UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

MEMORANDUM OPINION

I. Introduction

Six plaintiffs, known as John and Jane Doe #1 through #6, bring this action to challenge the lawfulness of the government's Anthrax Vaccination Immunization Program ("AVIP"). Specifically, plaintiffs, who are members of the active duty or National Guardsmen components of the Armed Forces and civilian contract employees of the Department of Defense ("DoD") who have submitted or have been instructed to submit to anthrax vaccinations without their consent pursuant to AVIP, have filed a Motion for Summary Judgment challenging the Food & Drug Administration's ("FDA") determination that anthrax vaccine adsorbed ("AVA") is licensed for the purposes of combating inhalation anthrax (also known as aerosolized or weaponized anthrax). Defendants, the Secretary of Defense (Donald Rumsfeld), the Secretary of Health and Human Services (Tommy Thompson), and the Commissioner of the Food and

Drug Administration (Mark McClellan) have filed a Cross Motion for Summary Judgment asking this Court to declare that FDA's Final Rule and Order determining that AVA is licensed for anthrax regardless of the route of exposure is not arbitrary and capricious.

In 1997, the Department of Defense ("DoD") instituted AVIP and began inoculating service members with AVA to prevent the harmful effects caused by exposure to anthrax.[1] Compl. ¶ 33. Anthrax is an acute bacterial disease caused by infection with spores of *Bacillus anthracis*, which can enter the body in three ways: by skin contact (cutaneous), by ingestion (gastrointestinal), and by breathing (inhalation). *See* 50 Fed. Reg. at 51,058.

The AVIP is a multi-service vaccination program for active duty, Reserve and National Guard service members. Compl. ¶ 33. Under AVIP, military personnel are ordered to submit to a series of AVA inoculations over the course of eighteen months, followed by an annual booster vaccine. Compl. ¶ 47. If military personnel refuse to submit to the AVA inoculations, plaintiffs claim that they will be subject to military disciplinary actions, including court-martial convictions, forfeitures of pay, incarceration and other sanctions. Compl. ¶ 35. Civilian

[1] For manufacturing-related reasons, the vaccine program was reduced and later suspended beginning in July 2000. DoD formally resumed the program in June 2002.

plaintiffs who refuse to comply with AVIP are subject to dismissal as DoD employees or defense contractors. *Id.*

II. Statutory & Regulatory Framework

A. The Public Health Service Act & The Food, Drug, and Cosmetic Act

The Public Health Service Act ("PHSA"), 42 U.S.C. §§ 201 *et seq.*, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*, govern the regulation of biological products in the United States. The FDCA charges FDA with approving drugs, including vaccines, that are safe, effective, and not misbranded. 21 U.S.C. § 355(d). The PHSA grants FDA authority to issue licenses for products that are "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i)(I).

Prior to 1972, the National Institute of Health ("NIH") was charged with implementing the PHSA's licensing requirement. In 1972, this authority was transferred to FDA. *See* Statement of Organization, Functions, and Delegations of Authority, 37 Fed. Reg. 12,865 (June 19, 1972). Upon the transfer of responsibility, FDA promulgated regulations establishing procedures for reviewing the safety, effectiveness, and labeling of all biological products previously licensed by the NIH. *See* Procedures for Review of Safety, Effectiveness and Labeling, 37 Fed. Reg. at 16,679. These regulations are codified in 21 C.F.R.

§ 601.25.

B. 21 C.F.R. § 601.25

21 C.F.R. § 601.25 established a two-stage process for reviewing biological products licensed prior to July 1, 1972. It directs FDA's Commissioner ("Commissioner") to appoint an advisory panel (1) to evaluate the safety and effectiveness of the previously licensed product, (2) to review the labeling of the product, and (3) to advise the Commissioner "on which of the biological products under review are safe, effective, and not misbranded." *See* 21 C.F.R. § 601.25(a).

Each panel must submit a report. *See* § 601.25(e). The report must contain a "statement . . . designat[ing] those biological products determined by the panel to be safe and effective and not misbranded" and this statement "may include any conditions relating to active components, labeling, tests required prior to release of lots, product standard, or other conditions necessary or appropriate for their safety and effectiveness." § 601.25(e)(1).

After reviewing the recommendation, the Commissioner must publish the panel report and a proposed order. *See* 21 C.F.R. § 601.25(f). After reviewing comments on the proposed order, the Commissioner "shall publish . . . a final order on the matters covered" therein, which shall "constitute final agency action

from which appeal lies to the courts." *See* §§ 601.25(g), 601.25(i).

C. Expert Panel Review

In 1973, FDA announced the Section 601.25 safety and effectiveness review of several "bacterial vaccine[s]" previously licensed under PHSA, including AVA, and solicited relevant data and information from manufacturers in order to determine whether the drugs were "safe, effective, and not misbranded." *See* Safety, Effectiveness and Labeling Review; Request for Data Information, 38 Fed. Reg. 5,358 (Feb. 28, 1973).

A scientific Advisory Panel was convened, and in 1980, after considering the relevant data and information, the Panel submitted its report. *See* A.R. 1-600. The Panel observed that AVA "appears to offer significant protection against cutaneous anthrax." The Panel noted that "there is sufficient evidence to conclude that anthrax vaccine is safe and effective under the limited circumstances for which [it] is employed." *See* A.R. at 338, 342. Therefore, the Report recommended that AVA "be placed in Category I" (safe, effective, and not misbranded) and that the appropriate licenses be continued because there is substantial evidence of safety and effectiveness for this product." *Id.* at 342. In the Panel's review of "recommended use," it found that "this product is intended solely for immunization of high-risk of

exposure industrial populations such as individuals who contact imported animal hides, furs, bone meal, wool, hair (especially goathair) and bristles" along with "laboratory investigators handling the organism." *Id.* at 340.

In arriving at this decision, the Panel considered two sets of data: (1) a human field trial conducted by Drs. Brachman, Glod, Plotkin, Fekety, Werrin, and Ingraham in the 1950's ("Brachman study"), A.R. 3732-45, and (2) surveillance data collected and summarized by the Center for Disease Control ("CDC"). *See* A.R. at 337-38.

The Brachman study involved 1,249 workers in four textile mills that processed imported goat hair. *See* A.R. 3732-33. A portion of the workers received the anthrax vaccine, a portion received a placebo vaccine, and a portion received no treatment. *See* A.R. 3737 (Table 2), A.R. 3736 (Table 4); 50 Fed. Reg. at 51,058 (Panel). During the evaluation period, which included an "outbreak" of inhalation anthrax, twenty-six cases of anthrax occurred. *See* A.R. 3733. The results can best be summarized as follows:

	Total Cases (26)	Anthrax Vaccine	Placebo	No vaccine
Inhalation	5	0	2	3
Cutaneous	21	3 (2 incomplete vaccine)	15 (2 incomplete vaccine)	3

A.R. 3733-36. The Brachman study calculated the effectiveness of the anthrax vaccine at 92.5 percent. *See* A.R. 3737. The authors

of the study based their calculations on a comparison between the placebo and the anthrax vaccine group regardless of the route of exposure.

While relying on the Brachman study for its recommendation of effectiveness, the Panel stated that the study demonstrates "93 percent . . . protection" against only cutaneous anthrax and that "[i]nhalation anthrax occurred too infrequently to assess the protective effect of vaccine against this form of the disease." 50 Fed. Reg. at 51,058 (Panel).

The Panel also considered surveillance data collected by the CDC "on the occurrence of anthrax in at-risk industrial settings." 50 Fed. Reg. at 51,058 (Panel). While twenty-seven cases were observed, no cases occurred in persons who were fully vaccinated. *Id*.

D. FDA's Proposed Rule and Order

In 1985, citing Section 601.25's procedural requirements, FDA published notice of a Proposed Rule to reclassify bacterial vaccines and toxoids covered by the Panel Report. *See* Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review; Proposed Rule, 50 Fed. Reg. 51,002 (Dec. 13, 1985) ("Proposed Rule").[2] The Proposed Rule adopted the Panel Report

[2] Although 21 C.F.R. § 601.25 contemplates the publication of the report and proposed *order*, FDA called its issuance a "proposed rule."

verbatim with respect to AVA, including the Panel's recommendation to classify AVA as Category I and the Panel's note that "[i]mmunization with this vaccine is indicated only for certain occupational groups with risk of uncontrollable or unavoidable exposure to the organism." *See* 50 Fed. Reg. at 51,058. The Proposed Rule found that "the benefit-to-risk assessment is satisfactory" for this "limited high-risk population." 50 Fed. Reg. at 51,059.

The Proposed Rule required comments "on the proposed classification of products into Category I ... be submitted by March 13, 1986." 50 Fed. Reg. at 51,002. Four total comments were received, none of them specifically addressing the proposal to reclassify AVA. *See* 69 Fed. Reg. 255, 256-259 ("Final Rule and Order"). FDA took no further action until December 30, 2003--eighteen years after the Proposed Rule, but only eight days after this Court's Order enjoining DoD's AVIP.

E. The Law Regarding Unapproved Drugs and Military Personnel

In 1998, in response to concerns about the use of investigational new drugs during the 1991 Gulf War that may have led to unexplained illnesses among veterans, Congress enacted 10 U.S.C. § 1107. This provision prohibits the administration of investigational new drugs, or drugs unapproved for their intended use, to service members without their informed consent. The

consent requirement may be waived only by the President. In 1999, the President signed Executive Order 13,139, pursuant to which DoD must obtain informed consent from each individual member of the armed forces before administering investigational drugs and under which waivers of informed consent are granted only "when absolutely necessary." Exec. Order No. 13,139, 64 Fed. Reg. 54,175 (Sept. 30, 1999). In August 2000, DoD formally adopted these requirements in DoD Directive 6200.2.

F. Citizen Petition

On October 12, 2001, a group of individuals filed a citizen petition requesting that FDA declare that AVA is ineffective for use against inhalation anthrax and issue a final order classifying AVA as a Category II product. *See* A.R. 1313-75. The petitioners argued that the Panel had erred in concluding that the Brachman study qualified as a well-controlled field trial for purposes of 21 C.F.R. § 601.25(d)(2). *See* A.R. 1316-17 & n.6. In its August 28, 2002 response, FDA explained that it was "working to complete this rulemaking as soon as possible," and that given "the pendency of this rulemaking," it could not "evaluate the adequacy of the Panel recommendation."[3] A.R. 1378.

[3] Again, although 21 C.F.R. § 601.25 contemplates the publication of a report and proposed order, FDA called its issuance a "proposed rule."

G. The Preliminary Injunction

In March 2003, plaintiffs filed suit in this Court, alleging that the AVIP violates federal law because AVA had never been approved as a safe and effective drug for protection against inhalation anthrax. Plaintiffs asked this Court to enjoin DoD from inoculating them without their informed consent.

On December 22, 2003, this Court issued a Preliminary Injunction enjoining inoculations under the AVIP in the absence of informed consent or a Presidential waiver. Because the record was devoid of an FDA final decision on the investigational status of AVA, the Court was persuaded that AVA was an investigational drug being used for an unapproved purpose in violation of 10 U.S.C. § 1107, Executive Order 13,139, and DoD Directive 6200.2. *See Doe v. Rumsfeld*, 297 F. Supp. 2d 119, 135 (D.D.C. 2003).

H. Final Rule and Order

Eight days after this Court's Preliminary Injunction and eighteen years after FDA proposed to reclassify AVA, the agency announced a Final Rule and Order classifying AVA as a Category I drug. *See* Bio. Prods; Bacterial Vaccines & Toxoids; Implementation of Efficacy Review; 69 Fed. Reg. 255, 265-66 (Jan. 5, 2004)("Final Rule and Order"). The Final Rule and Order stated that AVA was safe and effective "independent of the route of exposure." *See id.* at 257-59. At the same time, FDA issued a

press release noting that 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 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.

The Final Rule and Order relied on several sources of data to support its finding of safety and efficacy, including the Brachman Study, the CDC surveillance data, the results of a "small randomized clinical study of the safety and immunogenicity of AVA" conducted by the DoD, "post licensure adverse event surveillance data available from the Vaccine Adverse Event Reporting System (VAERS)," and an independent examination by the Institute of Medicine ("IOM"). *See* Final Rule and Order at 260.

In its discussion, FDA explained, for the first time, certain "points of disagreement with statements in the Panel Report." *See id.* at 259. Specifically, FDA disagreed with the Expert Panel's interpretation of the Brachman Study. FDA concluded:

> because the Brachman comparison of anthrax cases between the placebo and vaccine groups included both inhalation and cutaneous cases, FDA has determined that the calculated efficacy of the vaccine to prevent all types

> of anthrax disease combined was, in fact, 92.5 percent. . . . The efficacy analysis in the Brachman study includes all cases of anthrax disease regardless of the route of exposure or manifestation of disease.

Id. at 259-60.

FDA did note that the five cases of inhalation anthrax were "too few to support an independent statistical analysis." *Id.* at 260. However, FDA explained that:

> of these [five] cases, two occurred in the placebo group, three ocurred in the observation group, and no cases occurred in the vaccine group. Therefore, the indication section of the labeling for AVA does not specify the route of exposure, and the vaccine is indicated for active immunization against *Bacillus anthracis* [anthrax], independent of the route of exposure.

Id.

Moreover, FDA noted that the surveillance data was "supportive of the effectiveness of AVA." *Id.* at 260. FDA also discussed the independent examination by IOM of AVA's safety and effectiveness, during which the IOM Committee "reviewed all available data, both published and unpublished, [and] heard from Federal agencies, the manufacturer and researchers." *Id.* Noting that the abstract of the IOM's Report stated "that AVA, as licensed, is an effective vaccine to protect humans against anthrax including inhalation anthrax," FDA stated it

> agrees with the report's finding that studies in human and animal models support the conclusion that AVA is effective against *B. Anthracis* strains that are dependant upon the anthrax toxin as mechanism or virulence, regardless of the route of exposure.

Id. at 260 & n.5.

I. The Present Case

Following the announcement of FDA's Final Rule and Order, the Court granted defendants' request to stay the Court's earlier Preliminary Injunction except as it applied to the six Doe plaintiffs.[4] *See* Order dated January 7, 2004, at 1-2.

Plaintiffs now ask this Court to vacate FDA's recent Final Rule and Order and to remand the matter to FDA for proper consideration and a determination of the licensing status of AVA. In addition, plaintiffs request that the Court reinstate the injunctive relief, albeit now on a permanent basis, that was granted in its initial ruling of December 22, 2003, because absent a valid final rule and/or order, the Court's conclusion that the vaccine is improperly licensed for inhalation anthrax remains in effect. Alternatively, plaintiffs ask that summary judgment not be granted to defendants and ask that they be permitted to conduct discovery in order to ensure that the administrative record is complete and was not improperly influenced by DoD. Defendants ask this Court to grant summary judgment in their favor.

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[4] The parties consented to keeping the Preliminary Injunction in place with regard to the six Doe plaintiffs. Subsequently, at a Motions Hearing on March 15, 2004, the Court vacated its injunction as to the six Doe plaintiffs though the parties agreed that the six Doe plaintiffs would not be required to submit to the vaccination while this lawsuit was pending.

III. Standard of Review

Pending before this Court are cross motions for summary judgment. Summary judgment is granted pursuant to Federal Rule of Civil Procedure 56 only when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). The Court views the evidence in the light most favorable to the nonmoving party, according the party the benefit of all reasonable inferences. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Thus, in ruling on cross motions for summary judgment, the Court will grant summary judgment only if one of the moving parties is entitled to judgment as a matter of law upon material facts that are not in dispute. *See Rhoads v. McFerran*, 517 F.2d 66, 67 (2d Cir. 1975).

There are no genuine material facts that preclude judgment in this matter. If the FDA's Final Rule and Order categorizing AVA as safe and effective for protection against inhalation anthrax was issued in accordance with the relevant law, then DoD's AVIP is lawful; conversely, if FDA's Final Rule and Order is invalid, the AVIP is unlawful absent informed consent or a Presidential waiver.

Under the Administrative Procedure Act, a reviewing court may hold unlawful and set aside final agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not

in accordance with the law," or "without observance of procedure required by law." 5 U.S.C. § 706(2).

This Court is mindful that the standard of review for agency action is highly deferential. *See American Public Communications Council v. FCC*, 215 F.3d 51, 61 (D.C. Cir. 2000); *Bristol-Myers Squibb Co. v. Shalala*, 923 F. Supp. 212, 216 (D.D.C. 1996). Ordinary deference may be heightened even further in cases involving scientific or technical decisions. *See Serono Labs., Inc., v. Shalala*, 158 F.3d 1313, 1320 (D.C. Cir. 1998) (noting that an agency is entitled to a "high level of deference" when its regulatory determination rests on its "evaluation [] of scientific data within its area of expertise"). The "determination whether a drug is generally recognized as safe and effective within the meaning of [the FDCA] necessarily implicates complex chemical and pharmacological considerations." *Weinberger v. Bentex Pharms, Inc.*, 412 U.S. 645, 654 (1973). FDA's "judgment as to what is required to ascertain the safety and efficacy of drugs" thus falls "'squarely within the ambit of FDA's expertise and merit[s] deference from' the courts." *Bristol-Myers*, 923 F. Supp. at 220 (quoting *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir.), *cert denied*, 516 U.S. 907 (1995)).

Although FDA's scientific expertise is due great deference, it is well within this Court's scope of authority to ensure that

the agency adheres to its own procedural requirements. *See Service v. Dulles*, 354 U.S. 363 (1957) (seminal case standing for the proposition that judicial review is available to ensure that agencies comply with their own voluntarily-promulgated regulations, even where Congress has given the agency "absolute discretion" over the administrative action in question). *See also Rodway v. United States Dept. of Agric.*, 514 F.2d 809, 813-14 (D.C. Cir. 1975) (requiring the agency to comply with its own regulations "making the procedural requirements of [the APA] applicable" because "it is, of course, well settled that validly issued administrative regulations have the force and effect of law") (citing *Morton v. Ruiz*, 415 U.S. 199, 235 (1974); *Vitarelli v. Seaton*, 359 U.S. 535, 539-540 (1959); *Service*, 354 U.S. at 388). In this case, the Court focuses not on FDA's substantive--and highly technical--determinations regarding the safety of AVA, but rather on whether or not the Agency observed the relevant "procedure required by law."

IV. Discussion

A. Standing

The party asserting jurisdiction always has the burden to prove standing. *FW/PBS Inc. v. City of Dallas*, 492 U.S. 21, 23 (1990). To have standing, a plaintiff must allege: (1) an "actual or imminent" injury-in-fact; (2) "fairly . . .

trace[able] to the challenged action of the defendant"; and (3) "likely" to be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). At the summary judgment stage, "the plaintiff can no longer rest on . . . 'mere allegations'," but must "'set forth' by affidavit or other evidence 'specific facts'" establishing standing. *Lujan*, 504 U.S. at 561 (quoting Fed. R. Civ. P. 56(e)).

The Court has recognized that in order to establish injury plaintiffs must demonstrate that they have taken, or have been ordered imminently to take, the anthrax vaccine. *See Doe*, 297 F. Supp. 2d at 130-31. While defendants argue that plaintiffs have presented no "specific facts" in support of these claims, the Court accepts and credits the sworn affidavit of plaintiffs' counsel. Thus, plaintiffs have standing to challenge the FDA's actions.

B. The Status of FDA's December 30, 2003 Issuance

At the outset, the parties dispute whether the FDA's December 30, 2003 issuance, labeled a "Final Rule and Order," was in fact a Final Rule or a Final Order.[5] The Court will address this issue in the first instance.

The APA defines two broad, normally mutually exclusive

[5] Defendants claim that while part of the issuance is a Rule, the part that is relevant to AVA is an Order. Tr. 5/25/04 at 38.

categories of agency action - rules and orders. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 216 (1988)(Scalia, J., concurring) (distinction between rules and orders is "the entire dichotomy upon which the most significant portions of the APA are based"). The APA defines a "rule" as:

> the whole or a part of an agency statement of general or partial applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganization thereof, prices, facilities, appliances, services, or allowance therefor or of valuation, costs, or accounting, or practices bearing on any of the foregoing.

5 U.S.C. § 551(4). "[R]ule making," which can be formal or informal, is the "agency process for formulating, amending, or repealing a rule." *Id.* at § 551(5).

When promulgating a substantive rule, an agency must comply with the notice-and-comment requirements of 5 U.S.C. § 553. *See* 5 U.S.C. § 553(b). Notice and comment 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, the agency must "give interested persons an opportunity to participate in the rulemaking through submissions of written data, views, or arguments." 5 U.S.C. § 553(c).

The APA defines an "order" as:

> the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other then rule making but including licensing.

Id. at § 551(6). "Adjudication," which can also be formal or informal, is the "agency process for the formulation of an order." *Id.* at § 551(7).

Plaintiffs claim that in conducting its review of AVA, FDA acted in a manner consistent with the exercise of rulemaking and that it was not until the present litigation that defendants sought to recast the AVA certification process.[6] Plaintiffs allege that FDA's rulemaking denied affected parties the opportunity to effectively participate in the process, and that the Final Rule should be invalidated and remanded to the agency.

Defendants argue that a decision by FDA to place a biological product in Category I, thereby confirming its license, falls squarely within the definition of an "order" for purposes of the APA. *See* 5 U.S.C. § 551(6). Defendants note that Section 601.25 itself refers to FDA's determination as an "order." *See* 21 C.F.R. § 601.25(f). Defendants observe that FDA's process for licensing biological products is not itself subject to rulemaking requirements. *See, e.g.,* 42 U.S.C. § 262(a)(2)(A)("[t]he

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[6] Plaintiffs note that the original notice of final agency action that appeared in the Federal Register on January 5, 2004 described FDA's actions as a "Final Rule." The words "and Order" were added by hand. Until that final agency action, FDA and DoD spokespersons have consistently referred to this determination concerning AVA as a "Final Rule." *See* Pls.' Reply Brief 6-7.

Secretary shall establish, by regulation, requirements for approval, suspension, and revocation of biologics licenses"); 21 C.F.R. §§ 601.2 - 601.9. Thus, defendants note that were AVA a new biological product for which the manufacturer was seeking an initial license, FDA would not be required by the APA's rulemaking provision to publish its licensing decision for notice and comment.

Moreover, defendants allege that FDA's decision placing AVA in Category I bears none of the hallmarks of a "rule." It does not "implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). Instead, defendants claim, the decision merely applies already-existing legal standards to specific facts - the hallmark of adjudication. Defendants note that the decision has no "future effect" (5 U.S.C. § 551(4)); it merely determines the "past and present rights and liabilities" of AVA's manufacturer with respect to an already-issued license. *See Bowen*, 488 U.S. at 219 (Scalia, J., concurring); *see also Goodman v. FCC*, 182 F.3d 987, 994 (D.C. Cir. 1999). Defendants submit that consistent with Section 601.25(g), FDA referred to its licensing decision as a "Final Order" in several places. *See* Final Rule and Order at 257.

Plaintiffs claim that FDA has considered determinations like the one issued regarding AVA as rulemaking subject to judicial review. In *Contact Lens Manufacturers Ass'n v. FDA*, a commercial

association sued FDA over its decision to classify contact lenses according to the product's safety and effectiveness. 766 F.2d 592, 594 (D.C. Cir. 1985). In describing the safety and effectiveness of the lenses, FDA utilized a three class categorization system. Contact lens manufacturers whose products had been placed in Class III lobbied to reverse FDA's proposal to stop a transfer of a category of lenses from Class III to Class I. Plaintiffs claim that the determination made by FDA with regard to the products' status are virtually identical to the determination at issue here. Nevertheless, FDA provided extensive comment periods, and even a public hearing. *Id.* at 596-7.

In *Cutler v. Hayes*, FDA engaged in a comprehensive review of the safety and effectiveness of all over-the-counter drugs. 818 F.2d 879 (D.C. Cir. 1987). In doing so, FDA used a process, again, virtually identical to the one at issue here. To start, advisory review panels of experts were appointed to analyze existing test data and make recommendations in the form of monographs. *Id.* at 884. FDA reviewed the monographs, published them in the Federal Register, opened the period for public comment, and made a final recommendation, which was also open for public comment. *Id.* FDA then promulgated a determination classifying the drug as either Category I (safe and effective), Category II (not generally recognized as safe and effective), or

Category III (data is insufficient to classify as I or II). In making its determination, FDA invited public comment twice.

Defendants acknowledge that FDA did provide interested parties an opportunity to comment on its Proposed Order categorizing AVA as a Category I product. Defendants argue that while agencies have discretion to employ "extra procedural devices," the court may not second guess the agency's decision not to do so. *See Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.* 435 U.S. 519, 545 (1978).

The D.C. Circuit has explained that when determining whether agency action is rulemaking or adjudicating:

> the focus is not on whether the particular proceeding involved trial-type devices but instead turns on the nature of the decision to be reached in the proceeding. Rulemaking is prospective in scope and nonaccusatory in form, directed to the implementation of general policy concerns into legal standards. Adjudication, on the other hand, is "individual in impact and condemnatory in purpose," directed to the determination of the legal status of a particular person or practices through the application of preexisting legal standards.

FTC v. Brigadier Industries Corp., 613 F.2d 1110, 1117 (D.C. Cir. 1979).

It appears to the Court that the agency held AVA up to a pre-determined standard and made a judgment as to whether to classify AVA as safe and effective or otherwise. This suggests to this Court that FDA has issued an order. However, Section 601.25(g) and (i) instruct the agency to take comments for 90 days. While orders typically fall outside the confines of APA

rulemaking, *see* 5 U.S.C. § 553, here, the Court is confronted with a situation where the agency decided that notice and comment regarding the proposed order was the correct course of action. This procedure is not without precedent.[7]

In *Contact Lens Manufacturers*, the FDA reviewed products for safety and efficacy, provided opportunity for public input through the notice-and-comment process and public hearings, and published an Order as is evidenced by the D.C. Circuit's labeling of its review as a "Petition for Review of an *Order* of the Food and Drug Administration." 766 F.2d at 593 (emphasis added). *Cutler* also provided an opportunity for the public to submit comments following the publication of a proposed order. *See* 818 F.2d at 884. Thus, the Court is persuaded that the December 30, 2003 issuance was an order. While orders do not ordinarily require notice and comment, the plain meaning of Section 601.25 of FDA's regulations requires notice and comment on the classification of the biologics in question:

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[7] The Court is perplexed by the fact that both parties have looked at *Contact Lens Manufacturers* and *Cutler* and asserted that rulemaking took place. *See* Tr.5/25/04 (by counsel for defendants "Let me cut to the chase, *Contact Lens* involved what was a rule. It wasn't an order because it dealt with a broad category." The Court: "So it's the government view that it was a rule that was being challenged?" Counsel: "That was a rule." The Court: "And not an Order?" Counsel: "And unquestionably not an order."); *see also* Pls.' Reply at 4 ("A review of comparable FDA determinations [alluding to *Contact Lens Manufactures* and *Cutler*] demonstrates that this type of FDA action constitutes rulemaking subject to public comment."

> (4) The full report or reports of the panel to the Commissioner of Food and Drug. The summary minutes of the panel meeting or meetings shall be made available to interested persons upon request. Any interested person may within 90 days after publication of the proposed order in the Federal Register, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. . . .
> (g) Final order. After reviewing the comments, the Commissioner of Food and Drugs shall publish in the Federal Register a final order on the matters covered in the proposed order.

21 C.F.R. § 601.25(f)(4) & (g). This requirement is also reflected in FDA's Final Rule and Order:

> In accordance with § 601.25, after reviewing the conclusions and recommendations of the review panel, FDA would publish in the Federal Register a proposed order . . . After reviewing public comments, FDA would publish a final order on the matters covered in the proposed order.

69 Fed. Reg. 255.

Notice and comment gives interested parties an opportunity to participate through the submission of data, views and arguments.[8] See *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council*, Inc., 435 U.S. 519 (1978). Notice and comment also ensures fairness to all parties and provides a well-developed record - something this case is severely lacking. *See Sprint Corp v. FCC*, 315 F.3d 369 (D.C. Cir. 2003); *see also* Tr. 5/25/04 at 2 (by the Court "Let me just say at the outset

[8] It appears to the Court that the FDA was concerned about representation of divergent views as section 601.25(a) notes that the advisory review panels "shall include persons from lists submitted by organizations representing professional, consumer, and industry interests. Such persons shall represent a wide divergence of responsible medical and scientific opinion."

that the administrative record in this case is one of the most confusing, jumbled records this Court has ever seen. Indeed, the only thing that is clear is that confusion abounds.").

Although defendants are correct that the courts may not compel an agency to employ "extra procedural devices," this Court shall compel an agency to follow the procedures set forth in its own regulations. In this case, FDA's regulations require it to: (1) publish a proposed order in the Federal Register after considering the expert panel's recommendations; (2) provide 90 days for interested persons to file written comments on the proposal; and (3) publish a final order on the matters covered in the proposed order. *See* 21 C.F.R. § 601.25 (f)(4) & (g). Thus, this Court will concentrate its review on the sufficiency of FDA's compliance with these procedures. To guide its analysis, the Court will look to the substantial body of existing case law that gives meaning to what is meant by "notice and comment" under the APA.

C. Procedural Challenges to FDA's Final Rule and Order

1. Studies Outside the Comment Period

The public was invited to submit comments on the Proposed Order for 90 days, from December 13, 1985, until the period closed on March 13, 1986. However, eighteen years later when the Final Rule and Order was published, FDA relied on studies

and data that were not in existence at the conclusion of the comment period. Plaintiffs argue that the D.C. Circuit has frowned on this practice, noting that "[a]n 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." *Conn. Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530-31 (D.C. Cir. 1982). 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. *See* 939 F.2d at 1010.

Here, plaintiffs argue that FDA relied on at least four extensive studies that commenced and concluded after the comment period ended. *See* 69 Fed. Reg. at 265-66. For example, FDA

cites and relies on a report on the anthrax vaccine issued by the Institute of Medicine ("IOM") in 2002 - sixteen years after the comment period ended. *Id.* at 259-60. In issuing its report, the IOM evaluated "all available data, both published and unpublished" on the anthrax vaccine, specifically focusing on three studies from 1996, 1998, and 2001. *Id.* at 260 & n.5.

Moreover, plaintiffs note that of the 4,209 pages in the administrative record, approximately 2,653 (63%) post-date 1986. Plaintiffs allege that persons who submitted comments in late 1985 and early 1986 were deprived of the opportunity to comment on these studies. Plaintiffs argue that this procedural flaw is so fundamental as to require the invalidation of FDA's Final Rule and Order.

2. Deviations From The Proposed Rule

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. Donavan*, 757 F.2d 330, 338 (D.C. Cir. 1985). 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." *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).

In *Shell Oil Co. v. EPA*, 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 notice of the definition that was finally adopted. 950 F.2d 741, 748 (D.C. Cir. 1991). 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. In setting aside the rule and remanding it to the EPA, the D.C. Circuit held that an agency's "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 751-52.

Defendants argue that FDA's Final Rule and Order is identical to what it proposed in 1985 - to place AVA in Category I. *Compare* Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, 50 Fed. Reg. 51,002, 51,104 (Dec. 13, 1985) *with* Final Rule and Order at 259. They claim that plaintiffs' position is based on a misunderstanding of the Expert Panel's recommendation. Defendants state that when the

Panel issued its report, AVA was indicated for persons at risk to exposure to the anthrax bacterium and its label did not specify a route of exposure. *See* 50 Fed. Reg. at 51,059.

Moreover, defendants contend that the Panel recommended Category I notwithstanding the Panel's alleged erroneous belief that the Brachman study did not assess the protective effect of the vaccine against inhalation anthrax. Defendants claim that this "framed . . . for discussion" whether AVA should be placed in Category I for use against inhalation anthrax. *See Omnipoint Corp. v. FCC*, 78 F.3d 620, 631 (D.C. Cir. 1996). Thus, defendants argue that FDA provided adequate "opportunities for interested parties to offer comments that could persuade the agency to modify its rule." *See American Water Works,* 40 F.3d at 1274.

However, the Court finds that the public has never been afforded an opportunity to comment on the safety and efficacy of AVA as it pertains to inhalation anthrax. FDA's Proposed Order (though called a "Proposed Rule" when published) only contained the Panel's assessment of AVA. It found that the anthrax vaccine was safe and effective in "the limited circumstances for which this vaccine is employed." 50 Fed. Reg. at 51,059. At that time, the vaccine was employed for use by "certain occupational groups," mainly "individuals in industrial settings" who worked with animal furs, hides and hairs. 50 Fed.

Reg. at 51,058. The vaccine's use was intended to be for "protection against cutaneous anthrax in fully immunized subjects." 50 Fed. Reg. at 51,059. The Panel concluded that, "no meaningful assessment of the [the vaccine's] value against inhalation anthrax is possible." *Id*. It was under this premise that the public was on notice to submit comments.

Interested parties in 1985 could not have anticipated that FDA would permit the vaccine to be used for inhalation anthrax as a result of exposure through a biological attack.[9] In 1985 there would have been no reason to submit comments on the vaccine's use against other routes of exposure for the population at large; indeed, not a single comment was received on anthrax in response to the Proposed Rule.

Now, for the first time, eighteen years later, FDA's Final

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[9] Defendants' counsel conceded as much in response to a question by the Court: "But it's absolutely right, Your Honor, that the possibility of weaponized anthrax was not in the minds of the advisory panel and probably not in the minds of the FDA." Tr. 5/25/04 at 69.

Lending further support to the notion that the Expert Panel did not consider mass inhalational anthrax exposure is the Panel's own comment:

> Anthrax vaccine poses no serious special problems other than the fact that its efficacy against inhalation anthrax is not well documented. This question is not amenable to study due to the low incidence and sporadic occurrence of the disease. In fact, the industrial setting in which the studies above were conducted is vanishing, precluding any further clinical studies. In any event, further studies on this vaccine would receive low priority for available funding.

50 Fed. Reg. 51,058.

Rule and Order asserts that FDA "does not agree with the Panel report," and believes 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 259-60.

The Court finds that this significant post-comment expansion of the scope of FDA's inquiry deprived the public of a meaningful opportunity to submit comments and participate in the administrative process mandated by law. Because "a new round of notice and comment would provide the first opportunity for interested parties to offer comments that could persuade" the FDA to change its position with regard to the use of AVA against inhalation anthrax, the Agency's Final Rule and Order is by no means a "logical outgrowth" of the 1985 Proposed Rule. *See American Water Works,* 40 F.3d at 1274. This failure to provide for a meaningful opportunity to comment, as required by FDA's own regulations, violates the APA. *See* 5 U.S.C. § 706(2).

While vacatur is the normal remedy for an APA violation, a plaintiff must "show prejudice from an agency's procedural violation." *City of Waukesha v. EPA*, 320 F.3d 228, 246 (D.C. Cir. 2003). For a plaintiff to establish prejudice on the basis of a "logical outgrowth" argument, a plaintiff generally must show (1) that, "had proper notice been provided, they would have submitted additional, different comments that could have

invalidated the rationale for the revised rule;" or (2) that "the agency has entirely failed to comply with the notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration." *Id.*

Defendants argue that plaintiffs cannot make the first showing because FDA did consider and reject arguments against the rationale for its effectiveness determination in the course of responding to the citizen petition. *See, e.g.,* A.R. 1376-85. In its Final Rule and Order, FDA expressly referred to the citizen petition and its response. *See* FDA Rule and Order at 259 n.2. Further, defendants claim that FDA's citizen petition response provides "persuasive evidence" that it considered fully "possible objections" to the Order. *See City of Waukesha*, 320 F.3d at 246.

However, the Court is not persuaded. While some individuals may have submitted comments as part of a citizen petition, it is clear to this Court that if the status of the anthrax vaccine were open for public comment today, the agency would receive a deluge of comments and analysis that might inform an open-minded agency. Airborne exposure to anthrax was not an indication under the licensing contemplated by the 1985 Proposed Rule and a new notice-and-comment period would be the first opportunity that interested parties would have to

challenge the vaccine's efficacy against such exposure.

Thus, the Final Rule and Order shall be vacated and remanded to the agency for reconsideration following an appropriate notice-and-comment period in accordance with the APA, the Agency's own regulations, and this Memorandum Opinion and Order.[10]

V. Scope of Injunction

Having vacated and remanded FDA's Final Rule and Order, the posture of this case reverts back to where it was on December 22, 2003, when this Court granted plaintiffs' Motion for a Preliminary Injunction. Thus, for all the reasons stated in this Court's December 22, 2003 opinion, including Congress's prohibition on forced inoculations with "investigational" drugs, *see* 10 U.S.C. § 1107, the Court shall now issue a permanent injunction. Unless and until FDA follows the correct procedures to certify AVA as a safe and effective drug for its intended use, defendant DoD may no longer subject military personnel to involuntary anthrax vaccinations absent informed consent or a Presidential waiver.

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[10] Because the Court is granting plaintiffs' Motion for Summary Judgment, this Memorandum Opinion does not address plaintiffs' alternative argument for discovery or defendants' Motion for Summary Judgment. Moreover, since the Court's holding is based on procedural grounds, the Court does not reach plaintiffs' numerous substantive challenges to FDA's Final Rule and Order.

In the days after the Court issued its injunction, there was much discussion concerning whether the injunction applied to the six Doe plaintiffs or whether the injunction applied to all persons affected by the DoD's involuntary anthrax program. Because it is inevitable that this concern will be raised again, the Court shall address it now.[11]

Traditionally, "[l]itigation is conducted by and on behalf of the individual named parties only." *Califano v. Yamasaki*, 442 U.S. 682, 700-01 (1979). This general rule is based on the fundamental principles of due process and prudential standing. *See, e.g., Allen v. Wright*, 468 U.S. 737, 751 (1984)(noting "the general prohibition on a litigant's raising another person's legal rights"); *Singleton v. Wulff*, 428 U.S. 106, 113-14 (1976) ("[C]ourts should not adjudicate [the] rights [of third persons] unnecessarily, and it may be that in fact the holders of those rights either do not wish to assert them, or will be able to enjoy them regardless of whether the in-court litigant is successful or not.").

However, the Court notes that this litigation concerns the lawful status of the anthrax vaccine. Having found that the vaccine's use without informed consent or a Presidential waiver

[11] The parties briefed this issue in early 2004 which culminated in a Motions Hearing on March 15, 2004. At that time, the Court expressed its concern that a finding on this issue would have resulted in an advisory opinion. Thus, the Court denied the motion without prejudice.

is unlawful, this Court would be remiss to find that a conflict exists between service members who think that the DoD should be required to follow the law and those service members who think otherwise.

The Fourth, Fifth, Ninth, and D.C. Circuits have held that an injunction can benefit parties other than the parties to the litigation. *See, e.g., National Mining Ass'n, et. al., v. U.S. Army Corps of Engineers, et. al.*, 145 F.3d 1399 (D.C. Cir. 1998); *Bresgal v. Brock*, 843 F.2d 1163 (9th Cir. 1987); *Evans v. Harnett County Bd. of Educ.*, 684 F.2d 304 (4th Cir. 1982); *Meyer v. Brown & Root Construction Co.*, 661 F.2d 369 (5th Cir. 1981). The Supreme Court has implicitly agreed with this proposition. *Lujan v. National Wildlife Federation*, 497 U.S. 871, 913 (1990).

"There is no general requirement that an injunction affect only the parties in the suit. Where, as here, an injunction is warranted by a finding of defendants' outrageous unlawful practices, the injunction is not prohibited merely because it confers benefits upon individuals who were not named plaintiffs or members of a formally certified class." *McCargo v. Vaughn*, 778 F. Supp. 1341, 1342 (E.D. Pa. 1991). A district court has "broad power to restrain acts which are of the same type or class as unlawful acts which the court has found to have been committed or whose commission in the future, unless enjoined,

may fairly be anticipated from the defendant's conduct in the past." *N.L.R.B. v. Express Publ'g Co.*, 312 U.S. 426, 435 (1941).

The D.C. Circuit has found that when agency "regulations are unlawful, the ordinary result is that the rules are vacated – not that their application to the individual petitioner is proscribed." *National Mining Ass'n*, 145 F.3d at 1409 (citation omitted). In *National Mining Ass'n*, the district court invalidated a Corps of Engineers regulation and entered an injunction prohibiting the Corps and the Environmental Protection Agency from enforcing the regulation nationwide. 145 F.3d at 1408. The D.C. Circuit upheld that nationwide application, notwithstanding the fact that non-parties to the litigation would specifically be affected. *Id.* at 1409-10.

Government-wide injunctive relief for plaintiffs and all individuals similarly situated can be entirely appropriate and it is "well-supported by precedent, as courts frequently enjoin enforcement of regulations ultimately held to be invalid." *Sanjour v. United States EPA*, 7 F. Supp. 2d 14, 17 (D.D.C. 1998). *See, e.g., Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)(court decision invalidating unlawful agency regulation applies beyond just individual petitioners); *Planned Parenthood Fed'n of Amer., Inc., v. Heckler*, 712 F.2d 650 (D.C. Cir. 1983)(affirming final injunction prohibiting enforcement of

invalidated regulations); *Dimension Fin. Corp. v. Board of Governors of the Fed. Reserve Sys.*, 744 F.2d 1402 (10th Cir. 1984)(enjoining Board from enforcing or implementing invalid regulations) *aff'd*, 474 U.S. 361 (1986); *Service Employees Int'l Union v. General Servs. Admin.*, 830 F. Supp. 5 (D.D.C. 1993)(invalidating GSA regulation and enjoining further enforcement of the rule).

The Supreme Court has also embraced this view. Although written as part of a dissent, the D.C. Circuit has noted that it expressed the views of all nine Justices. Justice Blackmun wrote:

> The Administrative Procedure Act permits suit to be brought by any person 'adversely affected or aggrieved by agency action.' In some cases, the 'agency action' will consist of a rule of broad applicability; and if the plaintiff prevails, the result is that the rule is invalidated, not simply that the court forbids its application to a particular individual. Under these circumstances, a single plaintiff, so long as he is injured by the rule, may obtain 'programmatic' relief that affects the rights of parties not before the court. On the other hand, if a generally lawful policy is applied in an illegal manner on a particular occasion, one who is injured is not thereby entitled to challenge other applications of the rule.

Lujan, 497 U.S. at 913 (Blackmum, J. dissenting)(citation omitted). *See also id.* at 890 n.2 (majority opinion)(noting that under the APA, successful challenge by aggrieved individual can affect the entire agency program)(as cited in *National Mining Ass'n*, 145 F.3d at 1409).

However, defendants are correct in asserting that *National*

Mining Ass'n did not address a mandatory rule that requires district courts to issue nationwide injunctions as a matter of law in all cases where agency regulations are invalidated. Rather, the appropriate scope is in the court's discretion. *See* 145 F.3d at 1408-09 (noting the district court's "discretion in awarding injunctive relief" and holding that when "a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated"). Courts retain discretion to decline granting an injunction even where there is a conceded violation of law. *See Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312-13 (1982).

Defendants attempt to distinguish *National Mining Ass'n* from the present case by noting that the injunction there prohibited the enforcement by an agency of its own broadly applicable regulation deemed by the court to be facially invalid. *See* 145 F.3d at 1408. Here, plaintiffs seek an injunction that would prohibit DoD from taking action with respect to individual members of the military. Defendants claims that this is much broader than the injunction in *National Mining Ass'n.*[12]

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[12] Defendants also challenge the stability of *National Mining Ass'n* in the D.C. Circuit. Defendants note that the D.C. Circuit has recently questioned the viability of *National Mining Ass'n* for overlooking a key Supreme Court case in considering which test to apply to determine the merits of plaintiff's facial challenge. *See Amfac Resorts v. United States Dep't of Interior*, 282 F.3d 818, 826-27 (D.C. Cir. 2002) *rev'd on other grounds*, 538

Defendants note that the relief in *National Mining Ass'n* was also understandable in light of the broad representation of the plaintiffs before the court there. That case involved a challenge brought by several trade associations on behalf of their members. 145 F.3d at 1401. Defendants claim that the trade associations represented a much broader cross-section of affected parties than the six Doe plaintiffs.

However, it appears to this Court that the Court is faced with precisely the circumstances described by Justice Blackmun in his discussion of "programmatic relief." *See also Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 212 (D.D.C. 2002)(noting that *National Mining Ass'n* stands for the "proposition that a nationwide injunction invalidating an agency rule of broad applicability is appropriate even where a single plaintiff has challenged the legality of the rule"). Thus, the injunction issued today shall apply to all persons subject to DoD's involuntary anthrax inoculation program and not just the six Doe plaintiffs.

U.S. 803 (2003); *National Mining Ass'n v. United States Dep't of Interior*, 251 F.3d 1007, 1010 (D.C. Cir. 2001). However, in *Amfac Resorts*, the D.C. Circuit "called into question its holding regarding the dredging regulation." *Id.* at 826-27. Thus, the D.C. Circuit reconsideration of the standard it applied in its analysis of a constitutional challenge to the dredging regulation does not suggest that program-wide relief cannot be extended to non-plaintiffs.

VI. Conclusion

This Court has an obligation to ensure that FDA follow the law in order to carry out its vital role in protecting the public's health and safety. By refusing to give the American public an opportunity to submit meaningful comments on the anthrax vaccine's classification, the agency violated the Administrative Procedure Act. While the policy of submitting comments on an agency's proposed order may be unusual, it is the course the agency chose to take and this Court shall ensure that the agency follows through on its commitment to the public.

Congress has prohibited the administration of investigational drugs to service members without their consent. This Court will not permit the government to circumvent this requirement. The men and women of our armed forces deserve the assurance that the vaccines our government compels them to take into their bodies have been tested by the greatest scrutiny of all - public scrutiny. This is the process the FDA in its expert judgment has outlined, and this is the course this Court shall compel FDA to follow.

Accordingly, it is by the Court hereby

ORDERED that Plaintiff's Motion for Summary Judgment is **GRANTED**. The FDA's Final Rule and Order is vacated and shall be remanded to the agency for reconsideration in accordance with this Memorandum Opinion and Order. Unless and until FDA

properly classifies AVA as a safe and effective drug for its intended use, an injunction shall remain in effect prohibiting defendants' use of AVA on the basis that the vaccine is either a drug unapproved for its intended use or an investigational new drug within the meaning of 10 U.S.C. § 1107. Accordingly, the involuntary anthrax vaccination program, as applied to all persons, is rendered illegal absent informed consent or a Presidential waiver; and it is further

ORDERED that, in light of the finding with regard to Plaintiffs' Motion for Summary Judgment, Defendants' Motion for Summary Judgment is **DENIED.**

A separate Order and Judgment accompanies this Memorandum Opinion.

Signed: Emmet G. Sullivan
United States District Judge
October 27, 2004