UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NATURAL RESOURCES DEFENSE COUNCIL, INC.; CENTER FOR SCIENCE IN THE PUBLIC INTEREST; FOOD ANIMAL CONCERNS TRUST; PUBLIC CITIZEN, INC.; and UNION OF CONCERNED SCIENTISTS, INC.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; MARGARET HAMBURG, in her official capacity as Commissioner, United States Food and Drug Administration; CENTER FOR VETERINARY MEDICINE; BERNADETTE DUNHAM, in her official capacity as Director, Center for Veterinary Medicine; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and KATHLEEN SEBELIUS, in her official capacity as Secretary, United States Department of Health and Human Services,

Defendants.

11 Civ. 3562 (THK)
ECF Case

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THE GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT

PREET BHARARA
United States Attorney for the
Southern District of New York
Attorney for Defendant
86 Chambers Street, 5th Floor
New York, New York 10007
Tel.: (212) 637-2716

AMY A. BARCELO
Assistant United States Attorney
– Of Counsel –

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES AND REGULATIONS

ADMINISTRATIVE ADJUDICATIONS

OTHER AUTHORITIES

PRELIMINARY STATEMENT

Plaintiffs initiated this case with a simple, albeit incorrect claim: that "findings" made by FDA's BVM[1] 34 years ago (in 1977) could require this Court to mandate withdrawals of approvals for the use of penicillins and tetracyclines for use in animal feed—*i.e.*, the NOOH Products. In its Opening Brief, the Government demonstrated that Plaintiffs' claims have no merit, because an opportunity for a hearing on the proposed drug withdrawals had never been provided to the sponsors of the NOOH Products as required under the FDCA, and, accordingly, the Commissioner never made the findings upon which a withdrawal could be based. The Government also showed that BVM (as opposed to the Commissioner), did not have the authority to make findings upon which the NOOH Products could be withdrawn. Finally, the Government explained that any "unreasonable delay" claim seeking to compel hearings has become moot because the 1977 NOOHs have been withdrawn.

Now, conceding that a straightforward withdrawal of the NOOH Products would be unlawful under the FDCA, Plaintiffs admit that they are really seeking for this Court to order a multi-step regulatory campaign against the more than 73 NOOH Products, including a mandatory update of the 1977 NOOHs, followed by evidentiary hearings (including motions practice, testimony, oral argument, and post-hearing briefing) and formal Agency findings. But, as the Supreme Court has established, plaintiffs can seek to compel agency actions only if they are both "required" and "discrete"; they may not compel broad programmatic relief of the type now sought by Plaintiffs. Furthermore, Plaintiffs still cannot identify any "finding" by BVM in 1977 that could compel this Court to grant any relief at all. Finally, Plaintiffs have failed to rebut

[1] Abbreviations in this brief are the same as in the Government's opening brief dated January 9, 2012 (the "Opening Br.").

FDA's showing that, because the 34 year-old 1977 NOOHs have been formally withdrawn, any claim to compel a hearing based on those withdrawn notices is moot.

ARGUMENT

I. PLAINTIFFS' CLAIM MUST FAIL BECAUSE THEY DO NOT REQUEST THE COURT TO COMPEL "DISCRETE" ACTION THAT FDA IS "REQUIRED" TO TAKE

Plaintiffs concede that they are not entitled to an order compelling FDA to "withdraw its prior approvals" for the NOOH Products immediately. *See* Plfs' Opening Brief at 2, 10. Indeed, even under Plaintiffs' theory of the FDCA, currently FDA is not permitted (let alone *required*) to withdraw approval for the NOOH Products, *see* Plfs' Opp. at 3, 7, for FDA could withdraw such approvals only "if," at some later date and after a hearing is held, the Commissioner makes the required statutory determination set forth in section 21 U.S.C. § 360b(e)(1).[2] Plfs' Opp. at 3, 7; *see also id.* at 1, 6. Plaintiffs now concede also that, even had the 1977 NOOHs not been withdrawn, FDA could not convene hearings to withdraw approvals for the NOOH Products without first updating the 1977 NOOHs to account for the last 34 years of developments in scientific research and understanding. Plfs' Opp. at 20, 22.

The relief that Plaintiffs now seek is neither "required" nor "discrete," and their claim under 5 U.S.C. § 706(1) therefore cannot succeed. *See* Opening Br. at 11 (citing *Norton v. Southern Utah Wilderness Alliance*, 542 U.S. 55, 64 (2004) ("*SUWA*")). First, there is nothing in the FDCA or its implementing regulations "requiring" FDA to update 34 year-old withdrawal proposals. Neither is there any such basis to compel FDA to take any of the numerous additional

[2] In light of Plaintiffs' concessions, this is also now a textbook example of a case that should be dismissed on ripeness grounds. *E.g.*, *Thomas v. City of New York*, 143 F.3d 31, 34 (2d Cir. 1998) (no subject matter jurisdiction exists over a claim that "is based upon contingent future events that may not occur as anticipated, or indeed may not occur at all," because such a claim is not ripe) (internal quotations and citations omitted).

steps that would be required to lawfully withdraw any of the 73 or more NOOH Products.[3] Such steps would include, *inter alia*, FDA's Center for Veterinary Medicine ("CVM") (as successor to BVM) issuing an updated NOOH to provide notice to sponsors of the bases for withdrawal, and convening a hearing, which would include motions practice, testimony, oral argument, and post-hearing briefing. *See* 21 C.F.R. § 12.80 *et seq.* ("Hearing Procedures"). Then, assuming CVM were to initially prevail at the hearing, if the sponsors appealed the outcome, the Commissioner would need to review the record and make a final determination whether any approvals of the NOOH Products should be withdrawn. *See id.* at § 12.120 *et seq.* ("Initial and Final Decisions"). In similar situations in the past (where just *one* drug product was at issue), this process has taken almost five years.[4] *See* Barcelo Decl. Ex. I at 3; Barcelo Decl. Ex. J at 3.

Because this long chain of events is plainly neither "required" nor "discrete," Plaintiffs' claim constitutes a "broad programmatic attack" on FDA's regulation of animal drugs like those that the Supreme Court has held is unavailable under the APA. *SUWA*, 542 U.S. at 64; *accord Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871 (1990) (litigants may not bring suit pursuant to the APA "seek[ing] wholesale improvement of [an agency] program by court decree").

II. THERE HAS BEEN NO STATUTORY "FINDING" THAT CAN COMPEL AGENCY ACTION PURSUANT TO 21 U.S.C. § 360b(e)(1)

Even if Plaintiffs' claim were cognizable under the APA (it is not), it should fail for the independent reason that Plaintiffs have not identified (and cannot identify) any "finding" by

---

[3] As the Government noted in its brief opposing Plaintiffs' motion for leave to file a Supplemental Complaint, Dkt. No. 46, FDA estimates that there are at least 73 approved NOOH Products for use in animal feed, either alone or in combination with other approved drugs, *id.* at 6 n.1. This number does not include approvals for the use of the relevant antimicrobial drugs in water, inclusion of which would likely increase the total by several dozen. *Id.*

[4] Plaintiffs make no attempt to justify (or even explain) the basis for their claim that one year would be a reasonable period of time for FDA to complete these numerous tasks. There is no doubt, however, that a one year deadline would be insufficient in light of the five year period that the enrofloxacin withdrawal consumed. Barcelo Decl. Ex. I at 3; Barcelo Decl. Ex. J at 3.

FDA requiring the withdrawal of approval for the NOOH Products pursuant to 21 U.S.C. § 360b(e)(1). Opening Br. at 12-21.

A. BVM's Issuance of the 1977 NOOHs Was Not a "Finding" Within the Meaning of Section 360b(e)(1)

1. The Plain Language of the FDCA Supports the Government's Position

Plaintiffs are wrong that the rules of grammar require a reading of section 360b(e)(1) that would deem BVM's issuance of the 1977 NOOHs, which happened before any statutorily mandated hearing, to be a "finding" that could compel the withdrawal of the NOOH Products. *See* Plfs' Opp. at 3-5. The plain text of the statute reads as follows:

> [t]he [Commissioner] shall, *after due notice and opportunity for hearing to the applicant*, issue an order withdrawing approval of an [animal drug] . . . if the [Commissioner] finds . . . that new evidence . . . shows that such drug is not shown to be safe.

21 U.S.C. § 360b(e)(1)(B) (emphasis added). Congress's placement of the phrase "after due notice and opportunity for hearing" towards the beginning of the sentence conveys its intention that any of the events described following that phrase (including the Commissioner's findings) shall occur only "after" sponsors are granted "due notice and opportunity for hearing." Opening Br. at 13-15.

Plaintiffs' argue that, by placing the phrase "after due notice and opportunity for hearing" between the words "shall" and "issue," Congress expressed its intention that the only thing to happen after a hearing is the issuance of an actual order withdrawing approval (and not any "findings" based on the hearing). *See* Plfs' Opp. at 4. This reading is nonsensical, would undermine fundamental concepts of due process, and would render the statute's requirement for a hearing superfluous. *See, e.g.*, *Connecticut ex rel. Blumenthal v. U.S. Dep't of Interior*, 228

F.3d 82, 88 (2d Cir. 2000) ("we are required to disfavor interpretations of statutes that render language superfluous") (internal quotation omitted).

As Plaintiffs concede elsewhere, where (as here) hearing has been requested and granted, FDA *cannot* withdraw approval for the products at issue unless and until the Commissioner herself has made a final "determination," based on evidence adduced at the hearing, Plfs' Opp. at 7.[5] What Plaintiffs try to distinguish as a post-hearing "determination," however, is quite obviously the "finding" to which section 360b(e)(1) refers. *See* Opening Br. at 13-15.

Moreover, even if the language of section 360b(e)(1) were ambiguous (it is not), this Court should defer to FDA's longstanding interpretation that, when a hearing on a proposed withdrawal is granted, any "finding" that a drug is unsafe or not shown to be safe can only come *after* the hearing.[6] *See* Opening Br. at 12-13, 16-19. This is the clear import of FDA regulations providing that disputed issues of fact are to be referred for hearings and resolved by the Commissioner. *See id.*; *see also infra* Section II.B.2.

---

[5] Without such a determination, there is no appealable final agency action, which is yet another reason why the 1977 NOOHs would be an insufficient basis upon which to compel drug withdrawals. *See* Opening Br. at 14 n.11 (*citing Sterling Drug, Inc. v. Weinberger*, 384 F. Supp. 557, 561 (S.D.N.Y. 1974), *affd.* 509 F.2d 1236 (2d Cir. 1975) (issuance of NOOH is not an appealable agency decision; appeal to federal court may be taken from the Commissioner's final decision).

[6] Plaintiffs' citation of *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988), Plfs' Opp. at 15, is inapposite. The Government's proposed interpretation of section 360b(e)(1) is not a "novel[]" "litigating position" as was the government's position in that case. *Id.* at 212. Rather, the Government's "reasoned and consistent," position is supported by FDA's "rulings and administrative practice." *Id.* at 212; *see also* Opening Br. at 16-17. Furthermore, Plaintiffs never dispute that, even if FDA's interpretation of the statute were not entitled to *Chevron* deference (it is), the less deferential *Skidmore* deference doctrine would apply. Opening Br. at 18-19 n.17.

2. BVM's Decision to Issue the 1977 NOOHs Is Not A Sufficient Basis to Withdraw the NOOH Products

Plaintiffs' speculation about whether an NOOH could provide a sufficient basis for withdrawal if the drug sponsors never requested a hearing, Plfs' Opp. at 5, 10-11, is irrelevant in this case, where it is undisputed that: (i) numerous drug sponsors *requested* hearings pursuant to section 360b(e)(1), 43 Fed. Reg. 53827, 53827 (Nov. 17, 1978) (Barcelo Decl. Ex. G); (ii) the Commissioner *granted* those requests for hearings, *id.* at 53827-28; (iii) those hearings were *never held*; and (iv) BVM's decision to issue the 1977 NOOHs could not form a sufficient basis to revoke a drug's approval because hearings were requested, *see* Opening Br. at 15-16 (describing delegations to BVM and CVM). The Government is not arguing that BVM was not exercising properly delegated authority when it issued the 1977 NOOHs, but rather that, when numerous sponsors requested hearings on the proposed withdrawals, BVM was immediately divested of authority to move forward with such withdrawals on its own.[7] *Id.* The Commissioner has reserved that authority for herself. *Id.*

An analogy between FDA's procedures for drug withdrawals and a court's procedural rules is instructive. The issuance of an NOOH by an FDA bureau[8] (*i.e.*, BVM or CVM) is analogous to the filing of a complaint. Like in a civil case, if the sponsor (or "defendant") does not appear, the bureau prevails by default. *See* 21 C.F.R. § 514.200(b). Also like in a civil case, if the sponsor appears to defend, the Commissioner assumes the role of the court to decide if the

---

[7] Plaintiffs argument that 21 C.F.R. § 514.115(b)(3)(ii) provides for the issuance of an NOOH only upon a "finding" by BVM, and that such a finding necessarily provides (and indeed compels) a proposed withdrawal in all circumstances, *see* Plfs' Opp. at 5, 10, 15, ignores the fact that any "findings" by BVM are trumped when the Commissioner decides that they raise disputed issues of fact that must be resolved at a hearing. *See infra* pp. 6-7; *see also infra* at p. 9 (21 C.F.R. § 514.115(b)(3)(ii) (a hearing is required only if an NOOH is currently pending).

[8] FDA's main branches are now referred to as "centers," but the term "bureau" is used herein to reflect the terminology used in 1977. *See* Opening Br. at 5 n.7.

NOOH has merit. Initially, the Commissioner decides on "summary judgment"[9] whether a sponsor's request for a hearing raises an issue of fact. *See* 21 C.F.R. § 514.200(c); *see also* Opening Br. at 14 (citing cases). If the Commissioner discerns an issue of fact, then a "trial" is set. *Id.* Plaintiffs' argument that by issuing the 1977 NOOHs (*i.e.*, a complaint) BVM made a final determination that could compel withdrawals of the NOOH Products, *see* Plfs' Opp. at 6, turns this entire procedure on its head.[10]

Plaintiffs are similarly incorrect to argue that, by merely issuing the 1977 NOOHs, BVM satisfied its "burden of production," and thereby has shifted the burden of proof on the safety of the NOOH Products onto the sponsors. Plfs' Opp. at 7-10. On the contrary, at a withdrawal hearing, the bureau must first satisfy its burden of production by making out a *prima facie* case for withdrawal. *See* Final Decision of the Commissioner, Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry ("Enrofloxacin Withdrawal") at 7, Barcelo Decl. Ex. N. This is similar to a civil plaintiff seeking to survive a motion for judgment as a matter of law under Rule 50(a) of the Federal Rules of Civil Procedure. Only if the Commissioner concludes that BVM or CVM has actually carried its initial burden *at the hearing* will the burden then shift to the sponsor to defend its drug.[11] Enrofloxacin Withdrawal at 7. Indeed, to further the analogy to civil cases, it is like Plaintiffs are arguing that a civil plaintiff

---

[9] The Supreme Court has referred to this specific procedure as "administrative summary judgment." *See Weinberger v. Hynson, Wescott and Dunning, Inc.*, 412 U.S. 609, 617 (1973).

[10] The sharp difference between BVM's decision to issue an NOOH, and the Commissioner's subsequent decision on whether the standard under the FDCA for a drug's withdrawal has been satisfied, is also highlighted by the strict separation of functions that is enforced once a hearing is granted. *See, e.g.*, 21 C.F.R. § 10.55(b)(2)(i).

[11] Plaintiffs are therefore wrong to argue that the language in the Enrofloxacin Withdrawal tying the burden that CVM must carry in a hearing on a proposed withdrawal to the language of section 360b(e)(1), *see* Plfs' Opp. at 8 (citing Enrofloxacin Withdrawal at 45), supports their argument that by issuing an NOOH a bureau has already met that burden.

could avoid judgment under Rule 50(a) solely on the ground that it had previously decided to file a complaint.

Thus, neither the language of the statute, FDAs regulations, nor the mechanics of the withdrawal process, provide a basis to hold that, by issuing the 1977 NOOHs, BVM has made the statutory "finding" that could provide a basis for a drug's withdrawal under section 360b(e)(1).

B. Statements Made by FDA Officials Outside of the Context of the NOOH Proceedings Are Irrelevant to the Issues Before the Court

Next, Plaintiffs' citation to a 1983 Federal Register notice, in which the Commissioner observed (29 years ago) that the Director of BVM had not changed his position as stated in the 1977 NOOHs, Plfs' Opp. at 11-13 (citing Penicillin and Tetracycline in Animal Feeds, 48 Fed. Reg. 4554, 4555-56 (Feb. 1, 1983), Sorenson Decl. Ex. DD), is irrelevant to this case. The Commissioner did not issue that notice as a decision on the merits following the hearing required by section 360b(e)(1), but rather to announce FDA's position that it would hold off on taking action in light of ongoing research mandated by Congress. *See id.* at 4555.

Nor is Plaintiffs' case advanced by the more recent statements by FDA expressing concerns about the production use of antimicrobials in animals, *see* Plfs' Opp. at 13-14, because those statements also have no bearing on whether FDA's actions in 1977 could compel the withdrawal of the NOOH Products now. FDA does have such concerns, and it is implementing a regulatory strategy to address them. *See* Opening Br. at 8-10. The drug withdrawal process is not the only regulatory tool available to FDA. And there is no legal basis for Plaintiffs' implied argument that FDA cannot express concerns about drug safety unless it is prepared to proceed with formal withdrawal proceedings. Such an "all or nothing" approach has no basis in the law and would hamstring FDA's ability to advise the public on matters relating to public health.

III. PLAINTIFFS' CLAIM THAT THE GOVERNMENT IS REQUIRED TO PURSUE THE 1977 NOOHs EVEN THOUGH IT HAS WITHDRAWN THEM SHOULD BE DISMISSED AS MOOT

Finally, as the Government argued in its Opening Brief,[12] Plaintiffs' NOOH Claim should be dismissed because it is moot in light of FDA's withdrawal of the 1977 NOOHs on December 22, 2011. *See* Opening Br. at 21-24; *citing* Barcelo Decl. Ex. L. Because the 1977 NOOHs no longer exist, there is no basis for further proceedings based on an administrative proposal from decades ago.

Plaintiffs try to avoid a finding of mootness by arguing that an FDA regulation mandates that the Agency proceed with a hearing on the withdrawn 1977 NOOHs. *See* Plfs' Opp. at 6, 15 (*citing* 21 C.F.R. § 514.115(b)(3)(ii) (1977)). Plaintiffs are wrong, however, for the regulation provides that sponsors be given an "opportunity for hearing" prior to a drug's withdrawal, and this is needed only when there is an existing "proposal to withdraw approval." 21 C.F.R. § 514.115(b)(3)(ii). There is no longer any such proposal.

Plaintiffs do not raise any other argument apropos to mootness,[13] except to say that the 1977 NOOHs should not have been withdrawn in the first instance, and to accuse FDA of "game" playing. *See* Pls' Opp. at 16-22. But Plaintiffs never directly challenge the NOOH

---

[12] Plaintiffs mistakenly argue that the Government did not argue in its Opening Brief that any claim seeking to compel future withdrawal hearings was moot in light of FDA's recent withdrawal of the 1977 NOOHs. Plfs' Opp. at 16. To the contrary, the Government made precisely that point. *See* Opening Br. at 22-23 (arguing that such claim is properly characterized as a claim of "unreasonable delay" rather than a claim to "compel" agency action, and is moot).

[13] The cases cited by Plaintiffs on pages 18 and 19 of their brief have no bearing here. *See id.* (*citing Public Citizen v. Nuclear Regulatory Comm.*, 901 F.2d 147 (D.C. Cir. 1990); and *NRDC v. EPA*, 595 F. Supp. 1255, 1257 (S.D.N.Y. 1984)). These decisions address agencies' obligations to promulgate rules that have been specifically required by Congress, and none of them involved cases seeking to compel agency action pursuant to APA § 706(1).

withdrawals,[14] and their indignation is surprising in light of their agreement that the 34 year-old 1977 NOOHs were outdated and stale, *see* Plfs' Opp. at 20, 22.

Plaintiffs' remaining arguments have no bearing on the significance of the 1977 NOOHs, or on the consequences of their withdrawal. Instead, Plaintiffs raise arguments about FDA's general approach to the regulation of antibiotics in animal feed. *See, e.g,* Plfs' Opp. at 18-19 (positing that the FDCA does not provide for regulatory strategies based in part on voluntary compliance). These issues, however, all go to whether FDA's modern regulatory strategy is lawful, which is the subject of their new Citizen Petitions claim[15] that is due to be briefed beginning later this month. The Government will explain in the upcoming briefing that FDA's current approach is reasonable and lawful,[16] but this is an issue pertinent to the Citizen Petitions claim and not to the NOOH Claim. As part of their new Citizen Petitions claim, Plaintiffs will presumably argue that this Court should compel FDA to issue *new* withdrawal proposals based on the scientific understanding of antimicrobial resistance as it exists today. None of this, however, has any bearing on the simple fact that the long-outdated 1977 NOOHs no longer exist.

CONCLUSION

For the foregoing reasons, the Court should grant summary judgment in favor of the Government.

---

[14] In making this observation, the Government does not concede that the withdrawals of the 1977 NOOHs would be a legitimate subject for judicial review. Because the issuance of an NOOH is not a reviewable final agency action, *see supra* n. 5, its withdrawal is not either.

[15] *See* Plaintiffs' First Supplemental Complaint for Declaratory and Injunctive Relief. Dkt. No. 53.

[16] As FDA explained in the NOOH Withdrawal, in the 34 years since issuing the 1977 NOOHs, FDA has continued to develop its regulatory strategy with respect the use of antibiotics in animal feed, and its current strategy is different from the one it proposed in 1977. Barcelo Decl. Ex. L. FDA's current strategy involves the potential for withdrawal proceedings in the future, *id.* at 79700-01, if FDA determines that such proceedings are warranted.

Dated: New York, New York
February 10, 2012

Respectfully submitted,

PREET BHARARA
United States Attorney
Southern District of New York

/s/ Amy A. Barcelo
By: AMY A. BARCELO
Assistant United States Attorney
86 Chambers Street
New York, New York 10007
Tel.: (212) 637-6559
Fax: (212) 637-2730
Email: amy.barcelo@usdoj.gov

OF COUNSEL:

DAVID J. HOROWITZ
Deputy General Counsel

ELIZABETH H. DICKINSON
Acting Chief Counsel, Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel, Litigation

THOMAS J. COSGROVE
Associate Chief Counsel

U.S. Department of Health and Human Services
Office of the General Counsel
White Oak 31 Room 4331
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
(Tel): (301) 796-8613