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 (JCF)
ECF Case

REPLY MEMORANDUM OF LAW IN SUPPORT OF
THE GOVERNMENT'S MOTION FOR A STAY PENDING APPEAL

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PRELIMINARY STATEMENT

The Government has presented substantial—and indeed compelling—arguments that it will prevail on the merits in its forthcoming appeal. The appeal presents the novel question of whether proposals made 35 years ago by one FDA[1] bureau to withdraw approval for certain uses of penicillins and tetracyclines in animal feed (*i.e.*, the 1977 NOOHs), divest the Agency of all discretion on how best to address potential safety issues with those drugs today. The Court's ruling that FDA lacks such discretion is both unprecedented and contrary to FDA's interpretation of the FDCA.

The Government has also established that it would be irreparably harmed without a stay, and that a stay would be in the public interest. There is no dispute that withdrawal proceedings would divert resources from other important programs, and thwart the Agency's ability to pursue its priorities in accordance with its best judgment. For a public health agency to be forced to reallocate resources in a way that it believes will impede its mission constitutes irreparable harm.

ARGUMENT

THE COURT SHOULD GRANT A STAY OF THE ORDER PENDING APPEAL

A. The Government Will Present a Substantial Case on the Merits on Appeal

The Government's Opening Brief presented strong arguments that Magistrate Judge Katz erred in interpreting 21 U.S.C. § 360b(e)(1) as requiring FDA to revert to a regulatory strategy that the Agency has since abandoned in favor of a voluntary compliance strategy. The 1977 NOOHs constituted a preliminary proposal and not a binding Agency "finding" that could be a basis to compel Agency action then or now, and moreover, FDA has since exercised its discretion to withdraw the 1977 NOOHs. Opening Br. at 7-14. Plaintiffs do little to rebut the

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

Government's arguments for appeal, and their brief mainly reiterates Judge Katz's March 22 and June 1 Orders.[2] Plfs' Br. at 8-15.

The Government has presented substantial arguments that the March 22 Order erred in interpreting Congress' intent in enacting 21 U.S.C. § 360b(e)(1), *see* March 22 Order at 29-54. Opening Br. at 6-13. For instance, Judge Katz relied in part on a unique application of FDA's general mission statement, 21 U.S.C. § 393(b)(1)-(2), but as Plaintiffs effectively concede, such a "broad statutory mandate" is not enough to compel specific agency action that is not otherwise required by the statute. Plfs' Br. at 11; Opening Br. at 9 n.4. More importantly, 21 U.S.C. § 393(b)(1)-(2), does not limit FDA's discretion in deciding whether to initiate drug withdrawal proceedings pursuant to 21 U.S.C. § 360b(e)(1), but merely requires that the Agency take "appropriate" action. The broad language indicates Congress' intent to vest FDA with discretion, not detract from it.

Indeed, because of that grant of discretion, the Government will present a substantial case that, as discussed in *Heckler v. Chaney*, 470 U.S. 821 (1985), and its progeny, the FDCA grants broad discretion to FDA in deciding whether to pursue withdrawal proceedings or instead exercise its discretion to pursue a strategy that the Agency, in its expertise, has determined is the best way to address a public health issue. Opening Br. at 12-14.[3] In this case, the Court should

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[2] The "June 1 Order" refers to the Court's order dated June 1, 2012 and entered June 4, 2012 (Dkt. No. 95), granting Plaintiffs' motion for summary judgment on their claim challenging FDA's denials of two citizen petitions.

[3] Plaintiffs' reliance on the purported distinction between the "substantive" and "enforcement" provisions of the FDCA to argue that FDA's decision not to pursue withdrawal proceedings was not an exercise of such discretion, Plfs' Br. at 14-15 (relying on June 1 Order at 27-34), does not hold up. Indeed, in *Riverkeeper, Inc. v. Collins*, 359 F.3d 156 (2d Cir. 2004), the Second Circuit held that the *Chaney* presumption against judicial review applies beyond challenges to action that is "purely enforcement," and instead applies to any attempt to "convince the [agency] to enforce the statutes and regulations under its authority . . . in the manner in which [a plaintiff] thought they should be enforced." 359 F.3d at 166 n.11. As here, *Riverkeeper* did not involve

be particularly concerned about the effects of its injunction on other FDA programs during the pendency of the appeal, including those that FDA has deployed as part of its efforts to mitigate the development of antimicrobial resistance.

Plaintiffs are also wrong that the "rules of grammar" compel only their reading of 21 U.S.C. § 360b(e)(1). Plfs' Br. at 10. Judge Katz's decision never explains why the key phrase in the statute—"after due notice and opportunity for hearing"—cannot refer *both* to the timing of the "finding" *and* to the Commissioner's order. *See* March 22 Order at 30. Indeed, the Court relied on *United States v. Liranzo*, 729 F. Supp. 1012, 1014 (S.D.N.Y. 1990), in which the key phrase—"within one thousand feet"—modified multiple words, not just those closest to it. Thus, the Court's analysis just as easily supports the Government's interpretation of section 360b(e)(1).

At a minimum, the statutory language is ambiguous. Plaintiffs do not dispute that FDA's interpretation is entitled to *Chevron* deference in the event of ambiguity. *See* Opening Br. at 9. To be clear, FDA's longstanding interpretation is that the issuance of an NOOH is a proposal to withdraw a drug, rather than a final decision to withdraw such drug pursuant to section 360b(e)(1). That is because a final decision can only be reached after the drugs sponsors have been granted "due notice and opportunity for hearing," including an opportunity to present

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traditional enforcement against alleged wrongdoing, but rather requested changes to the terms of agency-granted licenses—in that case, for the operation of power plants.

The Court's June 1 Order was wrong to hold that the Second Circuit's decision in *Riverkeeper* is "irrelevant" to the issue of whether FDA's determination not to pursue the Withdrawal Proceedings contemplated by 21 U.S.C. § 360b(e)(1) is subject to judicial review. June 1 Order at 19. Although the *Riverkeeper* court noted that because the plaintiffs did not raise the argument that the agency action at issue was not "enforcement" until their reply brief and they had waived that argument, the Second Circuit nevertheless stated its "conclusion" that the agency action at issue was subject to the *Chaney* presumption against judicial review and applied, and explained the basis for that conclusion. *Riverkeeper*, 359 F.3d at 166 n.11. This same presumption applies here.

evidence that might change the ultimate decision.[4] Opening Br. at 9-10. Judge Katz incorrectly merged two separate steps in the course of a drug withdrawal proceeding: the issuance of a proposal for withdrawal, 21 C.F.R. § 514.115(b)(3)(ii), and the final decision on drug withdrawal, 21 U.S.C. § 360b(e)(1). March 22 Order at 35. As the context of the two provisions demonstrates, the regulatory determination to hold hearings is preliminary and initiates a process, whereas the statutory "finding" concludes the process and encompasses a full record, including any evidence that might counter the material that informed the notice. Opening Br. at 9-10. Plaintiffs ignore the FDA regulations that reflect this interpretation. *Id.* at 9 n.5 (discussing FDA regulations including 21 C.F.R. § 514.200(c) and 21 C.F.R. § 5.84 (1977)). At the very least, the Government has a substantial argument that Judge Katz erred in his interpretation, and that FDA's interpretation of its regulation is entitled to deference.[5] Opening Br. at 10.

Moreover, neither Judge Katz nor Plaintiffs have adequately accounted for the fact that—even assuming the 1977 NOOHs contain "findings"—FDA has since exercised its discretion to

[4] Indeed, due process considerations would argue against any interpretation under which the basis for the initiation of the NOOH process appears to represent a final agency determination. *See Gilligan, Will & Co. v. SEC*, 267 F.2d 461, 468-69 (2d Cir. 1959) (the agency's "reputation for objectivity and impartiality is opened to challenge by the adoption of a procedure from which a disinterested observer may conclude that it has in some measure adjudged the facts as well as the law of a particular case in advance of hearing it"); *Air Transp. Ass'n of Am, Inc. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011) ("[d]ecisionmakers violate the due process clause and must be disqualified when they act with an 'unalterably closed mind' and are 'unwilling or unable' to rationally consider arguments") (quoting *Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170, 1174 (D.C. Cir. 1979)).

[5] Even if deference set forth in *Auer v. Robbins*, 519 U.S. 452 (1997) were not to apply, FDA's interpretation would prevail as persuasive and entitled to *Skidmore* deference. *Cf. Encarnacion ex rel. George v. Astrue*, 568 F.3d 72, 79 (2d Cir. 2009) (declining to determine whether *Auer* deference applied, because the agency's interpretation of its own regulation was entitled to *Skidmore* deference).

withdraw those determinations.[6] Opening Br. at 11-14. As a preliminary matter, Judge Katz's conclusion that FDA's withdrawal was ineffective because the Agency did not separately withdraw scientific "findings" purportedly made in 1977, March 22 Order at 49-52, overlooked the fact that, before re-issuing the notices, the Agency would first have to "determine [its] current scientific positions" regarding the "microbial food safety of the NOOH Products." (First Flynn Decl. ¶ 13); *see also* Opening Br. at 11.

Even more importantly, however, the March 22 Order also did not grant appropriate scientific and regulatory deference to FDA's expertise regarding the best approach to the issue of antimicrobial resistance. Opening Br. at 11-14. Not only is FDA's determination that the voluntary compliance strategy is the most effective way to address concerns of antimicrobial resistance an archetypal exercise of the Agency's discretion, but in withdrawing the 1977 NOOHs, FDA specifically invoked the same type of discretion that was at issue in *Chaney*.[7] Opening Br. at 12-14. A 35-year-old preliminary scientific determination and proposal that has since been withdrawn should not serve as a basis to compel FDA to move forward today with withdrawal proceedings that it has since determined are not the most effective means to address the issue of antimicrobial resistance.

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[6] Because FDA's withdrawal of the 1977 NOOHs resolved the proceedings the Agency commenced in 1977 when it issued those notices, Plaintiffs' claim is also moot. Opening Br. at 14 n.8.

[7] The Government will also present strong arguments on appeal that the FDCA and FDA's related regulations do not overcome *Chaney*'s presumption against judicial review by providing "sufficient guidelines" to curb FDA's exercise of discretion under 21 U.S.C. § 360b(e)(1). Plfs' Br. at 15 (citing June 1 Order at 35-38). The regulatory provisions on which the Court relied in so ruling do not speak to that issue, because they do not instruct FDA regarding the circumstances in which the Agency must pursue withdrawal proceedings as opposed to pursuing other regulatory options.

B. The Government Will Be Irreparably Injured Absent a Stay

Plaintiffs significantly mischaracterize the Government's argument that FDA will be irreparably harmed without a stay. The Government is not, as Plaintiffs argue, alleging irreparable harm based exclusively on the prospect of wasted expenditure of resources. Plfs' Br. at 16. While it is certainly true that the Government might unnecessarily expend a substantial amount of resources without a stay, *see* Opening Br. at 14-15, the Government's argument is focused on the undisputed fact that resources committed to withdrawal proceedings will be diverted from other public health programs. This diversion of resources will compromise the Agency's ability to pursue its public health goals with respect to antimicrobial resistance and other important areas. Opening Br. at 15.

As the Government's cases demonstrate, an agency is irreparably harmed where, as would be the case here if no stay is granted, its ability to carry out its mission during the pendency of the appeal would be compromised. Opening Br. at 15-16 (citing cases). Plaintiffs provide no basis for their proposed distinction of those cases—that the agency action that was the subject of the injunction in those cases was the same action that the agency claimed was necessary to fulfill its mission, Plfs' Br. at 17. Indeed, such a distinction has logic backwards. That FDA's authority to pursue its mission through the voluntary compliance strategy is *not* subject to challenge in this litigation only serves to strengthen the Government's arguments that a stay is warranted.[8]

[8] Although the June 1 Order does not conclude that FDA lacks authority to pursue the voluntary compliance initiative, it does wrongly state that the initiative is "outside [the FDCA's] statutory regulatory scheme." Plfs' Br. at 17 (quoting June 1 Order at 52). On the contrary, while 21 U.S.C. § 360b(e)(1) provides one avenue through which FDA may pursue withdrawals of approvals for certain uses of new animal drugs, the FDCA also authorizes FDA to take all "appropriate" action to protect the public health, which, includes the voluntary compliance strategy. *See supra* pg. 2 (discussing FDA's authority under 21 U.S.C. § 393(b)(1)-(2)).

Plaintiffs' citation to *Shays v. FEC*, 340 F. Supp. 2d 39 (D.D.C. 2004), Plfs' Br. at 16, is therefore inapposite, because that case does not address whether an agency can be irreparably harmed by being required to divert resources away from programs that are important to its mission. Indeed, in *Shays*, not only did the Federal Election Commission ("FEC") not make any claim that its ability to fulfill its mission would be compromised without a stay, but it did not even claim that any specific programs would be harmed at all. Rather, the FEC made a general (and unsupported) claim of "diversion of resources from other agency priorities." 340 F. Supp. 2d at 423. In contrast, FDA has submitted two sworn declarations by William T. Flynn, D.V.M. M.S., CVM's Deputy Director for Science Policy (Dkt. Nos. 86, 94), that describe the specific CVM programs that are central to its public health mission and would be compromised if no stay is granted: the implementation of FDA's voluntary compliance strategy (Second Flynn Decl. ¶ 9), CVM's National Antimicrobial Resistance Monitoring System (*id.*¶ ¶ 10-11), and review of pending drug applications (*id.* ¶ 12). Dr. Flynn also explains the reason that these programs will necessarily be compromised without a stay—the limited number of CVM scientists who are qualified to work on issues related to antimicrobial resistance (Second Flynn Decl. ¶¶ 8, 11, 12).[9]

Furthermore, although Plaintiffs prefer their proposed regulatory strategy over FDA's current regulatory strategy to address the threat of antimicrobial resistance, Plfs' Br. at 19, 21-22, FDA—the agency tasked with regulating animal drug safety—has determined that a voluntary compliance strategy would yield benefits to public health more quickly and efficiently than would an immediate resort to drug withdrawal proceedings. *See* Opening Br. at 16-17. But unless a stay is granted, FDA expects that it will need to spend 11 to 17 months preparing new

[9] *FTC v. Standard Oil Co. of California*, 449 U.S. 232 (1980), Plfs' Br. at 16-17, is also not on point, because the Government does not base its claim of irreparable harm on the litigation expense that it will incur if the Court does not grant a stay. *Standard Oil*, 449 U.S. at 232.

NOOHs for penicillins and tetracyclines, instead of spending that time working collaboratively with drug sponsors to transition away from growth promotion uses for all 161 classes of Medically Important Antimicrobials. It makes sense to let the appeal resolve before FDA's preferred regulatory strategy is so radically redirected.

Plaintiffs' reliance on statements from Judge Katz's June 1 Order questioning FDA's regulatory strategy, Plfs' Br. at 17, 19, ignores Dr. Flynn's two declarations (which the June 1 Order does not address). For example, Judge Katz's speculation that the withdrawal proceedings may not be resource-intensive because sponsors may not "contest formal withdrawal proceedings or require time consuming hearings," Plfs' Br. at 19 (quoting the June 1 Order at 51), is beside the point. Before knowing whether sponsors will request hearings, FDA would first need to re-issue the 1977 NOOHs which, as Dr. Flynn also explained, would be one of the most resource-intensive parts of the withdrawal proceedings.[10] (First Flynn Decl. ¶¶ 8-16.) Indeed, and as Dr. Flynn also explained, FDA developed its voluntary compliance strategy after determining that it would be "impracticable to initiate and complete involuntary withdrawal proceedings for the approximately 161 existing individual approved applications for production uses for Medically Important Antimicrobials" (Second Flynn Decl. ¶ 5), which conclusion FDA reached after spending $3.3 million and more than five years to withdraw approval for a single drug, Baytril (enrofloxacin), through involuntary withdrawal pursuant to 21 U.S.C. § 360b(e)(1). (Second Flynn Decl. ¶ 4).[11]

[10] Moreover, and as the Government explained in its Opening Brief, by the time the instant appeal is decided, many (if not all) of the resources needed to prepare the revised NOOHs will likely have been expended. Opening Br. at 14.

[11] Nor does FDA's determination to pursue a voluntary compliance strategy rather than involuntary withdrawal proceedings amount to a "conce[ssion of] the absence of an effective regulatory mechanism." Plfs' Br. at 19 (quoting June 1 Order at 45 n.23). FDA has never taken the position that withdrawal proceedings pursuant to 21 U.S.C. § 360b(e)(1) would not

Similarly meritless is Plaintiffs' argument that FDA's claim of irreparable harm is speculative. Plfs' Br. at 18-19. First, Plaintiffs are wrong that the Government cannot claim irreparable harm if there is yet no court-ordered "deadline" for the withdrawal proceedings. Plfs' Br. at 17. As the Government's Opening Brief and Dr. Flynn's declarations reflect, the Government's arguments are based on FDA's current projections on the time and resources for withdrawal proceedings. *See* Opening Br. at 14. If the Court were to order a more condensed schedule than that proposed by the Government, it would only magnify the harm.

Plaintiffs' argument that "there is no reason to believe that withdrawal proceedings will detract from the agency's voluntary program to address antibiotic use in livestock production," Plfs' Br. at 19, and that there is no "evidence" that the Government will suffer harm if a stay is issued, Plfs' Br. at 17-18, also ignores Dr. Flynn's two sworn declarations. Those declarations describe the ways in which FDA's pursuit of its public health goals with respect to antimicrobial resistance would be harmed if the Agency is required to move forward with the withdrawal proceedings. Dr. Flynn's declarations do not contain "mere[] assert[ions] that burdens will be imposed" on FDA. Plfs' Br. at 18 (quoting *Barcia v. Sitkin*, 2004 WL 691390, *2 n.8 (S.D.N.Y. Mar. 31, 2004)). As explained above, Dr. Flynn's declarations describe the basis for that conclusion as well as the specific CVM programs that would be compromised. *See supra* pg. 7.

C. Issuance of a Stay Will Not Substantially Injure Plaintiffs and Is in the Public Interest

Finally, the public interest would be served by granting a stay. FDA has determined that the public health concerns regarding production uses of antibiotics in animal feed would be most quickly addressed by finalizing and implementing the voluntary compliance initiative described

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accomplish FDA's goals with respect to antimicrobial resistance, but rather has consistently stated its determination that the Agency's voluntary compliance strategy is an even more effective regulatory mechanism. *See, e.g.*, Second Flynn Decl. Ex. C.

in Guidance 209 and Draft GFI 213. Opening Br. at 16-17. Plaintiffs' own views that withdrawal proceedings are preferable to FDA's voluntary compliance strategy, Plfs' Br. at 20-22, do not supplant the agency's determinations. *See* Opening Br. at 11-12 (citing cases discussing deference to agencies on matters within their expertise).[12]

Indeed, and as Plaintiffs do not dispute, the success of the voluntary compliance strategy would result in the withdrawals of approvals from many more products than would the withdrawal proceedings. Opening Br. at 19. Moreover, and as Plaintiffs also do not dispute, were the March 22 Order to be reversed on appeal, it would not be in the public interest to have wasted public funds and resources in preparation for withdrawal proceedings. *Id.*

CONCLUSION

For the foregoing reasons, the Court should grant the Government's motion for a stay of the March 22 Order pending appeal. If the Court denies the Government's motion for a stay pending appeal, the Government respectfully requests an interim stay of the Order pending disposition of a possible motion for a stay in the United States Court of Appeals for the Second Circuit.

[12] Plaintiffs inaccurately describe FDA's voluntary compliance strategy. Plfs' Br. at 21 (citing FDA's denials of two citizen petitions filed by certain of the Plaintiffs). In April of this year, through Draft GFI 213, FDA stated its intention to request that sponsors of Medically Important Antimicrobials notify the Agency within three months of the date that Draft GFI 213 is finalized regarding whether they intend to participate in that voluntary strategy. *See* Second Flynn Decl. Ex. C at 7. As FDA stated in Draft GFI 123, the Agency then anticipates that the sponsors of the affected products should be able to complete implementation of the changes discussed in this draft guidance within three years from the date that guidance is finalized. *Id.*

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Respectfully submitted,

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