UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JOHN DOE #1 et al.,	*	
	*	
Plaintiffs,	*	
	*	Civil Action No.: 1:03CV00707 (EGS)
v.	*	
	*	
DONALD H. RUMSFELD et al.,	*	
	*	
Defendants.	*	

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PLAINTIFF'S MEMORANUM OF LAW IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND PERMANENT INJUNCTIVE RELIEF OR, IN THE ALTERNATIVE, FOR DISCOVERY

PRELIMINARY STATEMENT

Six plaintiffs, known to the public as John and Jane Does #1 through #6 for fear of retaliation by their commanding officers or civilian superiors (but known to this Court and, if necessary, willing to be revealed to the defendants), brought this action to challenge the unlawfulness of the government's Anthrax Vaccination Immunization Program ("AVIP").

Over the past five years nearly one million members of the military or federal civilian/contractor workforce have been inoculated illegally under the guise of the AVIP for the alleged purpose of obtaining protection from inhalation anthrax. Although it is the defendant Department of Defense ("DoD" or "Defense Department") that has (and is) engaging in the improper and unlawful use of the anthrax vaccine, the defendant Food & Drug Administration ("FDA") bears legal responsibility for the status of the vaccine and the extent to which DoD seeks to exploit that status.

This Motion for Summary Judgment does not call into question the DoD's decision to use the anthrax vaccine. It does not challenge any military decision or, for that matter, any level of expertise appropriately possessed or exercised by the Defense Department. The focus of this Motion is directly on an action by the FDA that determined that anthrax vaccine adsorbed

("AVA") is licensed for the purposes of combating inhalation anthrax (also known as aerosolized or weaponized anthrax).

On December 22, 2003, this Court issued a Preliminary Injunction based on a finding that "because the record is devoid of an FDA decision on the investigational status of AVA … [it] is persuaded that AVA is an investigational drug and a drug being used for an unapproved purpose. As a result of this status, the DoD is in violation of 10 U.S.C. § 1107, Executive Order 13139, and DoD Directive 6200.2." See Memorandum Opinion (dated December 23, 2003) at 32.

As a direct response to this Court's decision, on December 30, 2003, the FDA revived (and significantly modified) the proposed findings of one of its own expert panels that had disbanded nearly 20 years earlier and issued a Final Rule and Order to contradict the Court's findings. See Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review, 69 Fed. Reg. 255, 265-66 (Jan. 5, 2004)("Final Rule"). The timing of the release of this Rule, just one week after the Court issued its opinion, is hardly a coincidence. Confirming that its actions were driven more by legal strategy than by sound regulatory practice, the FDA's press release concerning the Final Rule specifically states that this Court should take note of FDA's action.[1] With this change in landscape, the Court reasonably choose to lift the Preliminary Injunction (except as it applied to the six plaintiffs), and proceed forward in the litigation.

[1] The press release concluded by noting a "recent ruling by a United States District Court for the District of Columbia gave the opinion that the anthrax vaccine should be classified as 'investigational' with regard to protecting against inhalation anthrax. Today's final rule and order make it clear that FDA does not regard the approved anthrax vaccine as 'investigational' for protection against inhalation anthrax. *FDA's final determination* of the safety and effectiveness of the anthrax vaccine, independent of route of exposure, as well as its conclusions regarding the Expert Panel's report, being announced today in the final order, *are relevant and should be considered in any further litigation in this matter*." See *http://www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html* (emphasis added). The extraordinariness of the FDA actually commenting on ongoing litigation with the issuance of regulatory action cannot be understated.

As a result of the FDA's hurried action[2], and since the Court's lifting of the Preliminary Injunction, the DoD, according to its own statements, has involuntarily inoculated approximately 60,000 individuals. However, the process and basis for the issuance of the FDA's Final Rule – the only existing legal support for the continuation of the AVIP – is invalid as a matter of fact and law. Thus, upwards of 60,000 additional individuals have been irreparably victimized and possibly harmed.

Based on the evidence and arguments expressed herein, this Court should vacate the FDA's recent Final Rule and Order and remand the matter to the FDA for proper consideration and determination, as is required by law, of the licensing status of AVA. Even a cursory review of the FDA's administrative record confirms that the Final Rule is simply a procedural sop thrown to the Court in an effort to lift the injunction. The Rule is fatally flawed in terms of both its procedural status (particularly with the FDA baldly considering additional evidence more than 17 years after it closed public comment on the proposed rule) and its factual basis. In granting this motion, the Court will show that the federal judiciary is not at the mercy of federal agencies and can refuse to simply rubber stamp or accept Executive Branch assertions.

At the same time, the Court should reinstate the injunctive relief, although this time on a permanent basis, that was granted in its initial ruling of December 22, 2003. In the absence of the FDA's Final Rule and Order, the Court's conclusion that the vaccine is improperly licensed for inhalation anthrax remains in effect.[3]

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[2] As but just one example of the haste exercised by FDA to publish its Final Rule, the version originally posted on its Website contained numerous handwritten notations where the drafters had neglected to include even some of the most basic words. See Exhibit "1".

[3] Alternatively, given the numerous factual inconsistencies in the record, summary judgment should not be granted to the Defendants. Instead, plaintiffs should be permitted to conduct discovery in order to ensure the administrative record is complete and explore the extent to which the DoD improperly influenced the FDA's licensing and rule-making process.

ARGUMENT

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is appropriate only if "'there is no genuine issue as to any material fact and ... the moving party is entitled to a judgment as a matter of law.'" Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247 (1986) (quoting Fed.R.Civ.P. 56(c)). In determining whether a "genuine issue" exists, courts "must view the evidence in the light most favorable to [the plaintiff] and draw all reasonable inferences in [its] favor." Waterhouse v. District of Columbia, 298 F.3d 989, 991 (D.C. Cir. 2002).

I. THE FDA'S FINAL RULE AND ORDER MUST BE INVALIDATED AND REMANDED TO THE AGENCY FOR FURTHER RULEMAKING

The Administrative Procedure Act "(APA") requires that an agency provide notice of a proposed rulemaking, and that notice must include "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b). Once a proposed rule is issued, it is black letter law that the agency must "give interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments." 5 U.S.C. § 553(c).

In its haste to publish something to save the DoD's ill-advised anthrax vaccine program, the FDA, in at least two significant ways, violated the procedures of notice and comment rulemaking, denying affected parties the opportunity to participate in the process in a meaningful way, much less in any way.

First, the Final Rule relies on studies and data that did not exist either at the time of the proposed rule or at the close of the comment period, thereby denying its own expert panel the opportunity to evaluate the information. More importantly, the hurried process stripped the affected parties of their right to present views on the data used by the FDA. Second, the FDA's Final Rule differs

in substance from the proposed rule, which had been issued nineteen years earlier. Either of these shortcomings is sufficient to require the Court to invalidate and remand the Final Rule to the FDA in order to complete the proper administrative process.

A. The Final Rule Is Procedurally Flawed Because The FDA Relied On Data That Came Into Existence After The Close Of The Comment Period, Which Improperly Denied Affected Parties An Opportunity To Respond

The role of timely public comments for executive rulemaking is so critical that it is embodied in a statute. 5 U.S.C. § 553 (c). As previously noted federal agencies are required to provide a period of public comment following the announcement of a proposed rule to allow interested citizens and others the opportunity to voice their concerns. Indeed, the original notice of proposed rulemaking for AVA contained a public comment period that ran from December 13, 1985, until March 13, 1986. Notwithstanding the proper notice and comment period, for reasons unknown, the FDA chose not to contemporaneously finalize the Proposed Final Rule concerning the AVA.

Nineteen years later, in promulgating its new Final Rule the, FDA deliberately violated the purposes of its own notice and comment timeframe by relying on studies and data that were not in existence at the conclusion of the comment period. It should come as no surprise that the D.C. Circuit has stated that "[i]n order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." Conn. Light & Power Co. v. Nuclear Regulatory Comm'n, 673 F.2d 525, 530 (D.C. Cir. 1982). "An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." Id. at 530-31. It is clear that when an agency relies on studies or data after the comment period has ended, no meaningful commentary on such data is possible. See American Iron & Steel Inst. v. OSHA, 939 F.2d 975, 1009-10 (D.C. Cir. 1991);

Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 540-41 (D.C. Cir. 1983); Sierra Club v. Costle, 657 F.2d 298, 398 (D.C. Cir. 1981).

In American Iron & Steel, OSHA relied on a professional industry analysis that was completed after the comment period had ended in evaluating the economic feasibility of certain workplace exposure levels. The D.C. Circuit held that "reliance on the [post-comment period data] without providing an opportunity for comment was improper," and the Court vacated the portion of the regulation that relied on the late data. 939 F.2d at 1010.

Here, the FDA relied on at least four extensive studies that commenced and concluded after the comment period ended in issuing the final rule. See 69 Fed. Reg. at 265-66. For example, the FDA cites to, and significantly relies on, a report on the anthrax vaccine issued by the Institute of Medicine ("IOM") in 2002—more than *sixteen years* after the comment period ended. Id. at 259-60.[4] Obviously, it would have been impossible for an interested party seeking to comment on the proposed Final Rule in late 1985 or early 1986, to have responded to studies and data that would not come into existence until over a decade later. Thus, like the plaintiffs in American Iron & Steel, neither the plaintiffs in this case or anyone who otherwise might have been interested parties were provided any notice that the FDA intended to rely on this data. Nor were they provided an opportunity to respond to the data. This flaw is so fundamental as to require the invalidation of the FDA's Final Rule.

In fact, the amount of information that post-dates the original notice and comment period (even beyond the four substantive studies) is voluminous. The FDA Administrative Record, as noted in the Administrative Record Index produced by the government as part of this litigation, lists 4,209 pages that were relied upon or at least considered by the FDA in issuing its Final

[4] The IOM Report evaluated "all available data, both published and unpublished" on the anthrax vaccine, specifically focusing on three studies from 1996, 1998 and 2001. See 69 Fed. Reg. at 260 & n.5.

Rule.[5] Of the 4,209 pages in the open record, approximately 2,653 (63%) post-dated 1986. In fact, the majority of these pages were created between 1996-2002. Of the remaining 1,556 pages, the vast majority pertain to the original licensing of the vaccine and were created between 1966-1971. Of course, evidence, much less a discussion, of whether the vaccine is effective against inhalation anthrax cannot be found within any of these pages.[6]

Nevertheless, the plaintiffs are mindful of the desire "to avoid perpetual cycles of new notice and comment periods," and concede that "a final rule that is a logical outgrowth of the proposal does not require an additional round of notice and comment." Bldg. Indus. Ass'n of Superior Cal. v. Norton, 247 F.3d 1241, 1246 (D.C. Cir. 2001)(internal quotation omitted). However, as explained below, the FDA's Final Rule is not, and cannot even be reasonably considered as, a "logical outgrowth" of the 1985 Proposed Final Rule.

In Building Industry Assoc., the Fish and Wildlife Service relied on a study that was released after the proposed rule to classify certain species as endangered. The D.C. Circuit upheld the final rule because the belated study only "confirmed the findings delineated in the proposal." Id. Here, however, the subsequent studies relied on by the FDA are not only an *illogical* outgrowth the Proposed Final Rule but *explicitly* contradict the very findings of the Proposed Rule that are directly relevant to this dispute.

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[5] There are also several thousand pages withheld by the FDA under the deliberative process privilege and by BioPort due to assertion of the trade secrets privilege. These documents were primarily created during the past 5 years.

[6] In addition to the licensing related documents, there is the Brachman study, various Federal Register pages, a published legal decision from 1996, and some procedural documents pertaining to the 1985 Proposed Final Rule. The only references to inhalation anthrax within these pages are that insufficient evidence exists to conclude the vaccine is effective. There is certainly no information contained therein that reasonably supports the FDA's new conclusions. Thus, not only did the FDA procedurally violate the APA, but its conclusions were also arbitrary and capricious, as further set forth below, as the relied upon documents do not provide the necessary

In the 1985 Proposal Final Rule, the FDA supposedly relied on a 1962 field study (the "Brachman Study") which indisputably concluded "inhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease." Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review; Proposed Rule, 50 Fed. Reg. 51002, 51058 (Dec. 13, 1985)("Proposed Final Rule"). Thus, the FDA's Expert Panel concluded that "no meaningful assessment of [the vaccine]'s value against inhalation anthrax is possible." Id. at 51059. Almost twenty years later, relying wholly on studies completed after the comment period had closed, the FDA now asserts that it "does not agree with the Panel report," and believes that the vaccine is effective against all forms of anthrax exposure. 69 Fed. Reg. at 259-60.

This statement, so key to the current litigation, constitutes a complete reversal of position. Yet, unlike the studies relied upon in Building Industry Assoc., the studies relied upon by FDA do not "provide support for the same decision it had proposed to take." 247 F.3d at 1246. In fact, the studies referenced in the Final Rule, all of which were undertaken in the last ten years, are substantively different than all the data known at the time of the 1985 Proposed Final Rule. There is no confusing the fact that these new studies are not simply "'supplementary' data, unavailable during the notice and comment period, that 'expand on and confirm' information contained in the proposed rulemaking." Solite Corp. v. EPA, 952 F.2d 473, 484 (D.C. Cir. 1991).

Therefore, in issuing its December 30, 2003, Final Rule, the FDA violated the procedural requirements of the APA by relying on studies and data not in existence at the close of the comment period, and by issuing a final rule substantially different from the proposed rule. For those reasons alone this Court should vacate the Final Rule and remand the matter to the FDA for further notice and comment rulemaking.

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support for its actions. See Lloyd Noland Hospital & Clinic v. Heckler, 762 F.2d 1561 (11th Cir. 1985).

B. The Final Rule Substantially Deviates From The Proposed Rule, Denying Affected Parties An Opportunity To Respond

While "a final rule need not be identical to the original proposed rule," when the final rule "deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal." AFL-CIO v. Donovan, 757 F.2d 330, 338 (D.C. Cir. 1985)(internal quotation omitted). The test is whether the final rule is a "logical outgrowth" of the proposed rule. If "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule," then the final rule is not a "logical outgrowth," and has not adequately served the purposes of notice and comment rulemaking. American Water Works Assoc. v. EPA, 40 F.3d 1266, 1274 (D.C. Cir. 1994). See also Nat'l Mining Assoc. v. Mine Safety & Health Admin., 116 F.3d 520, 531 (D.C. Cir. 1997); Nat'l Resources Def. Council v. EPA, 824 F.2d 1258, 1284 (1st Cir. 1987).

In Shell Oil Co. v. EPA, 950 F.2d 741 (D.C. Cir. 1991), the D.C. Circuit reviewed a final rule promulgated by the Environmental Protection Agency ("EPA") that dealt with hazardous waste. The plaintiffs asserted that the EPA's final rule contained a definition of "hazardous waste" that was much broader than the definition contained in the proposed rule and, as a result, they claimed not to have had notice of the definition that was finally adopted. Id. at 748. The EPA argued that it intended to include the broader aspects of the definition, and that interested parties should have anticipated the substance of the final rule. Id. at 749-50. The D.C. Circuit disagreed with EPA and ruled that "unexpressed intention cannot convert a final rule into a 'logical outgrowth' that the public should have anticipated. Interested parties cannot be expected to divine the EPA's unspoken thoughts." Id. at 751. "Because the EPA has not provided adequate notice and opportunity for comment," the D.C. Circuit opined, the final rule "must be set aside and remanded to the EPA." Id. at 752.

In the case of AVA, the FDA issued a notice of proposed rulemaking nearly 20 years ago in which it proposed that the anthrax vaccine be classified as safe and effective for use in "the limited circumstances for which this vaccine is employed." 50 Fed. Reg. at 51059. At the time, the vaccine was employed for use by "certain occupational groups," mainly "individuals in industrial settings" who worked with various animal furs, hides and hairs. Id. at 51058.[7] The vaccine's use was intended to be for "protection against cutaneous anthrax in fully immunized subjects." Id. at 51059. Thus, the 1985 Proposed Final Rule set out a very limited proposed use for the anthrax vaccine: to protect a small set of textile workers against *cutaneous* exposure to anthrax.

By contrast, the 2004 Final Rule issued by the FDA contemplates an obviously broader use of the vaccine that potentially affects millions of people. The Final Rule states that "the vaccine is indicated for active immunization against [anthrax], independent of the route of exposure," and that the vaccine will "protect humans against…*inhalation* anthrax." 69 Fed. Reg. at 260 (emphasis added).

Thus, rather than simply protect limited occupational groups from exposure to cutaneous anthrax, the FDA now believes that the vaccine protects all humans from exposure to either cutaneous or inhalation anthrax.[8] This is a substantial change from the Proposed Rule. It is certainly not a "logical outgrowth" to assert that because the vaccine is known to protect against

[7] And, as the FDA's Expert Panel noted, even this number of affected individuals was declining as the impacted industries underwent continuing transformation from human to machine labor. 50 Fed. Reg. at 51058.

[8] Apparently in an effort to be all inclusive, the FDA now notes that the vaccine is also effective against "all cases of anthrax disease regardless of the route of exposure", which necessarily includes gastrointestinal anthrax. 69 Fed. Reg. at 260. There is absolutely no evidence in any record (not even one page), including the Brachman study, studies undertaken by the CDC, or any Defense Department study, that AVA has ever been tested against gastrointestinal anthrax or would prove effective against this method of exposure. The sweeping nature of the FDA's pronouncement underscores its basic unreliability.

one method of exposure – again, for a limited population working exclusively in certain industrial settings - it will protect individuals in a wide-ranging population from another method of exposure as a result of a biological attack. In fact, such a conclusion is absurd given that the 1985 Experts Panel specifically stated that the vaccine's "efficacy against inhalation anthrax is not well documented;" thus, "[n]o meaningful assessment of [the vaccine]'s value against inhalation anthrax is possible." 50 Fed. Reg. at 51058-59.

There is no way around the fact that the 2004 Final Rule is the first time the FDA publicly proposed approving the anthrax vaccine for protection against inhalation anthrax. Therefore, there was no way that interested parties could have possibly commented on an FDA response to the Panel's report that would include approval of the vaccine for use against inhalation anthrax. As the D.C. Circuit has continually noted, a final rule is invalid if a "new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade the agency to modify its rule." American Water Works Assoc., 40 F.3d at 1274. See also Fertilizer Institute v. EPA, 935 F.2d 1303, 1311 (D.C. Cir. 1991); United Steelworkers of Am. v. Marshall, 647 F.2d 1189, 1225 (D.C. Cir. 1980).

In American Water Works, the Court of Appeals reviewed the EPA's adoption of a definition of the word "control" in its final rule; a change that was seen not have been contemplated at the time of the proposed rule. Therefore, the Circuit Court vacated the rule because "interested parties could not reasonably have anticipated the final rulemaking from the draft rule." 40 F.3d at 1275 (internal quotation and alteration omitted). Similarly, interested parties in 1985 could not have anticipated that – nineteen years later – the FDA would interpret the limited use recommendations from its expert panel as describing an anthrax vaccine believed to be safe and effective when used by millions of people as protection against inhalation anthrax as a result of exposure through a biological attack. Airborne exposure to anthrax was not an

indication under the licensing contemplated by the 1985 Proposed Final Rule; thus, a new notice and comment period would be the first opportunity that an interested party would be able to address the vaccine's efficacy against such exposure.

The 2004 Final Rule is far from a logical outgrowth of the 1985 Proposed Final Rule. It is instead "the result of a complex mix of controversial and uncommented upon data and calculations," and should be remanded for a new round of notice and comment. Weyerhaeuser Co. v. Costle, 590 F.2d 1011, 1031 (D.C. Cir. 1978).

C. The FDA's Issuance Of The Final Rule Was Arbitrary And Capricious, An Abuse Of Discretion, Unsupported By Substantial Evidence And Unwarranted By The Facts And, Therefore, Must Be Invalidated

Even if this Court finds that FDA's bizarre procedure to issue the Final Rule was legally sound, the substance of the rule is arbitrary and capricious and should be invalidated. See Spirit of the Sage Council v. Norton, 294 F. Supp. 2d 67, 90 (D.D.C. 2003).

1. The FDA Relied Upon Animal Efficacy Studies That Have No Correlation To Humans Thereby Invalidating The Final Rule

The Final Rule relies on the IOM report, which is based principally on animal studies which are, as a matter of uncontroverted law, inadmissible under FDA's own regulations and applicable statutes. For an FDA final rule to be valid, it must be based on some factual or clinically proper analysis. Indeed, the FDA is required to license drugs according to a "substantial evidence" standard of safety and efficacy. See Weinberger v. Hynson 412 U.S. 609 (1973).

In the Final Rule at issue, it is undisputed that the sources FDA substantially relies on for its determination that the AVA is effective against inhalation anthrax are animal efficacy studies. See 69 Fed. Reg. at 266 (listing three animal studies). These studies are nothing more than tests of the vaccine's effectiveness for protecting various types of animals, such as guinea pigs, rabbits and monkeys, from inhalation exposure to anthrax. Not one of them, however, contains a shred

of evidence that a correlation exists between the studies' results and the impact on humans. The importance of this fact cannot be underscored – none of the animal studies, no matter how favorable the results may be, can be extrapolated to apply to humans, i.e., simply because the vaccine *may* appear to protect a monkey against inhalation exposure to anthrax does not mean it will do the same for a human.[9]

For example, in the 1998 Vaccine article, cited by the FDA as source reference 5, the authors discuss the differences they noted in how effective the vaccine appeared to be depending upon the animal that was exposed to the spores. As non-human primates (in this case rhesus macaques) survived in greater numbers than guinea pigs or mice, it was no surprise that the authors (all of whom are employed by the defendant DoD) rely heavily on these test results. Although the authors appeared to comprehend why the animals reacted differently, the same assurance did not exist for humans. "It is unknown what immune mechanisms in humans are important in specific resistance to anthrax," they wrote. See B.E. Ivins et al., "Comparative efficacy of experimental anthrax vaccine candidates against inhalation anthrax in rhesus macaques", *Vaccine*, 16 (11-12): 1141, 1146 (1998)(Bates #000635 in the Administrative Record Index). Moreover, the authors' failed "efforts to find a single surrogate marker or correlate of immunity indicate that specific immunity to anthrax in primates may be complex and involve multiple mechanisms of immunity." Id. See also Department of Defense Chemical and Biological Defense Program, Vol. II, April, 2002, p. 100, at *http://www/acq/osd.mil/cp/nbc02/vol2-2002cbdpperformanceplan.pdf* ("Preliminary efficacy experiments in a rabbit model have already demonstrated that protection is afforded by rPA produced from either B. anthracis or E.

[9] In fact, the success of these non-human primate tests has been called into question. See "Anthrax Shots' Effect Challenged; Army Disputes Expert Who Reviewed Vaccine Tests", Washington Post, July 18, 2000 (noting review of Ft. Detrick anthrax text notebooks revealed immunized monkeys exposed to anthrax remained ill for up to two weeks).

coli. To date, an in vitro correlate in humans to vaccine-induced immunity against anthrax does not exist.")

Beyond the fact that absolutely no evidence exists correlating animal efficacy studies with human efficacy, until May 31, 2002, it was improper – indeed, unlawful - for a drug manufacturer to rely on animal testing as a means of validating the requirement that a drug or vaccine be shown to be effective for human beings. However, the FDA promulgated a new Final Rule ("Animal Efficacy Rule") allowing animal testing data to be used to validate the effectiveness of certain kinds of drugs or vaccines. Specifically, animal testing was allowed to provide substantial evidence of effectiveness for drugs or vaccines needed in biological radiological or chemical warfare situations, where human testing could not ethically be conducted. See Final Rule, New Drugs and Biological Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies are Not Ethical or Feasible, 21 CFR Parts 314 and 601, Docket No. 98N-0237 (May 31, 2002), codified at 67 Fed. Reg. 37988-37998.

The Animal Efficacy Rule provided for animal efficacy testing as a stand-in for human efficacy testing if four conditions were met:

- There is a reasonably well understood pathophysiological mechanism for the toxicity of the chemical, biological, radiological, or nuclear substance and its amelioration or prevention by the product;

- The effect is demonstrated in more than one animal species expected to react with a response predicted for humans, unless the effect is demonstrated in a single animal species that represents a sufficiently well characterized animal model (meaning that the model has been adequately evaluated for its responsiveness) for protecting the response in humans;

- The animal study and point is clearly related to the desired benefit in humans, which is generally the enhancement of survival or prevention of major morbidity; and

- The data or information on the pharmacokinetics and pharmacodynamics of the product or other relevant data or information in animals and humans is sufficiently well understood to allow selection of effective dose in humans and that it is therefore

> reasonable to expect the effectiveness of the product in animals to be a reliable indicator of its effectiveness in humans.

Id.

It is undisputed that the AVA, despite years of investigational testing, does not meet the criteria for the so-called animal efficacy rule listed above. Accordingly, it is entirely improper to allow reliance on animal efficacy testing data in order to validate an FDA final rule on the efficacy of the AVA. Yet for no apparent or justifiable reason, the FDA has bowed to pressure exerted by the DoD in order to preserve the AVIP and abandoned its long-standing prohibition on utilizing animal efficacy tests in the place of human testing. From the DoD's standpoint, the need to do so was imperative as it was the only way to validate the claim that the AVA is effective against inhalation anthrax exposure.

Because the entire substantive basis of the Final Rule relies on animal studies and data regarding the efficacy of the vaccine that have absolutely no correlation to human efficacy, the Court should invalidate the Rule and remand the matter to the FDA for proceedings consistent with the law (as well as the proper public comment).

2. The FDA's Final Rule Fails To Take Into Account Significant Changes In The Manufacturing Process Of The Vaccine And, Therefore, Must Be Invalidated

One of the more curious discussions in the FDA's Final Rule concerns the finding by the 1985 Expert Panel that the vaccine originally tested in the Brachman study was manufactured by Merck Sharp & Dohme. See 69 Fed. Reg. at 260. The FDA, in the 2004 Final Rule, objected to its panel findings and clarified that the original vaccine tested by Dr. Brachman was actually provided by the United States Army and its bioweapons facility at Fort Detrick, Maryland. Id. The FDA then went on to note that the vaccine went through two additional manufacturers, Merck and the Michigan Department of Public Health, as well as undergoing formulation and manufacturing changes, before reaching its current form. Id.

Typically, these types of changes in manufacturer and formulation require a new license application and testing. See FDA Guidance Concerning Demonstration of Comparability of Human Biological Products, Including Therapeutic Biotechnology-derived Products, Center for Biologics Evaluation and Research (CBER), Center for Drug Evaluation and Research (CDER), April 1996, found at http://www.fda.gov/cber/gdlns/comptest.txt; First Amended Complaint (filed January 6, 2004), Exhibit D, Response to Citizen Petition, Docket No.01P-0471/CPI, Aug. 28, 2002, at 7-8. This was not done in the case of AVA, and the FDA, well aware of these shortcomings in the licensing process, attempts to deal with this problem in the Final Rule by bestowing the mantle of "manufacturer" on the Defense Department.[10] This regulatory slight-of-hand to create a manufacturing status out of the whole cloth for a federal executive agency on the basis of its oversight of a manufacturing process is unprecedented and flies in the face of FDA's previous regulatory framework.

Again, the bizarre procedural twists and turns involved in this licensing process require public comment. The Court should remand the Final Rule so that these considerations can be publicly vetted.

D. The Final Rule Violates Federalism Concerns And, Therefore, Must Be Invalidated

The FDA's Final Rule notes that it:

> has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as

[10] The Final Rule states that "FDA has reviewed the historical development of AVA and concluded that DoD's continuous involvement with, and intimate knowledge of, the formulation and manufacturing processes of all of these versions of the anthrax vaccine provide a foundation for a determination that the MDPH anthrax vaccine is comparable to the original DoD vaccine." See 69 Fed. Reg. at 260-61.

> defined in the Executive order and, consequently, a federalism summary impact statement is not required.

See 69 Fed. Reg. at 265 (Section IX.D).

No doubt this language was included by FDA officials who were drafting the Final Rule with no more than an afterthought. Identical language has probably been incorporated in dozens of FDA Final Rules. Indeed, has the FDA ever drafted a "federalism summary impact statement"? Probably not very often, for there are likely very few circumstances where FDA action would implicate States' rights. After all, why would there be federalism concerns with whether the FDA approves a new form of foot crème?

However, this is not one of the FDA's typical cases. The use of the anthrax vaccine very clearly has "substantial direct effects on the States", particularly because hundreds of thousands of the involuntary recipients of the vaccine are members of Army and Air National Guard units across the United States; more commonly known as the state militia.[11] Thus, this is very much "a case about federalism," Coleman v. Thompson, 501 U.S. 722, 726 (1991), that is, about respect for "the constitutional role of the States as sovereign entities." Alden v. Maine, 527 U.S. 706, 713 (1999).

This concern is "crucial when the pre-emptive effect of an administrative regulation is at issue. Unlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad pre-emption ramifications for state law." Geier v. American Honda Motor Co., 529 U.S. 861, 908 (2000)(Stevens, J., dissent).

This judicial expectation is shared by the Executive Branch; hence, the adoption of Executive Order 13132, which serves to ensure that States will be afforded a dialog with

[11] For a discussion of the National Guard's history and interplay between federal and state status, see e.g., Perpich v. Dep't of Defense, 496 U.S. 334, 345-9 (1990).

agencies regarding federal regulations that will have substantial direct effects on them. This is to be achieved through the normal APA notice-and-comment procedure. 5 U.S.C. § 553. See Exec. Order No. 12612, § 4(e), 3 C.F.R. § 252, 255 (1988)("When an Executive department or agency proposes to act through adjudication or rule-making to preempt State law, the department or agency shall provide all affected States notice and an opportunity for appropriate participation in the proceedings."); Exec. Order No. 13132, § 4(e), 64 Fed. Reg. 43255, 43257 (1999)(same); cf. Medtronic, Inc. v. Lohr, 518 U.S. 470, 496 (1996)(discussing 21 C.F.R. § 808.5 (1995), an FDA regulation allowing a State to request an advisory opinion regarding whether a particular state-law requirement is pre-empted, or exempt from pre-emption, under the Medical Device Amendments of 1976).

The opening section of Executive Order 13132 states that "'[p]olicies that have federalism implications' refers to regulations … and other policy statements or actions that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." Exec. Order No. 13132, § 1(a), 64 Fed. Reg. 43255, 43255. Of course, as a superficial matter, it should be clear that use of the AVA is having at least "substantial direct effects on the States." If a member of a state's national guard, for example, becomes ill as a result of the forcible inoculation of the vaccine, as tens of thousands have, there will be a significant direct impact on the involved state. There may be medical costs, job impact (such as loss of work because of illness, unemployment costs, etc) and other strains on the economic and family state system.

The Executive Order requires a federal agency that intends to promulgate a regulation that has federalism implications to consult, "prior to the formal promulgation of the regulation,"

with "State and local officials early in the process of developing the proposed regulation." Id. at § 6(b), 64 Fed. Reg. 43255, 43257. The FDA failed to adhere to this requirement.

In fact, at least one state has implicitly, if not explicitly, raised federalism concerns directly with the defendants FDA and DoD over how the AVIP is impacting the members of its National Guard, as well as everyone subject to the forcible inoculations. In 2001, the Attorney General of the State of Connecticut, Richard Blumenthal, wrote separate letters to both Defense Secretary Donald Rumsfeld and Acting FDA Deputy Commissioner Dr. Bernard Schwetz asserting that the compulsory vaccination program is compelling military personnel, including members of the Connecticut Air National Guard, to "put either their health or their careers at risk." See Exhibit "2" (FDA version), a copy of which can also be found at *http://www.cslib.org/attygenl/press/2001/health/fda.pdf*.[12]

There is no evidence in the existing record that the State of Connecticut's concerns were ever heeded. Nor did the FDA ever consult with Connecticut, or any other State, in violation of Executive Order 13132. Given that compliance with the Executive Order is mandatory for the FDA in order to validate its promulgated Final Rule, the Final Rule is invalid until such time

[12] Interestingly, Attorney General Blumenthal has advocated identical arguments to that espoused by the plaintiffs. He asserted that "directly contrary to law, the AVA is being administered to military personnel under threat of imprisonment, loss of pay and discharge" and that "[i]n effect, the military is forcing its personnel to serve as human guinea pigs for an unlicensed drug that has not been proven to be safe or effective." See Exhibit "2". He also noted that the only license for the manufacture of Anthrax vaccine, granted in 1970 to MBPI/Bioport Corporation, was obtained exclusively for agricultural and veterinary settings as protection against cutaneous exposure, not inhalation exposure. Id. Furthermore, he argued that because AVA's present use is inconsistent with its original licensing and is for a purpose that was never tested, the vaccine is therefore an Investigational New Drug under FDA regulations and may not be used on humans without their specific and informed consent. Id. Additionally, the State of Connecticut believes the mandatory vaccination of troops with a biologic product not licensed for its current use violates the Federal Food, Drug, and Cosmetic Act. Id. A copy of Attorney General Blumenthal's letter to the DoD can be found at *http://www.cslib.org/attygenl/press/2001/health/dod.pdf*.

federalism concerns are properly addressed. Therefore, the Final Rule must be invalidated and remanded to the FDA for appropriate proceedings.

II. ALTERNATIVELY, SHOULD SUMMARY JUDGMENT IN FAVOR OF THE PLAINTIFFS NOT BE GRANTED AT THIS TIME, DISCOVERY IS JUSTIFIED

Although the plaintiffs firmly believe they are entitled to summary judgment based on the arguments above, the defendants are contemporaneously cross-filing their own Motion for Summary Judgment. Should this Court determine, for some reason, that the plaintiffs are not yet entitled to summary judgment, then very similar arguments exist to justify discovery before summary judgment is accorded the defendants.

The APA requires courts to "review the whole record or those parts of it cited by a party." 5 U.S.C. § 706. Ordinarily, courts confine their review to the "administrative record." Edison Elec. Inst. v. OHSA, 849 F.2d 611, 617-18 (D.C. Cir. 1988). The administrative record includes all materials "compiled" by the agency, Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 419 (1971), that were "before the agency at the time the decision was made," Environmental Defense Fund, Inc. v. Costle, 657 F.2d 275, 284 (D.C. Cir. 1981).

Although discovery is not routinely granted in APA record review cases, there are exceptions that apply here. For example, discovery is permitted when the agency deliberately or negligently excluded documents that may have been adverse to its decision. See Kent County v. EPA, 963 F.2d 391, 395-96 (D.C. Cir. 1992).[13] It is also permissible when a party demonstrates that it is necessary to supplement the record with "background information" in order to determine whether the agency considered all of the relevant factors, Environmental Defense

[13] The Circuit noted that in San Luis Obispo Mothers for Peace v. NRC, 751 F.2d 1287, 1327 (D.C. Cir. 1984), vacated in another part, 760 F.2d 1320 (D.C. Cir. 1985)(en banc), aff'd 789 F.2d 26 (D.C. Cir.)(en banc), cert. denied 479 U.S. 932 (1986), it had recognized that supplementing the administrative record might be proper "if petitioners made a prima facie showing that the agency excluded from the record evidence adverse to its position ...."

Fund, Inc., 657 F.2d at 285 (quotation omitted), or where an agency failed "to explain administrative action [so] as to frustrate effective judicial review." Id. (quoting Camp v. Pitts, 411 U.S. 138, 142-43 (1973).

A. The FDA Administrative Record Is Woefully Inadequate And Documents Were Either Deliberately Or Negligently Excluded From Consideration

As referenced earlier, 4,209 pages have been placed into the public record by the government on the basis that they were relied upon or at least considered by the FDA in issuing its Final Rule. Of the 4,209 pages in the open record, approximately 2,653 (63%) post-date 1986, and primarily originate during the period 1996-2002. Not surprisingly, there are very few pages that are part of the administrative record which are adverse to the stated DoD/FDA conclusion that the AVA is safe and effective. How can the FDA arrive at this decision, particularly after 19 years following issuance of the Proposed Final Rule, without considering *all* the relevant evidence? A list of just a sampling of relevant scientific studies concerning the anthrax vaccine, none of which were apparently considered by the FDA, is attached at Exhibit "3".

As another example, over two thousand pages of the FDA's Administrative Record pertain to VAER's reports. See Bates #001417-003244, 003584-003606. VAERs refers to Vaccine Adverse Event Reporting System, which is a cooperative program for vaccine safety of the CDC and FDA. These reports are filed as part of a post-marketing safety surveillance program, and attempt to collect information about adverse events (possible side effects) that occur after the administration of vaccines such as AVA. See *www.vaers.org*. Within the FDA administrative record there are a few VAERS reports from 2003. Yet, the vaers.org Website lists nearly 700 VAERS reports for the first half of 2003. Why the discrepancy?

B. Prima Facia Evidence Exists Indicating The DoD Exerted Improper Pressure Upon FDA

Based on the documentary record and the available evidence, it would be reasonable to conclude that the DoD has exerted improper pressure upon the FDA when it comes to the AVA, and in particular the issuance of the Final Rule. Were it just the fact that throughout this case it has been the DoD asserting all the primary arguments and filing substantive declarations that address specific FDA matters rather than the FDA, the plaintiffs might not be concerned. Were it just the fact that in the aftermath of the Court's December 22, 2003, ruling it was DoD officials, rather than those from the FDA, who publicly condemned the Court's decision regarding FDA legal issues, the plaintiffs might not have thought twice. Indeed, were it just the fact that the FDA had magically issued its Final Rule just one week after this Court's decision, the plaintiffs still would pause for just a moment. However, taken together, and considering so much other evidence of strong DoD influence and pressure upon FDA, the entire validity of the administrative process that led to the issuance of the Final Rule is in question, thereby justifying discovery.

For example, on May 3, 1999, when the controversy over the AVA was truly in its infancy, senior DoD officials responsible for AVIP exchanged emails discussing the second Congressional hearing on the anthrax vaccine that had just taken place. These e-mails provide a glimpse of the degree of pressure applied by DoD on FDA and the Government Accounting Office, and the latitude DoD was given by FDA to act as the de-facto manufacturer. Brigadier General Eddie Cain, director of the Joint Program Office for Biological Defense, wrote: "And if you think Congressman Shays was critical of the current relationship between FDA & DoD, wait until he finds out that DoD is calling all the shots onsight [sic][i.e. at BioPort]." BG Cain's subordinate, Colonel John V. Wade, replied that senior Pentagon civilian appointees would have

"SECDEF calling either FDA or HHS with the message 'we (DoD/FDA) didn't do to [sic] well on this one...'" See Exhibit "4".

This request is not unheard of or unsupported by law. At least one court has *invalidated* agency action where it was based, *even in part*, on pressure from Congressional sources. Congressman Texas Medical Assoc. v. Mathews, 408 F.Supp. 303 (W.D. Tex 1976). It should be no different when the pressure is from a non-expert federal agency (DoD) on the expert federal agency (FDA). Of course, here the plaintiffs are merely seeking discovery on the issue, not outright invalidation. Inquiry into the mental processes of an administrative decision is appropriate where there is a strong showing of bad faith or improper behavior. Citizens to Preserve Overton Park, Inc., 401 U.S. at 420.

The DoD has been in the background and foreground of the entire history of the AVA. See 69 Fed. Reg. at 260-61. Very few meetings since the first Gulf War, when the DoD began down the slippery slope of utilizing the AVA to combat inhalation anthrax, have occurred involving the FDA where DoD presence was not felt. This Court has already recognized some of the interplay between the two organizations. See Memo Op. at 5-7. The relationship, though one-sided it was, has a lengthy history. Yet, a review of the FDA's Administrative Record Index reveals that just two pages relate to communications between the DoD and FDA. See Bates #004031-32 (correspondence between Stephan Joseph/DoD and Michael Friedman/FDA); Memo Op. at 6-7.24-25.

Where is the documentary record of the numerous years of DoD-FDA interaction on the very questions now at issue in this litigation, much of which has been cited by the defendants themselves in briefs and oral arguments before this Court? To what extent did the DoD improperly or unduly influence the FDA's actions with respect to the Final Rule. These are legitimate questions and grounds for permitting discovery.

CONCLUSION

Based on the foregoing, the Court should grant the plaintiffs' motion for summary judgment and impose a permanent injunction or, alternatively, permit the plaintiffs to conduct discovery.

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Respectfully submitted,

/s/

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