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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 707; 2004 U.S. Dist. Ct. Motions LEXIS 6629

January 5, 2004

Motion to Stay

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TITLE: [**1] **DEFENDANTS' REPLY IN SUPPORT OF EMERGENCY MOTION FOR IMMEDIATE ADMINISTRATIVE STAY PENDING DISPOSITION OF DEFENDANTS' MOTIONS**

TEXT: In response to this Court's January 5, 2004 Minute Order, Defendants file this reply in support of their Emergency Motion For Immediate Administrative Stay Pending Disposition Of Defendants' Motions ("Emergency Motion For Administrative Stay"). Defendants do so well in advance of this Court's January 6, 2004 4:00 p.m. deadline for filing a reply, and note that they would be available at any time prior to this Court's January 7, 2004 scheduled hearing if this Court could dispose of Defendants' Emergency Motion For Administrative Stay prior to the time set in the Minute Order.

Plaintiffs' Opposition To Emergency Motion For Administrative Stay ("Opposition") is bereft of any evidence -- or, indeed, any argument -- that Plaintiffs would be harmed by the limited stay sought by Defendants. It would, in fact, be impossible for Plaintiffs to put forth such an argument because the interim stay sought here would not affect in any way the relief granted to these six Doe Plaintiffs in this Court's December 22, 2003 Preliminary Injunction Order.

[*2] [**2] Instead, the administrative stay sought by Defendants would simply limit the effect of that preliminary injunction to those Doe Plaintiffs during the time that the Court considers the pending motions.

Plaintiffs' only grounds for opposing the stay are two-fold. First, they argue that the preliminary injunction should be read broadly to reach service members not before the Court because Plaintiffs will, at some uncertain point in the future, be seeking class certification. Second, they contend that the substantial injury suffered by the military as a result of the preliminary injunction is both of its own making and easily corrected. But neither argument is a reason for denying the relief sought by Defendants in their Emergency Motion For Administrative Stay.

First, because Plaintiffs' original complaint did not properly make class allegations or seek class certification, preliminary injunctive relief issued on a nationwide and military-wide basis is far too broad to remedy the injuries

purportedly suffered by the Plaintiffs here. Plaintiffs, apparently recognizing this flaw, now contend that they are "preparing a First Amended Complaint specifically asserting class allegations" which [**3] they intend to file, n1 and that if necessary they will "seek class certification." Opposition at 2. But such a process of establishing entitlement to class certification requires a "specific presentation" by the Plaintiffs that the various requirements of Rule 23 have been satisfied, and the Court, in turn, must undertake a "rigorous analysis" of this presentation, because "actual, not presumed, conformance" with Rule 23 is "indispensable." *General Telephone Co. of Southwest v. Falcon, 457 U.S. 147, 158, 160-61* [*3] *(1982)*. There is no reason to conclude at this stage that Plaintiffs would be successful in making this "specific presentation" with respect to all the requirements or that the Court, upon "rigorous analysis," would certify a class. There is no reason to believe, for instance, that these six Doe Plaintiffs speak for all of their military colleagues when they argue that they would not receive the anthrax vaccine in the absence of informed consent. Given their potential exposure to deadly biological weapons, many members of the military overseas may well be eager to receive the full compliment of shots as soon as possible. Thus, serious questions of [**4] commonality and adequacy of representation would be raised by any attempt to certify a class. n2 See *Falcon 457 U.S. at 156, 161* (noting the Supreme Court's repeated holding "that a class representative must be part of the class and possess the same interest and suffer the same injury as the class [*4] members," and further noting as "most significant" the "potential unfairness to the class members bound by the judgment if the framing of the class is overbroad").

n1 Mere conclusory averments or parroting of the elements of Rule 23 are insufficient to obtain class certification. See, e.g., *In re American Medical Systems, 75 F.3d 1069, 1083, 1086 (6th Cir. 1996)*.

n2 Plaintiffs' vague citation to *National Mining Ass'n v. Army Corps of Engineers, 145 F.3d 1399 (D.C. Cir. 1998),* for the proposition that the current preliminary injunction is not overbroad is unhelpful to them here. That case did not involve a *preliminary* injunction; rather, it spoke to the proper scope of permanent injunctive relief where a court had ruled on the substantive issues in the case and had finally adjudged an agency rule to be invalid. The Court here has not, of course, adjudged an applicable agency rule to be invalid and has only found preliminarily that the Plaintiffs have a fair chance of prevailing on the merits of their claims. The scope of preliminary and permanent injunctive relief is different, and with respect to preliminary relief should be narrowly tailored to remedy the harm demonstrated by parties before the court. See, e.g., *Bresgal v. Brock, 843 F.2d 1163, 1169-71 (9th Cir. 1987)* (distinguishing scope of preliminary and permanent injunctive relief, noting that "where relief can be structured on an individual basis it must be narrowly tailored to remedy the specific harm shown" and that an injunction should not extend beyond giving the "prevailing parties the relief to which they are entitled."). Importantly, National Mining involved a rule of general applicability, and the only way to accord plaintiffs the relief they requested there was to invalidate the rule in its entirety. Here, by contrast, a more narrowly tailored injunction could accord Plaintiffs the relief they seek without unduly affecting others or doing unnecessary harm to Defendants. Where there are significant questions regarding the continuing viability of this Court's preliminary injunction ruling in light of a subsequent FDA Final Order, moreover, a more modest preliminary injunction, directed only at the six Doe Plaintiffs, is sufficient to afford them all the relief they require while the Court considers and disposes of pending motions.

[**5]

Second, Plaintiffs' suggestion that the substantial harm suffered by the military as a result of this Court's preliminary injunction Order is self-inflicted ignores both the nature of the preliminary injunction and the regulatory scheme to which it relates. As long as the preliminary injunction is in effect and is read broadly, as Plaintiffs suggest, then the military had no choice but to shut down the anthrax vaccination program. This result follows from the detailed regulatory scheme that arises from "informed consent" requirements. As Assistant Secretary of Defense William Winkenwerder Jr., M.D. explains in his Declaration (Exhibit 2 to Defendants' Emergency Motion To Vacate And In The Alternative For Stay), obtaining informed consent would mandate compliance with Investigational New Drug ("IND") requirements of the Federal Food, Drug, and Cosmetic Act. Winkenwerder Declaration at P 14. Dr. Winkenwerder attests that "the development of a detailed IND 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 [**6] of the IND, execution and storage of consent forms, and other steps required by 21 CFR Part 312, is a several-month undertaking, even with a generous allotment of personnel to implement it." Id. He adds, furthermore, that "the additional labor required to diligently execute an IND protocol would be massive . . . and divert scarce labor from other defense missions." Id.

Thus, even if the Department of Defense wanted to comply with this Court's preliminary injunction Order through the informed consent route, it could not do so in the immediate future, and certainly not before this Court's January 14, 2004 hearing. Nor could a Presidential Waiver [*5] be obtained under the governing Executive Order in such a short period of time. Id. at PP 14-15. n3 To be clear, in either circumstance, an average of 1,000 soldiers per day would go without any form of protection from anthrax exposure during the interim period, at a cost both to the individuals and to the military's missions. Id. P 11. Given the impossibility of immediate compliance, this is a direct result of the Preliminary Injunction Order. n4

n3 As we have explained in previously filed papers, given the December 30, 2003 FDA Final Order making clear that AVA is safe and effective for exposure to anthrax by inhalation, neither the Presidential Waiver nor the "informed consent" option is required by *10 U.S.C. § 1107*.

[**7]

n4 Any claims that the government should have anticipated this Court's preliminary injunction ruling by devoting numerous scarce resources to developing these protocols or taking the steps necessary to obtain a waiver in advance is absurd. The government has respectfully and in good faith maintained throughout the course of this litigation that Anthrax Vaccine Adsorbed ("AVA") is and has been fully approved for use as a vaccine against inhalation anthrax and need not have acted to the contrary prior to this Court's ruling.

Finally, Plaintiffs' own characterization of the nature of the injunction at issue in this case -- as "requiring the defendants to abide by the law, *at least as the law existed up to December 22, 2003*", Opposition at 2 (emphasis added) -- underscores the reason for granting Defendants' request for administrative stay here. By their own admission, the law and facts underpinning this Court's forward-looking preliminary injunction Order have changed. As a result, the legal basis for that relief no longer exists. While Defendants respect this Court's desire for more time to [**8] resolve that underlying question, their urgent need to restart their vaccination program as to persons not before this Court -- unanswered by the Plaintiffs and certainly not offset by countervailing harm to the Plaintiffs as a result of the limited nature of the request -- dictates the grant of the administrative stay sought by Defendants' Emergency Motion For Administrative Stay.

[*6] Respectfully submitted,

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