the motion for expedited consideration of the motions. Out of an abundance of caution and to ensure that the Court understood the urgent nature of those requests, therefore, defendants file the instant motion with the Court.

By its Minute Order, the Court effectively denied Defendants' request for such a stay by granting Plaintiffs' Motion for Extension of Time and setting a hearing on Defendants' pending motions for January 14, 2003. Without a stay pending disposition of the motions, the effect of the Court's [**8] Minute Order is to keep the injunction in place, without clarification as to its scope, until at least January 14, 2004 and some indefinite period of time thereafter necessary for the Court to render a decision. That is too long given the substantial and irreparable injury that flows from the Court's preliminary injunction.

In their Emergency Motion, together with accompanying memorandum and supporting documents, all of which are incorporated by reference herein, Defendants set forth the reasons that justify immediate relief from the Court's preliminary injunction order. As noted therein, the propriety of a stay turns on whether (1) '"the petitioner [has] made a strong showing that it is likely to prevail on the merits of its appeal'"; (2) '"the petitioner [has] shown that without such

relief, it will be irreparably injured'"; (3) '"issuance of a stay [would] substantially harm other parties interested in the proceedings'"; and (4) the public interest favors a stay. *Washington Metropolitan Area Transit Commission v. Holiday Tours. Inc., 559 F.2d 841, 843 (D.C. Cir. 1977)* (quoting *Virginia Petroleum Jobbers Assoc. v. FPC, 259 F.2d 921, 925 (D.C. Cir. 1958))*. [**9] [*5] Each of those factors, as already set forth in Defendants' prior submissions in support of their pending motions, militates in favor of a stay. n3

n3 Without restating all of the arguments in support of Defendants' showing with respect to each factor set forth in Defendants' pleadings already submitted, Defendants herein focus primarily on the substantial and irreparable harm that demonstrates the urgency of the situation and, therefore, explains why the Court should issue an immediate stay pending disposition of Defendants' motions.

Without restating our arguments in full, Defendants are likely to succeed on the merits of their pending motions for two major reasons. First, this Court lacks authority to issue a preliminary injunction for service members not before this Court, since Plaintiffs have not sought class certification and no class has been certified. See, e.g., *Zepeda v. United States INS, 753 F.2d 719, 728 & n.1* (9th Cir, 1983) (in the absence of class certification, preliminary [**10] injunctive relief may cover only the named plaintiffs); *Easyriders Freedom F.I.G.H.T. v. Hannigan, 92 F.3d 1486, 1501 (9th Cir. 1996)* (injunctive relief should be limited to apply only to named plaintiffs in the absence of class certification); *Davis v. Romney, 490 F.2d 1360, 1366 (3d Cir. 1974)* ("Relief cannot be granted to a class before an order has been entered determining that class treatment is proper."). Second, since the Court issued its decision in this case, the Food and Drug Administration ("FDA") has issued a Final Order categorizing Anthrax Vaccine Adsorbed ("AVA") as safe and effective for the treatment of inhalation anthrax. See Final Rule/Final Order, Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, Food and Drug Administration, Health and Human Services, December 30, 2003 ("Final Order"). This Final Order removes the legal rationale underpinning the Court's earlier decision, i.e., that FDA had not definitively spoken to this issue. The arguments setting forth the reasons Defendants are likely to succeed on the merits of their claims are developed more fully in the [*6] papers and [**11] supporting documents Defendants have previously submitted in support of their pending motions. See, e.g., Memorandum in support Of Defendants' Emergency Motion, pp. 4-8; Memorandum in support of Defendants' Motion For Clarification, pp. 2-6.

Significant and irreparable harm will result if Defendants are not allowed to expeditiously resume the anthrax inoculation program. Anthrax is a deadly disease, the only known effective prevention against which is the anthrax vaccine known as Anthrax Vaccine Adsorbed. Declaration of William Winkenwerder, Jr., M.D., Assistant Secretary of Defense (Health Affairs) (Exhibit 2 to Defendants' Emergency Motion) ("Winkenwerder Declaration"), at P 4. Men and women of the United States armed forces face a continuing significant threat from the use of anthrax as a biological weapon by enemy forces. Id. at P 5. Those risks not only have been present in the conflict in Iraq but also are a constant presence in the more widely dispersed Global War on Terrorism. Id Chemical and biological weapons could be used in a regional conflict or a terrorist attack, particularly in southwest Asia and other areas outside the United States where our service members [**12] are deeply engaged against adversaries in the Global War on Terrorism. Id. The anthrax threat does not need a massive program or sophisticated delivery devices, and our adversaries possess the potential capability to attack with the deadly anthrax spores. Id. at P 6. Indeed, it was the threat of anthrax exposure to our service members engaged in military operations that led the Department of Defense ("DoD") to activate the Anthrax Vaccine Immunization Program. Id. n4

n4 The judgment of the military that service members should be vaccinated for their protection and for the accomplishment of their military missions is entitled to some measure of deference. *Goldman v. Weinberger, 475 U.S. 503, 507 (1986)* (courts "must give great deference to the professional judgment of military authorities concerning the relative importance of a particular military interest.")

[*7] The anthrax vaccination is mandatory for designated personnel at high risk "because the vulnerability of any individual [**13] to anthrax threatens the life of that individual, endangers others in his or her unit, and jeopardizes the success of the military mission." Id. at P 10. Approximately 30,0000 new troops begin the anthrax vaccination series each month, and more than 100,000 service members receive one in the series of anthrax vaccinations during the same period. Id. at P 9. Thus, on average, approximately 1,000 new service members begin the anthrax vaccination series each day, and more than 3,300 service members receive one in the series of anthrax vaccinations each day. In light of the continuing threat of anthrax attack from hostile forces or terrorist organizations, it is imperative that DoD's ability to vaccinate personnel at risk be restored as quickly as possible. Id. at P 8. Large scale troop movements are underway in connection with ongoing military operations in Iraq and elsewhere in the Global War on Terrorism. Id. at P 8.

Ceasing anthrax vaccinations threatens significant harm to the health and safety of service members and to military readiness. Id. at P 10. "If this interruption [in the vaccination program occasioned by the Court's injunction] were to continue, it [**14] would leave masses of military personnel without the best around-the-clock protection against the bioweapon that demonstrated its lethality in the fall of 2001 in our own country." Id. at P 7. Without a clarification that the Court's injunction applies only with respect to the six Doe Plaintiffs or without a stay of the injunction pending resolution of Defendants' motions, a significant number of service members would be deployed to hostile regions without adequate protection against the deadly anthrax [*8] disease. The longer the injunction remains in place, the fewer service members who are deployed to hostile regions will be protected against the deadly anthrax disease. These service members serve in positions that are the most distant on the globe from medical reinforcement in the event of a catastrophic release of anthrax spores. Id. Sending them to these military operations without the only known effective protection against anthrax is akin to sending them into combat without their flack jackets. "If service members who did not receive the vaccine were subjected to an anthrax attack, they would be much more likely to contract inhalation anthrax and become a casualty. [**15] " Id. at P 10. The substantial and irreparable harm to the lives and safety of our service members alone justifies entry of an immediate stay of the injunction with respect to all but the six Doe Plaintiffs.

But the injunction not only endangers the lives and safety of our service members, it comes at a great cost to the military missions of the United States. As Dr. Winkenwerder attests, "[i]f this preliminary injunction applies to the worldwide program, rather than only the six named plaintiffs in the case before this Court, it will inflict substantial and irreparable harm on combat readiness and military preparedness." Id. at P 7. Dr. Winkenwerder attests that, if troops are not given the vaccine prior to deployment as a consequence of "the current disruption in the [vaccine] program [it] will result in the need to provide many more shots to units widely dispersed in overseas field settings, increasing the burden on combat commanders who should instead focus on other operational and force protection issues." Id. at P 8. And the vulnerability of individual service members to anthrax "endangers others in his or her unit, and jeopardizes the success of the military [**16] mission." Id. at P 10. If a service member contracts anthrax while deployed in combat with his unit, it would require other unit members "to divert attention from [*9] the battle to render aid." Id. "[S]tricken service members would have to be sent quickly to a medical facility for treatment," where they "would require significant attention from medical personnel, attention that would be diverted from other wounded." Id. "Vaccinated troops could be harmed by the loss or absence of their unvaccinated colleagues," and [t]heir loss from the unit would degrade the unit's combat effectiveness." Id.

While the Court's injunction does not, by its terms, preclude inoculations if service members provide informed consent under the FDA's investigational new drug regulations or the President waives the consent requirement, neither of those options is viable here. Because the Food and Drug Administration has made clear that AVA is safe and effective against inhalation anthrax, requiring service members to consent to treatment or compelling the President to waive the consent requirement would improperly "sen[d] a conflicting message to service members about whether the [**17] vaccine has been determined to be safe and effective or whether it is investigational and experimental." Id. P 15. "Even if the President waived informed consent under *10 USC 1107*, because those consent requirements only apply to clinical investigations, AVIP [the Anthrax Vaccine Inoculation Program], by definition, would proceed as a clinical research trial, with requirements including notice that the vaccine is unapproved." Id. But the AVIP is not and never has

been a clinical research trial. Id. To qualify would require "the development of a detailed IND [Investigational New Drug] protocol, approval through necessary channels, approval by an Institutional Review Board, submission and discussions with the FDA, FDA's 30-day review period, training of principal and associate investigators, education of recipients of the IND, execution and storage of consent forms, and other steps required by [regulation], [all of which] is a several-month undertaking, even with a generous allotment of [*10] personnel to implement it." Id. at P 14. According to Dr. Winkenwerder, "[i]f the use of AVA for protection against inhalation exposure required [**18] compliance with Investigational New Drug requirements of the Federal Food, Drug, and Cosmetic Act, it would be extraordinarily difficult to continue the program in relation to current military operations against Iraq or the continuing Global War on Terrorism." Id. Even if it qualified, "[t]he additional labor required to diligently execute an FND protocol would be massive ... and divert scarce labor from other defense missions." Id. Dr. Winkenwerder attests that "[a]n order that DoD must comply with IND requirements in the AVIP could stop the program cold for a very substantial period of time." Id.

In the face of the complications associated with obtaining consent or a Presidential waiver under the circumstances concerning use of AVA for inhalation anthrax, Plaintiffs have introduced no evidence, and the Court has made no finding, that the six Doe Plaintiffs adequately represent the interests of all service members. For all of the reasons just set forth, the effect of the Court's injunction, read literally, would be to preclude even those service members who want to get the vaccine from getting it, thus subjecting them to risk of contracting a fatal disease when they [**19] would rather get the vaccine. This is the precise type of fundamental unfairness that is to be avoided by the rule against granting injunctions that affect an entire class without having satisfied the requirements of class certification. n5 The interests of absent service members is thus yet an additional compelling reason to grant Defendants' motion for an immediate stay pending disposition of Defendants' motion absent clarification that the injunction applies only to the six Doe Plaintiffs.

n5 *Zepeda, 753 F.2d at 728-30* ("A person who desires to be a 'self-chosen representative' and 'volunteer champion'... must qualify under [*Fed. R. Civ. P] 23*.")

[*11] The greater the number of service members who are deployed to hostile regions without the vaccine, the greater is the danger to their own protection and to the military missions to which they have been tasked. Given the magnitude of irreparable harm that would result, the lack of any harm to Plaintiffs, and the likelihood of Defendants' [**20] success on the merits of the arguments set forth in their pending motions, an immediate and limited administrative stay as to all but the six Doe Plaintiffs until the motions are disposed of is warranted.

For all of the reasons set forth above, Defendants ask that the Court grant this emergency motion and issue an immediate administrative stay of its injunction with respect to all but the six Doe Plaintiffs pending disposition of Defendants' motions. Such an administrative stay would have no effect whatsoever on the rights of the Plaintiffs, because the injunction can remain in effect as to them at least until this Court's January 14 hearing. As noted above, Defendants respectfully urge the Court to decide this motion on or before January 7, 2004 so that Defendants may seek an immediate administrative stay or other relief in the D.C. Circuit on January 8, 2004 if necessary.

[*12] Respectfully submitted,

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[EDITOR'S NOTE: See JOHN DOE # 1, et al., Plaintiffs, v. DONALD H. RUMSFELD, SECRETARY OF DEFENSE, et al., Defendants., 1:03-cv-00707-EGS, IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA]