View U.S. District Court Opinion

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

Civil Action No. 03-707(EGS)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2003 U.S. Dist. Ct. Motions 707; 2004 U.S. Dist. Ct. Motions LEXIS 6278

April 7, 2004

Motion for Summary Judgment

VIEW OTHER AVAILABLE CONTENT RELATED TO THIS DOCUMENT: U.S. District Court: Brief(s); Motion(s); Pleading(s)

COUNSEL: [**1] Respectfully submitted, PETER D. KEISLER, Assistant Attorney General, ROSCOE C. HOWARD, JR. United States Attorney, BRIAN D. BOYLE, Principal Deputy Associate Attorney General, SHANNEN W. COFFIN, Deputy Assistant Attorney General, JOSEPH H. HUNT, VINCENT M. GARVEY, CRAIG M. BLACKWELL, DC Bar # 438758, RONALD J. WILTSIE, ANDREW H. TANNENBAUM, Attorneys, Civil Division, U.S. Department of Justice, P.O. Box 883, Washington, D.C. 20044, Tel: (202) 307-1401, Fax: (202) 616-8470.

Attorneys for defendants.

TITLE: DEFENDANTS' MEMORANDUM OF POINTS AND AUTHORITIES IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

TEXT: PRELIMINARY STATEMENT

The broad Administrative Procedure Act ("APA") challenge in plaintiffs' amended complaint has been reduced almost entirely to a claim that the Food and Drug Administration ("FDA"), in issuing its Final Order categorizing Anthrax Vaccine Adsorbed ("AVA") as a Category I, safe and effective, biological product, see Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review ("FDA Order" or "Order"), *69 Fed. Reg. 255* (Jan. 5, 2004), violated certain *procedural* requirements for rulemakings under the APA. Indeed, plaintiffs, in their summary judgment brief ("P1. [**7] Br."), barely discuss the *substance* of FDA's determination or the critical scientific evidence upon which FDA relied, namely, the adequate and well-controlled study conducted by Drs. Brachman, Gold, Plotkin, Fekety, Werrin, and Ingraham ("Brachman" or "Brachman study").

Plaintiffs' procedural claim, however, like their now de-emphasized substantive challenge, is meritless. The procedural challenge proceeds, initially, from an incorrect premise: that the Order is a "rule" subject to APA rulemaking requirements. It is not. FDA's determination to confirm AVA's previously-issued license by categorizing it in Category I is an "order," not a "rule," and, as such, is not subject to APA requirements for rulemaking.

Even if those requirements do apply, however, the Order is procedurally sound. Again, plaintiffs' arguments proceed from faulty assumptions. Plaintiffs' "logical outgrowth" argument, for example, assumes that the Order represents a change in agency position. But as we explained in our opening brief ("Def. Br."), FDA's final decision is identical to what FDA proposed in 1985 -- i.e., to place AVA in Category I, thereby confirming it as a properly-licensed, safe and effective, [**8] biological product -- and to the recommendation of the Panel on Review of Bacterial Vaccines and Toxoids ("Panel"). Moreover, plaintiffs' argument that FDA erred in considering [*2] post-comment studies and data assumes that these post-comment sources formed the basis for FDA's determination that AVA is effective. Not so. FDA relied for its effectiveness determination on the Brachman study. The post-comment sources corroborated FDA's determination.

Plaintiffs' narrow substantive challenge -- that FDA relied improperly on animal studies for its effectiveness determination -- flows from their procedural argument with respect to post-comment sources and is wrong for the same reason. FDA relied on the Brachman study for effectiveness and considered the Panel's summary of the CDC surveillance data and the animal study data as corroborative information, as it was entitled to do. Plaintiffs' brief argument that FDA failed to take into account historical changes in the vaccine also lacks merit. The Order explains at length the basis for FDA's determination that AVA is comparable to the predecessor versions of the anthrax vaccine, including the vaccine used in the Brachman study.

Plaintiffs' [**9] remaining arguments are also easily dismissed, and only serve to illustrate how marginal their challenge has become. Plaintiffs contend the Order violates an Executive Order dealing with federalism issues, but the Executive Order, by its very terms, does not create privately enforceable rights, and, in any event, has no conceivable bearing on any issue in this case. Plaintiffs' argument for discovery is grasping at straws. Plaintiffs acknowledge, as they must, the fundamental rule that review in APA cases should be confined to the administrative record. Although plaintiffs contend discovery is appropriate under that rule's "bad faith" exception, they offer *no* credible reason in support of their assertion that FDA's decision was the product of bad faith. Nor could they. FDA's decision to agree with the Panel's recommendation and affirm the Category I classification for AVA was based on the merits, and it is the merits for [*3] which plaintiffs simply have no answer. For all these reasons, and those explained at length in our opening brief and below, plaintiffs' motion for summary judgment should be denied.

ARGUMENT n1

n1 This brief responds only to the arguments raised in plaintiffs' brief in support of their motion for summary judgment. We incorporate by reference arguments in our opening brief which provide additional grounds for denying plaintiffs' motion. See, e.g., Def. Br. at 29-31 (demonstrating that plaintiffs lack standing).

[**10]

I. PLAINTIFFS' PROCEDURAL APA CHALLENGE IS MERITLESS

A. The Order Is Not Subject to APA Rulemaking Requirements in *5 U.S.C. § 553*

Plaintiffs' challenge to the Order is largely procedural. They claim that FDA failed to comply with certain notice-and-comment requirements under the APA's rulemaking provision, *5 U.S.C. § 553*. See P1. Br. at 4-12. This argument is wrong, however, because the Order is not subject to APA rulemaking requirements.

The APA defines two broad, mutually exclusive 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"); see also *id at 218-19* (citing Attorney General's Manual on the Administrative Procedure Act ("AG Manual") 13-14 (1947)). The APA defines a "rule" as:

> the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, [**11] procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices [*4] bearing on any of the foregoing.

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

> 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 than rule making but including licensing an agency in a matter other than ruling.

Id. § 551(6). n2 "Adjudication," which also can be formal or informal, is the "agency process for the formulation of an order." Id. § 551(7). Agency action which falls outside the definition [**12] of a "rule" is not subject to APA rulemaking requirements. See Id. § 553 (establishing procedures for "rule making"); see also, e.g., *Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 401, 414, 417 (1971)* ("procedural requirements" in *5 U.S.C. § 553* related to formal rulemaking "do not apply" to agency action deemed "not an exercise of a rulemaking function"); *Sprint Corp. v. F.C.C., 315 F.3d 369, 373 (D.C. Cir. 2003)* (noting that, "in contrast to an informal adjudication," agency action meeting the definition of a substantive rule "triggers the APA notice requirement"); *Underwater Exotics, Ltd. v. Secretary of the Interior, 1994 WL 80878,* at *9-10 (D.D.C. Feb. 28, 1994) (licensing determination not subject to APA notice and comment [*5] requirements).

> n2 The APA defines a "license" as "the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission." *5 U.S.C. § 551(8)*. "Licensing" is further defined as the "agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license." Id. § 551(9). APA requirements for licensing proceedings are set out in *5 U.S.C. § 558*.

[**13]

FDA's decision to place AVA in Category I, thereby confirming it as a properly-licensed, safe and effective biological product, is not a "rule" within the meaning of the APA. As we explained in our opening brief (see Def. Br. at 6), prior to 1972, a predecessor agency, the National Institutes of Health ("NIH"), was responsible for licensing biological products under the Public Health Service Act. See Redelegation of Authority to Administer Certain Provisions of the Federal Food, Drug, and Cosmetic Act, *37 Fed. Reg. 4,004, 4,005* (Feb. 25, 1972). In 1972, NIH's licensing authority was transferred to FDA. See Statement of Organization, Functions, and Delegations of Authority, *37 Fed. Reg. 12,865* (June 29, 1972). That same year, FDA, of its own accord, determined to review the safety, effectiveness, and labeling of all previously-licensed biological products. See Procedures for Review of Safety, Effectiveness and Labeling, *37 Fed. Reg. 16,679* (Aug. 18, 1972).

In its Federal Register notice proposing the review procedures -- which ultimately were codified at *21 C.F.R. § 601.25* ("Section 601.25") -- FDA explained that, at the end [**14] of the review process, the "applicable product licenses" would be "confirmed, revoked, or permitted to remain in effect on an interim basis pending further study." See *37 Fed. Reg. at 16,679*. The regulations thus require FDA to designate products under review as either (a) "safe and effective and not misbranded" ("Category I"); (b) "unsafe, or ineffective, or . . . misbranded" ("Category II"), in which

case the product licenses "shall be proposed to be revoked"; or (c) neither category, because "the available data are insufficient to classify such biological products" ("Category III"). See *21 C.F.R. §§ 601.25(f)*, (g); see also id. § 601.26 (procedures for reclassifying certain products in Category III into Category I or II).

[*6] 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)* (defining "order" to mean "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but *including licensing*" [**15]) (emphasis added). n3 Section 601.25 itself refers to FDA's determination as an "order." See *21 C.F.R. § 601.25(f)* (requiring FDA to publish a "proposed order" designating the products under review according to their safety, effectiveness, and labeling); Id. § 601.25(g) (requiring FDA to publish a "final order on the matters covered in the proposed order").

n3 The process by which FDA reviewed NIH's prior licensing determinations is best characterized, for APA purposes, as an "informal" adjudication. See *Bettucci v. United States, 14 F. Supp. 2d 45, 51 (D.D.C. 1998)* (noting that "an informal adjudication . . . is a residual category including all agency actions that are not rulemaking and that need not be conducted through' on the record' hearings'") (internal citation omitted).

Indeed, it is hard to see how FDA's decision could be viewed as anything but an "order" for purposes of the APA. For example, FDA's process for licensing biological products is not itself subject to rulemaking [**16] requirements. See, e.g., *42 U.S.C. § 262(a)(2)(A)* ("the Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses"); *21 C.F.R. §§ 601.2-601.9* (procedures for applying for, issuing, denying, suspending, and revoking biological licenses). Thus, if AVA were a new biological product for which its manufacturer were seeking an initial license, FDA, in determining whether to grant the license, would not be required by the APA's rulemaking provision to publish its licensing decision for notice and comment. It follows, *a fortiori*, then, that FDA's review of AVA's *existing* license -- to confirm, or not, whether the license continues to be appropriate -- is not [*7] subject to notice-and-comment requirements.

FDA's decision placing AVA in Category I and confirming its status as properly licensed also bears none of the hallmarks of a "rule." For example, the decision does not "implement, interpret, or prescribe law or policy." *5 U.S.C. § 551(4)*. It merely applies already-existing legal standards (those set forth in Section 601.25(d)) to specific facts involving a specific [**17] party before the agency. This is the very hallmark of adjudication. n4 And the decision also 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. *Bowen, 488 U.S. at 219* (Scalia, J., concurring) (quoting AG Manual at 13-14); see also *Goodman v. F.C.C., 182 F.3d 987, 994 (D.C. Cir. 1999)* ("also like an adjudicatory decision, and unlike a rule, the Implementation Order was retrospective in that it extended the build out deadline to licenses that had already been issued") (citing, e.g., Justice Scalia's concurring opinion in Bowen).

n4 See, e.g., *Bowen, 488 U.S. at 221* (Scalia, J., concurring) ("adjudication deals with what the law was; rulemaking deals with what the law will be") (emphasis deleted); *United States v. Florida East Coast R.R. Co., 410 U.S. 224, 245-46 (1973)* (in discussing distinction between rulemaking and adjudication, noting the "recognized distinction in administrative law between proceedings for the purpose of promulgating policy-type rules or standards, on the one hand, and proceedings designed to adjudicate disputed facts in particular cases on the other"); *F.T.C. v. Brigadier Indus. Corp., 613 F.2d 1110, 1117 (D.C. Cir. 1979)* ("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 particular persons or practices through the application of preexisting legal standards") (internal citations and footnotes omitted). FDA complied with APA rulemaking requirements in promulgating Section 601.25. See Procedures for Review of Safety, Effectiveness and Labeling, *37 Fed. Reg.*

16,679-80 (Aug. 18, 1972) (proposed regulation); Procedures for Review of Safety, Effectiveness and Labeling, *38 Fed. Reg. 4,319* (Feb. 13, 1973) (final regulation).

[**18]

Consistent with Section 601.25(g), FDA referred to its licensing decision as a "final order" in several places in the Order. See FDA Order at 257 ("IV. Categorization of Products -- [*8] Final Order"); accord id. at 255 ("Action: Final rule and final order"); Id. ("Dates: This rule is effective January 4, 2003. The final order on categorization of products is effective January 5, 2004"). n5 We acknowledge, however, that the label an agency puts on a given exercise of administrative power is not conclusive. See, e.g., *National Family Planning and Reproductive Health Assoc., Inc. v. Sullivan, 979 F.2d 227, 237 (D.C. Cir. 1992)*. In fact, the Federal Register document containing FDA's proposal concerning the Panel report was called a "proposed rule," see Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, *50 Fed. Reg. 51,002* (Dec. 13, 1985), because it also "proposed to amend certain existing biologics regulations." See AR1377 n.4 (FDA citizen petition response). n6 Moreover, the Federal Register document publishing the Order also refers generically at times to "this final rule." See, e.g. [**19] , FDA Order at 258, 259 n.2. n7 In any event, to the extent the label ("order") in Section 601.25 is relevant, it is because the label is consistent with what FDA has, in fact, done -- confirm a predecessor agency's licensing determination. See *5 U.S.C. § 551(6)* (defining "order" to include "the whole or a part of a final disposition . . . of an agency in a matter . . . including licensing"); see also *Goodman, 182 F.3d at 994* ("that the Implementation Order appeared under the [*9] heading Final Rules' may reveal something about the care taken in writing headings when documents are published in the Federal Register but does not alter the clearly adjudicatory nature of the Order itself").

n5 As noted in our opening brief (see Def. Br. at 19 n.20), the Federal Register document publishing the Order was designated a "Final Rule and Final Order" (see FDA Order at 255) because it also contained a final rule relating to certain additional standards for one of the biological products under review. See id. at 265
.

n6 Thus, the citizen petition response also referred to the review process related to AVA as the "Biologics Review rulemaking for anthrax vaccine." AR1378; see also id (stating that "FDA should complete the Biologics Review for anthrax vaccine by issuing a final rule pursuant to *21 CFR 601.25*"). Under Section 601.25(f), the Federal Register document publishing FDA's proposal concerning the Panel report could properly have been called a "proposed rule and proposed order." See *21 C.F.R. § 601.25(f)*
[**20] .

n7 Some such statements in the Order are references to the part of the document that is, in fact, a final rule. See FDA Order at 265 (Part IX.A).

Finally, as plaintiffs note (Pl. Br. at 5), FDA did provide interested parties an opportunity to comment on its proposed order categorizing AVA as a Category I product. FDA was required to do so under Section 601.25, which, as a matter of agency discretion, affords interested persons 90 days to comment on a proposed order after publication in the Federal Register. See *21 C.F.R. § 601.25(f)(4)*. Agencies, of course, have such discretion to employ "extra procedural devices," *Vermont Yankee Nuclear Power Corp. v. N.R.D.C., Inc., 435 U.S. 519, 546 (1978); Brigadier Indus. Corp., 613 F.2d at 1116,* and FDA's decision to provide *more* procedures than the APA required did not transform the license review into a rulemaking proceeding. See *Florida East Coast R.R., 410 U.S. at 236 n.6; Goodman, 182 F.3d at 994* (noting that an agency may seek comment in an "adjudicatory" proceeding). [**21] It is the "nature of the decision to be reached in the proceeding" which is decisive. *Brigadier Indus. Corp., 613 F.2d at 1117*. The substance of FDA's decision was to "confirm" a predecessor agency's licensing decision; that action, we have explained,

is not a "rule" for purposes of the APA. See *Goodman, 182 F.3d at 994* (although proceeding bore some "semblance of a rulemaking," resulting decision was a "non-rulemaking" order because, among other things, it had a "clearly adjudicatory nature"). For all these reasons, FDA's decision to place AVA in Category I, thereby confirming its license, was not an exercise of a rulemaking function, and plaintiffs' procedural challenge based on *5 U.S.C. § 553* should be rejected.

[*10] B. Even Assuming Rulemaking Requirements Apply, the Order is Consistent with *5 U.S.C. § 553*

Even if FDA's licensing decision could somehow be considered a "rule" for purposes of the APA, the Order is fully consistent with APA rulemaking requirements. Plaintiffs contend the Order is procedurally invalid for two related reasons (both based on the incorrect assumption that the Order [**22] is a rule). Plaintiffs claim the Order is not a "logical outgrowth" of the classification FDA proposed in 1985. Pl. Br. at 9-12. Plaintiffs also claim FDA improperly "relied on studies and data that were not in existence at the conclusion of the comment period." Pl. Br. at 5, 6-8. Both arguments are wrong. Moreover, even if FDA technically violated rulemaking requirements, any error is not reversible because plaintiffs have suffered no prejudice.

1. The Order is a "Logical Outgrowth" of FDA's Category I Proposal

Plaintiffs argue the Order violates the APA because it is not a "logical outgrowth" of the proposed classification FDA published for comment in 1985. See Pl. Br. at 9-12. Courts use "logical outgrowth" analysis to determine whether a final rule so differs from a proposed rule that it requires an additional round of notice and comment. The logical outgrowth test does not apply to the Order because it is not a rule. Assuming, arguendo, however, that logical outgrowth applies, the logical outgrowth test is a "functional[]" one, which, as plaintiffs note (see Pl. Br. at 11), asks "whether the purposes of notice and comment have been adequately served,' that [**23] is, whether 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 Ass'n v. E.P.A., 40 F.3d 1266, 1274 (D.C. Cir. 1994)* (internal citation omitted); see also *Spirit of the Sage Council v. Norton, 294 F. Supp. 2d 67, 89 (D.D.C. 2003)*. An agency need not [*11] include "every possible version of a proposed rule in its notice of proposed rulemaking"; so long as it includes a "description of the subjects and issues involved," the APA is satisfied. *National Ass'n of Psychiatric Health Sys. v. Shalala, 120 F. Supp. 2d 33, 39 (D.D.C. 2000);* see also *5 U.S.C. § 553(b)(3)*.

The "logical outgrowth" doctrine would not apply to this case even if the Order were a rule. The entire premise of logical outgrowth analysis is that an agency's final decision has *differed* in some way from its proposal. See, e.g., *City of Waukesha v. E.P.A., 320 F.3d 228, 245 (D.C. Cir. 2003)* ("the traditional APA logical outgrowth' test applies where an agency changes its final regulation in some [**24] way from the proposed regulation for which it provided notice and requested comment"). Here, FDA's final decision is *identical* to what it proposed in 1985, i.e., to place AVA in Category I, thereby confirming it as a properly-licensed, safe and effective, biological product. Compare Biological Products; Bacterial Vaccines and Toxoids; Implementation of Efficacy Review, *50 Fed. Reg. 51,002, 51,104* (Dec. 13, 1985) (proposing, consistent with Panel recommendation, that AVA be placed in Category I); with FDA Order at 259 (FDA "continues to accept the Panel's recommendation and places AVA in Category I"); see also id. at 258 (Table I); Def. Br. at 14.

Plaintiffs' argument that the proposed and final orders differ is based on a misunderstanding of the Panel's recommendation (which FDA proposed to adopt). The Panel did not, as plaintiffs contend in their brief, recommend that AVA be licensed only "to protect a small set of textile workers against *cutaneous* exposure." Pl. Br. at 10 (emphasis in original); see also id. at 11 (arguing that the Order is "the first time the FDA publicly proposed approving the anthrax vaccine for protection against inhalation [**25] anthrax"). As we have explained (see Def. Br. [*12] at 37-38), when the Panel issued its report, AVA, as it is today, was indicated for persons at risk of exposure to the anthrax bacterium ("*B. anthracis*"), and its label did not specify a route of exposure. See, e.g., *50 Fed. Reg. at 51,059* (Panel) (noting AVA's risk-based indication); AR3291-92 (NIH-approved package insert); PL First Amd. Compl., Ex. A (1979 revised package insert). n8 The Panel recommended, and FDA agreed, that AVA, *as licensed*, be categorized as safe and

effective. See *50 Fed. Reg. at 51,059* (Panel); see also id at 51,104. Indeed, in their statement of facts, plaintiffs acknowledge that AVA originally was licensed by NIH "for use against anthrax" -- i.e., without specifying a route of exposure -- and that the Panel recommended that AVA be classified as "'not misbranded.'" See Plaintiffs' Statement of Material Facts as to Which There Is No Genuine Issue, PP 1, 5. n9

n8 Plaintiffs note (see Pl. Br. at 10) that AVA's package insert identified classes of persons presumed to be at risk of exposure to *B. anthracis* for which the manufacturer recommended immunization. But this has no bearing on the route of exposure issue. AVA's package insert, as noted above, does not specify a route of exposure. Moreover, the classes of persons identified in no way implies a limitation in the use of AVA to people only at risk of cutaneous exposure. To the contrary, in addition to recommending immunization for persons "who may come in contact with" certain imported animal hides and furs, etc., the package insert also recommended immunization for "*all personnel* in factories handling these materials" and for "individuals contemplating investigational studies involving *[B. anthracis]*" See AR3291 (NIH-approved package insert) (emphasis added); Pl. First Amd. Compl., Ex. A (package insert as revised in 1979) (emphasis added). Indeed, the Brachman study makes clear that, even for persons "who may come in contact with" imported animal hides and hair, there is a risk of inhalation exposure. See AR3736 at Table 4.
[**26] .

n9 For these reasons, and as we explained in our opening brief (see Def. Br. at 37), the Court erred in its preliminary injunction opinion when it stated that the Panel found "insufficient data to license [AVA] for use against inhalation anthrax." *Doe v. Rumsfeld, 297 F. Supp. 2d 119, 133 (D.D.C. 2003)*. We note that, since the Court issued its opinion, FDA, in its Order, plainly has interpreted the Panel's ultimate Category I recommendation as a recommendation that AVA be categorized as safe and effective regardless of the route of exposure. See FDA Order at 259 (noting that, while "FDA has identified points of disagreement with statements in the Panel report," FDA "has determined that the data do support the safety and efficacy of the vaccine and, thus, the agency continues to accept the Panel's recommendation and places AVA in Category I").

[*13] Plaintiffs note (Pl. Br. at 8, 10-11) that FDA, although adopting the Panel's recommendation, disagreed in its Order with certain statements in the Panel report about whether the Brachman study supported the vaccine's [**27] use as protection against inhalation anthrax (suggesting, in effect, that this disagreement represents a "departure" from FDA's proposal). See FDA Order at 259; see also Def. Br. at 20-21, 36-39. But this does not change the fact that FDA and the Panel reached the same conclusion with respect to AVA's license. Moreover, FDA, in its 1985 proposal, was not seeking comment on specific statements in the Panel report; it was seeking comment on its "proposed classification of products into Category I." See *50 Fed. Reg. at 51,002;* see also FDA Order at 257 ("the purpose of the opportunity for comment was to allow comment on FDA's responses to the Panel's report and not on the Panel's report directly"). All aspects of FDA's proposed Category I designation for AVA were open for public comment, including, of course, the issue of the vaccine's effectiveness against inhalation exposure.

To the extent the Panel statements are relevant, they show the degree to which the inhalation issue *was* presented for public comment. The Panel recommended Category I *notwithstanding* its (erroneous) belief that the Brachman study did not assess the protective effect [**28] of the vaccine against inhalation anthrax. This plainly "framed . . . for discussion,'" *Omnipoint Corp. v. F.C.C., 78 F.3d 620, 631 (D.C. Cir. 1996)* (internal citation omitted), the issue whether AVA *should* be placed in Category I for use against inhalation exposure. n10 Thus, even if the [*14] logical outgrowth doctrine applies, FDA provided the "opportunity for interested parties to offer comments that could persuade the agency to modify its rule." *American Water Works Ass'n, 40 F.3d at 1274;* see also *Spirit of the Sage Council, 294 F. Supp. 2d at 89* (same). n11 For all these reasons, plaintiffs' logical outgrowth argument should be rejected.

n10 In fact, for other products under review, the Panel did recommend different categories for different product uses. See, e.g., *50 Fed. Reg. at 51,019* (Panel) (for Diphtheria Toxoid, Fluid, manufactured by Texas Department of Health Resources, recommending Category I "as regards its use for booster immunization" and Category IIIA "as regards its use for primary immunization"); *Id. at 51,021* (Panel) (for Tetanus Toxoid Adsorbed, manufactured by Michigan Department of Public Health, recommending Category I "as regards its use for booster immunization" and Category IIIA "as regards its use for primary immunization") (license revoked in 2000 at request of manufacturer).

[**29]

n11 Indeed, the October 2001 citizen petition discussed in our opening brief (see Def. Br. at 17-19) specifically requested that FDA "issue a Final Rule on the drug category placement of anthrax vaccine as Category II." AR1313. The petition -- which was signed by plaintiffs' counsel John Michels, Jr. (see AR1344) -- argued, among other things, that the scientific evidence the Panel discussed did not establish AVA's effectiveness, see, e.g., AR1316, AR1319, AR1320, and specifically noted the Panel's statement that the vaccine's "'efficacy against inhalation anthrax is not well documented.'" AR1319 (quoting *50 Fed. Reg. at 51,058* (Panel)). Thus, members of the public, including plaintiffs' counsel, plainly interpreted FDA's proposal as raising the issue of the vaccine's effectiveness "against inhalation anthrax." Pl. Br. at 11.

2. Consideration of the IOM Report and Animal Study Data as Corroborating Evidence Was Appropriate

Plaintiffs contend FDA violated APA notice-and-comment [**30] requirements by "relying on studies and data that were not in existence at the conclusion of the comment period." Pl. Br. at 5. Specifically, plaintiffs contend FDA improperly "relied" on (i) the Institute of Medicine report ("IOM report") prepared by the "Committee to Assess the Safety and Efficacy of the Anthrax Vaccine" ("IOM Committee"); and (ii) three animal studies considered by the IOM Committee and FDA. See Pl. Br. at 6 (citing references in the FDA Order). This argument is wrong.

As an initial matter, the Order is not a rule, but even assuming that it should be treated as a rule, plaintiffs' argument is fully answered by our showing, supra, that the Order satisfies "logical outgrowth" analysis. Where a final rule is a logical outgrowth of the proposal, an agency may consider post-comment sources without submitting those sources for notice and comment. See *Spirit of the Sage Council, 294 F. Supp. 2d at 88* ("'a final rule that is a logical outgrowth of [*15] the proposal does not require an additional round of notice and comment even if the final rule relies on data submitted during the comment period'") (quoting *Building Indus. Ass'n of Superior California v. Norton, 247 F.3d 1241, 1246 (D.C. Cir. 2001),* [**31] cert. denied, *534 U.S. 1108(2002)).*

But even if a separate analysis is required, plaintiffs' argument lacks merit. Plaintiffs acknowledge, as they must, that the APA does not bar agencies from using post-comment studies and data in all circumstances. For example, as plaintiffs note, an agency may consider post-comment studies that "provide support for the same decision [the agency] had proposed to take,'" Pl. Br. at 8 (quoting *Building Indus. Ass'n, 247 F.3d at 1246),* or "supplementary data, unavailable during the notice and comment period, that expand on and confirm' information contained in the proposed rulemaking." Pl. Br. at 8 (quoting *Solite Corp. v. E.P.A., 952 F.2d 473, 484 (D.C. Cir. 1991));* accord *Community Nutrition Inst. v. Block, 749 F.2d 50, 58 (D.C. Cir. 1984)* (Scalia, J.) (distinguishing such data from "entirely new information critical' to the [agency's] determination").

The IOM report and animal studies fall squarely within this rule. First, these post-comment sources merely "provided support for the same decision" FDA proposed in 1985 -- i.e., to place AVA in Category I, thereby confirming [**32] it as a properly-licensed, safe and effective, biological product. See discussion supra Part I.B.1. And second, as explained in our opening brief (see Def. Br. at 41 n.35), and in more detail below (see infra Part II), FDA relied on the Brachman study for proof of AVA's effectiveness. See FDA Order at 259-60. The post-comment sources were

"supplementary" data (*Solite Corp, 952 F.2d at 484),* which corroborated Brachman, et al.'s findings. FDA agreed with these sources, but did not rely on them for proof of effectiveness for purposes of Section 601.25(d)(2). See FDA Order at 260 ("FDA agrees with [*16] the [IOM] report's finding that studies in humans and animal models support the conclusion that AVA is effective against *B. anthracis* . . . regardless of the route of exposure"). n12 Plaintiffs' post-comment-studies argument, accordingly, should be rejected.

n12 Indeed, FDA reached the same conclusions about AVA's effectiveness in its citizen petition response without citing the IOM report or the animal studies referenced in the Order. See AR1379-81 (concluding that the Brachman study qualifies as a well-controlled study for purposes of evaluating AVA's effectiveness); AR1381 (concluding that "the efficacy analysis actually conducted in the Brachman study includes all cases of anthrax disease regardless of the route of exposure or manifestation of the disease"); Id. (concluding that, consistent with the Brachman study findings, "the indication section of the [vaccine's] labeling does not specify the route of exposure and thus includes both cutaneous and inhalation exposure").

[**33]

3. Plaintiffs Cannot Establish Prejudice from the Alleged Procedural Violations

Even if (i) FDA's decision to confirm AVA's license could somehow be considered a "rule" for purposes of the APA, and (ii) plaintiffs' procedural argument is accepted, the Court should not, as plaintiffs request, "vacate" the Order and "remand the matter to the FDA for proper consideration and determination . . . of the licensing status of AVA." Pl. Br. at 3. Although vacatur is the normal remedy for an APA violation, a plaintiff must still "show prejudice from an agency procedural violation." *City of Waukesha, 320 F.3d at 246;* accord *5 U.S.C. § 706(2)* (in determining whether to "set aside" agency action taken "without observance of procedure required" by law, "due account shall be taken of the rule of prejudicial error"). Plaintiffs cannot make such a showing here.

To establish prejudice on the basis of their "logical outgrowth" argument (i.e., their argument that FDA failed to seek public comment on the vaccine's effectiveness against inhalation exposure (see Pl. Br. at 11)), plaintiffs generally must show (i) that, "had proper notice been provided, [**34] they would have submitted additional, different comments that could have [*17] invalidated the rationale for the revised rule"; or (ii) that "the agency has entirely failed to comply with notice-and-comment requirements, and the agency has offered no persuasive evidence that possible objections to its final rules have been given sufficient consideration'" (in which case prejudice is presumed). *City of Waukesha. 320 F.3d at 246* (internal citations omitted). n13

n13 See also id. (leaving "open the possibility that there may be situations" where a plaintiff "is unable to provide a proffer of additional comments for valid reasons"); *Sprint Corp., 315 F.3d at 377* (showing of actual prejudice not required in situation similar to (ii)).

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., AR1376-85 (FDA [**35] citizen petition response dealing at length with, among other things, arguments about the Brachman study); see also supra n.10. In its Order, FDA expressly referred to the citizen petition and its response. See FDA Order at 259 n.2. Plaintiffs likewise cannot make the second showing for the same reason. Even assuming that the Order is subject to rulemaking requirements and that FDA "'entirely failed'" to comply with notice-and-comment procedures (an unwarranted assumption given that FDA in fact provided a 90-day comment period), FDA's citizen petition response provides "'persuasive evidence'" that it considered fully "'possible objections'" to the Order. *City of Waukesha, 320 F.3d at 246* (internal citations omitted); compare *Sprint Corp., 315 F.2d at 377* (finding reversible error where the effect of a procedural error is "uncertain").

As for plaintiffs' post-comment studies argument, consideration of a post-comment source "is reversible error" where an agency rule "cannot be supported without it or where there is [a] substantial likelihood [the] rule would have been significantly changed had opportunity for [*18] comment existed. [**36] " *American Iron and Steel Inst. v. O.S.H.A., 939 F.2d 975, 1010 (D.C. Cir. 1991)* (summarizing, in a parenthetical, *Small Refiner Lead Phase-Down Task Force v. E.P.A., 705 F.2d 506, 541 (D.C. Cir. 1983))*. As we explained at length in our opening brief, see Def. Br. at 36-39 & 41 n.35, FDA's effectiveness determination is fully, and adequately, supported by the Brachman study, upon which FDA relied for proof of AVA's effectiveness under Section 601.25(d)(2). See also infra Part II (discussing this issue in detail). Although the IOM report and animal studies corroborated FDA's effectiveness decision, see id., the Order plainly can be "supported without [them]." *American Iron and Steel Inst., 939 F.2d at 1010*. Moreover, and for this same reason, there is no "substantial likelihood" the Order would have changed if FDA had published the IOM report and animal studies for comment. For all these reasons, plaintiffs' procedural APA challenge should be rejected.

II. PLAINTIFFS' SUBSTANTIVE APA CHALLENGE IS MERITLESS

Plaintiffs' substantive challenge is most notable for what plaintiffs do *not* argue. Plaintiffs do [**37] not, for example, challenge the Order to the extent it confirms AVA as safe for human use, or as safe and effective for use against cutaneous anthrax; they do not challenge FDA's interpretation of the Brachman study, or contend that study is not a controlled clinical investigation for purposes of assessing AVA's effectiveness; and they do not challenge FDA's interpretation of AVA's label as "indicated for active immunization against *Bacillus anthracis*, independent of the route of exposure." FDA Order at 260. What plaintiffs do raise are two narrow challenges to the Order. They contend, first, that FDA improperly "relied" on animal studies for substantial evidence of AVA's effectiveness; see Pl. Br. at 12-15; and, second, that FDA "failed to take into account significant changes in the manufacturing process of the [*19] vaccine." See Id. at 15. Both contentions are wrong. n14

n14 Plaintiffs acknowledge that the Order's substance should be judged under the "arbitrary and capricious" standard of review set forth in *5 U.S.C. § 706(2)(A)*. See Pl. Br. at 12 (citing *Spirit of the Sage Council, 294 F. Supp. 2d at 90))*. We explained the deferential nature of this review at length in our opening brief. See Def. Br. at 26-28. Plaintiffs also acknowledge that judicial review in APA cases should be limited to the administrative record. See Pl. Br. at 20; see also, e.g., *Berlex Labs., Inc. v. FDA, 942 F. Supp. 19, 23 (D.D.C. 1996)* (refusing to consider extra-record materials submitted by plaintiff). Notwithstanding this latter acknowledgment, plaintiffs, at various points throughout their brief and in their exhibits, cite extra-record sources in support of their position. See, e.g., Pl. Br. at 13 n.9 (citing a Washington Post article); *Id. at 19 & n.12* (citing a letter from the Connecticut Attorney General, also attached as an exhibit). Plaintiffs do not seek to "supplement" the record with these extra-record sources (nor could they), and the Court, accordingly, may not consider them. See, e.g., *National Treasury Employees Union v. Hove, 840 F. Supp. 165, 169 (D.D.C. 1994)* ("consideration of outside evidence to determine the correctness or wisdom of the agency's decisions is not permitted'") (internal citation omitted). In Part IV infra, we explain that plaintiffs' request for discovery should be denied.

[**38]

Plaintiffs' first argument is based on a misreading of the Order. That is, plaintiffs' contention that "the entire substantive basis" of the Order "relies on animal studies and data regarding the efficacy of the vaccine" (Pl. Br. at 15) is simply wrong. FDA has never contended that the animal efficacy rule (see Part 601, Subpart H) formed the basis for its decision to retain the Category I classification for AVA. Rather, as we have explained, see, e.g., Def. Br. at 36-39 & 41 n.35, FDA relied on the Brachman study-a "controlled clinical investigation" -- to provide "proof of effectiveness" for purposes of Section 601.25(d)(2). n15 See also AR1379-81 (citizen petition response explaining that the Brachman study qualifies as an adequate and well-controlled investigation for purposes of *21 C.F.R. § 601.25(d)*).

n15 Section 601.25(d)(2), which defines the standard for determining "effectiveness," states that: "proof of

> effectiveness shall consist of controlled clinical investigations as defined in § 314.126 of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the biological product or essential to the validity of the investigation, and that an alternative method of investigation is adequate to substantiate effectiveness." *21 C.F.R. § 601.25(d)(2)*.

[**39]

[*20] Plaintiffs are correct that FDA cited the IOM Committee's findings with respect to animal data and three animal studies in its Order. See FDA Order at 260; see also Def. Br. at 40-41 (reviewing these sources). But FDA did not rely on animal studies to establish effectiveness under Section 601.25; it relied on the Brachman study for that point, and considered the IOM Committee's findings and the animal studies as corroborating evidence. n16 See FDA Order at 260 ("FDA agrees with the [IOM] report's finding that studies in humans and animal models *support* the conclusion that AVA is effective against *B. anthracis* strains that are dependent upon the anthrax toxin as a mechanism of virulence, regardless of the route of exposure") (emphasis added); *id at 260 n.5* (citing three animal studies from the IOM report). n17

> n16 As noted in our opening brief (see Def. Br. at 39), FDA also considered the Panel's summary of the CDC surveillance data as corroborating evidence of effectiveness. See FDA Order at 260
>
> .

> n17 The animal studies FDA considered as corroborative evidence are: P.F. Fellows, et al., "Efficacy of a Human Anthrax Vaccine in Guinea Pigs, Rabbits, and Rhesus Macaques Against Challenge by *Bacillus Anthracis* Isolates of Diverse Geographical Origin," 19 *Vaccine* 3241-47 (2001) ("Fellows") (AR621-27) (cited in the IOM report at AR3397); B.E. Ivins, et al., "Efficacy of a Standard Human Anthrax Vaccine Against *Bacillus Anthracis* Aerosol Spore Challenge in Rhesus Monkeys," 87 *Salisbury Medical Bulletin* 125-26 (1996) ("Ivins, *Salisbury*") (AR628-29) (cited in the IOM report at AR3398); B.E. Ivins, et al., "Comparative Efficacy of Experimental Anthrax Vaccine Candidates Against Inhalation Anthrax in Rhesus Macaques," 16 *Vaccine* 1141-48 (1998) ("Ivins, *Vaccine*") (AR630-37) (cited in the IOM report at AR3398).

[**40]

Plaintiffs contend these studies are "inadmissible" (Pl. Br. at 12), but offer no support for that point. Nor could they. Section 601.25 specifically states that clinical investigations "may be corroborated" by data which, standing alone, would not be adequate to substantiate effectiveness. See *21 C.F.R. § 601.25(d)(2)* ("investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during marketing"). And even without Section 601.25, plaintiffs offer no [*21] reason why FDA should be precluded from considering the IOM Committee's findings with respect to animal data. That Committee was specifically charged by Congress with considering AVA's safety and effectiveness, including the "correlation of animal models to safety and effectiveness in humans." See H.R. Rep. No. 106-371, at 254 (1999).

In terms of their weight, the animal studies FDA considered as corroborating evidence demonstrate that humans and nonhuman primates both manifest anthrax disease after infection with *B. anthracis* and that both are protected by immunization with AVA, which elicits [**41] the production of antibodies to protective antigen ("PA"). See Def. Br. at 40-41 (summarizing animal data); AR626 (Fellows); AR629 (Ivins, *Salisbury*); AR635 (Ivins, *Vaccine*); see also AR3387-88 (IOM); Def. Br. at 10-11 & 39 n.34 (explaining the pathogenesis of *B. anthracis* and the importance of PA antibodies to establishing immunity).

It is true that researchers have not yet established a quantitative correlation of the protective levels of PA antibodies in animals with the antibodies obtained after immunization in humans. See, e.g., AR 629 (Ivins, *Salisbury*); see also

AR3392 (IOM). n18 But again, the animal studies were not the basis for FDA's effectiveness determination; they simply corroborated that determination and were cited to illustrate additional support for FDA's decision. FDA's consideration of the IOM Committee's findings and animal data as corroborating evidence thus plainly is reasonable, and certainly not arbitrary, capricious, or an abuse of discretion. See, e.g., *Bristol-Myers Squibb Co. Shalala, 923 F. Supp. 212, 220 (D.D.C. 1996).*

> n18 We note that, notwithstanding the lack of a quantitative correlation between human and animal models, see AR3329 (IOM), the IOM Committee concluded, based on "evidence from studies in both humans and animals," that "AVA, as licensed, is an effective vaccine to protect humans against anthrax, including inhalation anthrax." AR 3323.

[**42]

[*22] Plaintiffs' second basis for challenging the Order is difficult to follow. Plaintiffs note that there were two prior versions of the anthrax vaccine -- the PA-based vaccine manufactured by the Department of Defense ("DoD") at Fort Detrick (which Brachman, et al., used in their study), and a subsequent PA-based vaccine manufactured by Merck Sharp & Dohme. See Pl. Br. at 15 (discussing FDA Order at 260). Plaintiffs then state that "typically, these types of changes in manufacturing and formulation require a new license application and testing." Pl. B. at 16. But the "changes in manufacturing" plaintiffs cite occurred *prior* to licensure of AVA by NIH (the manufacturer at the time of licensure was the Michigan Department of Public Health). By definition, therefore, these "changes" could not have required a "new" license. Compare *21 C.F.R. § 601.12* (requiring manufacturers to submit to FDA for approval changes made to manufacturing *after* licensure is approved).

Moreover, plaintiffs' argument also misunderstands FDA's comparability policy, under which a manufacture may use data gathered with a previous version of a product to support the effectiveness [**43] of a comparable version of the same product after a manufacturing change. See AR 1400 (FDA comparability guidance). In its Order, FDA explained at length the basis for its conclusion that AVA is comparable to the original DoD vaccine used in the Brachman study. See FDA Order at 260-61; Def. Br. at 21-22 & n.23. Indeed, plaintiffs' concession that AVA is effective for cutaneous exposure presumably is based on the Brachman study. For all these reasons, plaintiffs' substantive APA challenge should be rejected.

III. AGENCY COMPLIANCE WITH EXECUTIVE ORDER 13,132 IS NOT SUBJECT TO JUDICIAL REVIEW

Plaintiffs contend the Order should be "invalidated" because it "violates federalism concerns." Pl. Br. at 16. In support, plaintiffs cite Executive Order ("EO") 13,132, *64 Fed. Reg.* [*23] *43,255* (Aug. 4, 1999), which establishes guidelines and criteria for federal agencies to follow in formulating and implementing policies with federalism implications. See Pl. Br. at 17-20. According to plaintiffs, FDA violated EO 13,132 because it failed to consult with "State and local officials'" prior to issuing the Order. See Pl. Br. at 19 (quoting EO 13,132, § [**44] 6(b)). This farfetched claim, which plaintiffs did not even raise in their complaint, is meritless for numerous reasons.

First, FDA's compliance with EO 13,132 is not subject to judicial review. Section 11 expressly states the EO is not intended to create privately enforceable rights:

> Judicial Review. This order is intended only to improve the internal management of the executive branch, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

EO 13,132, § 11. Courts have interpreted similar language in other executive orders as precluding judicial review of an agency's compliance with the order's underlying provisions. n19 In particular, courts have noted that judicial review is

not available for agency compliance with EO 12,612, *52 Fed. Reg. 41,685* (Oct. 26, 1987), the predecessor executive order to EO 13,132 which contained a provision identical to Section 11. n20 This is consistent with the test courts [*24] apply in determining whether statutes create privately enforceable rights, where "the dispositive question" is "whether [**45] Congress intended to create any such remedy." *Transamerica Mortgage Advisors, Inc. v. Lewis, 444 U.S. 11, 24 (1979);* see also *Alexander v. Sandoval, 532 U.S. 275, 285-287 (2001)* ("the judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy"). EO 13,132 expressly *disclaims* any intent to create privately enforceable rights.

n19 See *State of Michigan v. Thomas, 805 F.2d 176, 187 (6th Cir. 1986)* ("given this clear and unequivocal intent that agency compliance with Executive Order 12,291 not be subject to judicial review, we hold that the Order provides no basis for rejecting the [agency's] final action"); cf. *In re Surface Mining Regulation Litig., 627 F.2d 1346, 1357 (D.C. Cir. 1980)* (stating general rule that "executive orders without specific foundation in congressional action are not judicially enforceable in private civil suits").

.

n20 See *Hecht v. Barnhart, 217 F. Supp. 2d 356, 359-60 (E.D.N.Y. 2002)* (denying motion to remand to agency for purpose of complying with various executive orders, including EO 12,612, because the executive orders at issue did not create private rights of action); *State of Kansas ex rel. Todd v. United States, 995 F.2d 1505, 1511 (10th Cir. 1993)* ("judicial review is not available for the [agency's] alleged violations of the various Executive Orders [including EO 12,612], which [plaintiff] concedes in its brief"); *Murphy v. Smithkline Beecham Animal Health Group, 898 F. Supp. 811, 815 (D. Kan. 1995)* (citing State of Kansas holding regarding EO 12,612, and noting that "the order serves only as a guideline for executive agencies"); cf. *Public Citizen v. H.H.S., 795 F. Supp. 1212, 1221 (D.D.C. 1992)* (noting that EO 12,612 "specifically states that it does not create a private right of action").

[**46]

Second, even if Section 11 were not dispositive, plaintiffs would lack standing to challenge FDA's compliance with EO 13,132. The executive order (which bears the title "Federalism") is addressed to "the division of governmental responsibilities between the national government and the States"; EO 13,132 (preamble); it does not purport to govern private individual rights. See *City of Roseville v. Norton, 219 F. Supp. 2d 130, 147-48 (D.D.C. 2002)* (holding, in analogous context, that private citizens lack standing to bring claims under the Tenth Amendment), aff'd on other grounds, *348 F.3d 1020 (D.C. Cir. 2003),* petition for cert. filed, No. 03-1156 (Feb. 11, 2004). Moreover, the "federalism" interest plaintiffs seek to raise on behalf of states relates to an issue -- vaccine safety (see Pl. Br. at 18) -- which plaintiffs do not even challenge in this litigation. See *Singleton v. Wulff, 428 U.S. 106, 115 (1976)* (noting that, in "third-party" standing context, courts consider in part whether "the relationship between the litigant and the third party may be such that the former is fully, or very nearly, as effective a proponent [**47] of the right as the latter").

[*25] Third, EO 13,132 does not apply to FDA's decision confirming AVA as a properly-licensed biological product. The EO provision plaintiffs cite -- § 6(b) (see Pl. Br. at 19) -- requires agencies, in certain circumstances, to "consult[]" with State and local officials before "promulgating any *regulation* that has federalism implications, that imposes substantial direct compliance costs on State and local governments, and that is not required by statute." EO 13,132 § 6(b) (emphasis added). n21 But these conditions are not applicable to the FDA Order, which, among other things: (a) is not a "regulation"; see supra Part LA; (b) does not purport to address state law or the relationship between the states and the federal government; and (c) does not impose "compliance costs" on state and local governments. n22 For all of these reasons, plaintiffs' challenge based on EO 13,132 should be rejected.

n21 Plaintiffs contend this consultation process "is to be achieved through the normal APA

notice-and-comment procedures" (Pl. Br. at 18), but nothing they cite even remotely supports that claim. Indeed, EO 13,132, which does not mention the APA, expressly states it is *not* intended to create "procedural" rights. See EO 13,132, § 11.

[**48]

n22 Plaintiffs claim the Order has "substantial direct effects on the States" for purposes of EO 13,132 because DoD, under its mandatory vaccination program ("AVIP"), requires inoculation of State National Guard members called for duty in the National Guard of the United States. See Pl. Br. at 17-18. But the burdens plaintiffs cite -- health-related "strains on the economic and family state system" (id at 18) -- are not ones "imposed" by FDA. See EO 13,132, § 6(b). Moreover, to the extent plaintiffs challenge *DoD's* conduct (which, as plaintiffs note (see Pl. Br. at 1), is not at issue in their motion), AVIP raises no federalism issues. States have no constitutional authority over their guard members ordered to active federal duty in the U.S. National Guard. See *Perpich v. Department of Defense, 496 U.S. 334, 347 (1990)* (members of state guard "ordered into federal service with the National Guard of the United States lose their status as members of the state militia during their period of active duty"); *Id. at 348* (when state guard members called into federal service, "the second Militia Clause is no longer applicable").

[**49]

IV. PLAINTIFFS ARE NOT ENTITLED TO DISCOVERY

Finally, in the event their summary judgment motion is denied, plaintiffs seek discovery "to ensure the administrative record is complete" and to "explore the extent to which the DoD [*26] improperly influenced the FDA's licensing and rule-making process." Pl. Br. at 3 n.3; see also id. at 21-23. Neither ground provides a basis for discovery in this case.

Plaintiffs begin their argument by acknowledging, as they must, that discovery "is not routinely granted in APA record review cases." Pl. Br. at 20. But plaintiffs then confuse the issue by discussing circumstances under which a court may *supplement* an administrative record with specifically-identified documents (something plaintiffs do not seek). See Id. & n.13; see also discussion supra n.11; *James Madison Ltd. v. Ludwig, 82 F.3d 1085, 1095 (D.C. Cir. 1996)* (describing all of the circumstances cited by plaintiffs as related to "supplementation" issues), cert. denied, *519 U.S. 1077 (1997)*. Although courts permit supplementation by a plaintiff in certain narrow instances (but never to determine the wisdom of [**50] an agency's decision), *discovery* of an agency's decisionmaking process is permissible in only two circumstances: (i) where there is a "strong showing of bad faith or improper behavior"; *Community for Creative Non-Violence v. Lujan, 908 F.2d 992, 997 (D.C. Cir. 1990);* or (ii) where discovery "provides the only possibility for effective judicial review and when there have been no contemporaneous administrative findings." Id. (citing *Overton Park, 401 U.S. at 420);* accord *Saratoga Dev. Corp. v. United States, 21 F.3d 445, 457-58 (D.C. Cir. 1994)*. Neither exception applies here.

For example, plaintiffs contend discovery is appropriate because FDA did not "consider[] *all* the relevant evidence." Pl. Br. at 21 (emphasis in original). In support, plaintiffs attach a so-called list of "relevant scientific studies concerning the anthrax vaccine, none of which were apparently considered by the FDA." Id. But this is an (improper) argument about the merits of FDA's decision, see infra n.20, not an argument for discovery. See *National Treasury Employees Union v. Seidman, 786 F. Supp. 1041, 1046 (D.D.C. 1992)* [**51] (rejecting request for discovery of [*27] information plaintiff alleged the agency "should have considered"; noting in part that such discovery "would create a new administrative record for the purpose of second-guessing the agency"). Indeed, notwithstanding the statement in their argument heading (see Pl. Br. at 21), plaintiffs do not contend that FDA *excluded* evidence it considered from the record, or that it failed to produce the "whole" record; they contend only that FDA failed to consider evidence it *should* (by plaintiffs' reckoning) have considered. Discovery can shed no light on that issue; it is undisputed that the sources in

plaintiffs' exhibit were *not* considered. Plaintiffs, tellingly, do not even argue that the sources they cite undermine in any way the merits of FDA's effectiveness decision.

Nor, contrary to plaintiffs' suggestion, is it in any way significant that FDA failed to consider every conceivable article concerning a widely-discussed topic such as AVA. In making effectiveness determinations, FDA is required to rely on scientific data -- i.e., primary data adduced from "controlled clinical investigations." See *21 C.F.R. § 601.25(d)(2)*. [**52] *None* of the sources in plaintiffs' list contains such data. n23 Rather, the sources that discuss effectiveness -- and many of the sources are concerned primarily, if not solely, with issues of safety (which plaintiffs do not challenge) -- merely review, summarize, and/or analyze the existing data and literature. This is no surprise. As we have explained, see, e.g., Def. Br. at 39, the *only* controlled [*28] clinical investigation of effectiveness involving anthrax vaccine -- the Brachman study -- was conducted in the 1950s; for ethical and other reasons, there have been no subsequent controlled clinical effectiveness studies. See, e.g., FDA Order at 260 n.4. n24

n23 After receiving plaintiffs' brief, FDA obtained and reviewed the sources listed in plaintiffs' Exhibit 3. By briefly discussing these sources, we in no way suggest they should be considered by the Court. They may not. See, e.g., *National Treasury Employees Union v. Hove, 840 F. Supp. at 169* ("consideration of outside evidence to determine the correctness or wisdom of the agency's decision is not permitted'") (internal citation omitted); *Doraiswamy v. Secretary of Labor, 555 F.2d 832, 842 (D.C. Cir. 1976)* (affirming denial of discovery where plaintiffs challenged "the correctness" of the agency's decision as opposed to the "fullness of the reasons" given).

[**53] .

n24 Plaintiffs also attempt to raise questions about the Vaccine Adverse Event Reporting System ("VAERS") reports in the record, suggesting a "discrepancy" because the record does not include all VAERS reports from 2003. See Pl. Br. at 21. But this is just another red herring. As the Order states, FDA considered VAERS reports in reviewing "labeling revisions [to AVA's package insert] approved by FDA in January 2002." See FDA Order at 260. Thus, the VAERS reports in the record -- which, for all but a small number of pages, encompass the time period from 1993 through 2001 -- are the reports FDA considered during that process. See AR1418-AR3227.

Plaintiffs also argue they are entitled to discovery into the "validity of the administrative process" under the "bad faith" exception, because (plaintiffs say) they have "evidence of strong DoD influence and pressure upon FDA." Pl. Br. at 22. This is meritless. Agencies are entitled to a "presumption of administrative regularity and good faith." *TOMAC v. Norton, 193 F. Supp. 2d 182, 195 (D.D.C. 2002)*. To overcome that presumption, [**54] and justify "court-sanctioned probing of the administrative process," a plaintiff must make a "'strong showing' of corrupt decisionmaking." *Saratoga Dev. Corp., 21 F.3d at 458;* see also *Balaton. Inc. v. Reno, 93 F. Supp. 2d 61, 62 (D.D.C. 2000)* (assertion that agency "rubber stamps decisions . . . hardly makes out a showing of the kind of devious or corrupt behavior that could qualify as bad faith'"); *TOMAC, 193 F. Supp. 2d at 195*. Conclusory statements of bad faith are insufficient. See *James Madison Ltd., 82 F.3d at 1095* (citing *Overton Park, 401 U.S. at 420)*.

Plaintiffs have not even come close to making this showing. Plaintiffs "evidence" is a series of (what appear to be) almost-five-year-old internal DoD e-mails purporting to discuss a 1999 congressional hearing at which representatives from DoD and FDA testified. See Pl. Br. at [*29] 22-23 & Ex. 4. Plaintiffs note (see Id. at 22) that one email states "'DoD is calling all the shots'" onsite at BioPort (AVA's manufacturer). But even taking this assertion at face value, nothing in DoD's relationship with BioPort suggests that FDA's [**55] decisionmaking process was "corrupt." To the contrary, during this time period, FDA actively carried out its oversight responsibilities with respect to AVA's manufacturer. See AR3511-14 (detailing FDA inspections between 1998 and 2001); AR1326 (citizen petition noting that "FDA has regularly inspected the vaccine production facility").

Indeed, in January 1998, the Michigan Biologics Products Institute ("MBPI"), AVA's prior manufacturer, voluntarily suspended production of AVA to begin a comprehensive renovation of its anthrax vaccine production facility. See AR1388 (FDA citizen petition response). These renovations, while not required by FDA, see id, were corrective actions voluntarily undertaken by MBPI as part of a comprehensive plan to respond to a 1997 Notice of Intent to Revoke letter issued by FDA, see AR1388-89, and it was necessary for FDA to approve the renovations before MBPI could resume shipping licensed anthrax vaccine made in the renovated facilities. See AR1388. Thus, BioPort, which purchased MBPI in September 1998, see AR1377 n.l, did not even ship any licensed finished product anthrax vaccine, made after January 1998, until FDA approved two [**56] license supplements related to the renovations, the last of which was approved in January 2002. n25 See AR 1388.

n25 Indeed, plaintiffs contend that DoD, in 2000, was forced to "suspend[] AVA vaccinations for all but a limited number of personnel because of a shortage of the vaccine." First Amd. Compl. P 52.

Finally, plaintiffs argue that the very fact there *is* no evidence of DoD "influence" in the administrative record justifies discovery into the question whether "DoD improperly or unduly [*30] influenced the FDA's actions with respect to the [Order]." See Pl. Br. at 23. But this turns the presumption of regularity on its head. Courts do not authorize discovery to *find* evidence of bad faith or some interagency "conspiracy"; there is a presumption of administrative regularity, and, absent strong evidence of impropriety, judicial review is confined to the agency record. See *TOMAC, 193 F. Supp. 2d at 195*. We note, moreover, that the Order is not limited to AVA; it addresses [**57] the range of products discussed in the Panel's report and FDA's 1985 proposal. See, e.g., FDA Order at 257 (Table I).

The Order sets out, at length, the reasons for FDA's decision to confirm AVA as a properly-licensed, safe and effective biological product. The administrative record is comprehensive, and provides ample support for FDA's decision. The Order and the record together make clear that FDA reached its decision on the merits, without reference to extraneous considerations or pressures. Plaintiffs have submitted no evidence suggesting otherwise, and its request for discovery, accordingly, should be denied.

[*31] **CONCLUSION**

For all the foregoing reasons, the Court should deny plaintiffs' motion for summary judgment.

Respectfully submitted,

PETER D. KEISLER

Assistant Attorney General

ROSCOE C. HOWARD, JR.

United States Attorney

BRIAN D. BOYLE

Principal Deputy Associate Attorney General

SHANNEN W. COFFIN

Deputy Assistant Attorney General

/s

JOSEPH H. HUNT

VINCENT M. GARVEY

CRAIG M. BLACKWELL, DC Bar # 438758

RONALD J. WILTSIE

ANDREW H. TANNENBAUM

Attorneys

Civil Division

U.S. Department of Justice

P.O. Box 883

Washington, D.C. 20044 [**58]

Tel: (202) 307-1401

Fax: (202) 616-8470

Attorneys for defendants

Date: April 7, 2004