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

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

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The above-captioned defendants (the "Government"), by their attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submit this memorandum of law in support of their motion to stay this Court's order of March 22, 2012 (the "March 22 Order") (Dkt. No. 70), pending the Government's appeal of that Order to the United States Court of Appeals for the Second Circuit. If the Court denies the Government's motion for a stay pending appeal, the Government respectfully requests an interim stay of the March 22 Order pending disposition of the Government's motion for a stay in the United States Court of Appeals for the Second Circuit.

PRELIMINARY STATEMENT

This Court should stay the March 22 Order pending appeal. In that order, the Court held that a preliminary proposal, announced almost 35 years ago, to withdraw approvals for certain non-therapeutic uses of the penicillin and tetracycline classes of drugs in animal feed constituted a "finding" under Section 512(e)(1) (21 U.S.C. § 360b(e)(1)) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), and requires the United States Food and Drug Administration ("FDA" or the "Agency") to initiate adversarial proceedings to withdraw approvals for those classes of drugs. That holding is unprecedented and contrary to FDA's understanding of its authority under the FDCA, the statute it is tasked with administering. Accordingly, the Government presents a substantial case for appeal.

The March 22 Order also compels sweeping, resource-intensive agency action. FDA is currently implementing a regulatory strategy to end the use of medically important antimicrobial drugs to promote growth in animals. FDA believes that its current approach will help achieve its public health goals more quickly and efficiently than the strategy the Agency proposed decades ago (and this Court has ordered FDA to readopt). Initiating withdrawal proceedings now would

require FDA to expend substantial resources towards a regulatory strategy that the Agency has abandoned for now, and would draw resources away from FDA's current and broader strategy to address antimicrobial resistance and other work.

A stay pending appeal is necessary because the beginning phases of those withdrawal proceedings would be resource-intensive. FDA would need to expend a substantial amount of resources during the course of its appeal, which it could not recapture even if the Second Circuit reverses or vacates the March 22 Order.

Neither Plaintiffs nor the public interest would suffer substantial harm if a stay is granted. If initiation of the withdrawal proceedings is stayed, FDA would continue to work toward implementing its regulatory strategy to mitigate the problem of antimicrobial resistance.

BACKGROUND

A. Factual Background

The Government assumes the Court's familiarity with the legal framework and factual background of the claim at issue here, which is explained in detail in the Government's Opening Brief in Support of its Motion for Summary Judgment, dated January 9, 2012 ("Govt's S.J. Br.") at 2-10 (Dkt. No. 41). As a brief summary of the facts most relevant here: in 1977, the Bureau of Veterinary Medicine ("BVM"), a subsidiary bureau of FDA,[1] published two Notices of Opportunity for Hearings proposing to withdraw the approval of penicillins and tetracyclines in animal feeds for certain "nontherapeutic" uses (the "1977 NOOHs") because of concerns that it had about antimicrobial resistance.[2] 42 Fed. Reg. 43772, 43773 (Aug. 30, 1977), attached as

[1] In 1984, BVM became known as the Center for Veterinary Medicine ("CVM"), as it is known today.

[2] Antimicrobial resistance is a decreased susceptibility of bacteria to an antimicrobial drug, which is a drug that works against a variety of microorganisms, such as bacteria, viruses, fungi,

Exhibit D to the Declaration of Amy A. Barcelo dated January 9, 2012 ("Jan. Barcelo Decl."); 42 Fed. Reg. 56264, 56266 (Oct. 21, 1977), Jan. Barcelo Decl. Ex. E. In response to the 1977 NOOHs, numerous manufacturers (also known as "sponsors") of products subject to the notices (the "NOOH Products") requested hearings pursuant to the FDCA, 21 U.S.C. § 360b(e)(1), to contest the proposed withdrawals. 43 Fed. Reg. 53827, 53828 (Nov. 17, 1978), attached as Ex. G to the Jan. Barcelo Decl. FDA granted the requests for hearings, but soon after, the Congressional committee responsible for FDA's appropriations requested that the Agency abstain from holding hearings and instead study the issue of antimicrobial resistance in more depth. March 22 Order at 13.

FDA decided to study the issues of antimicrobial resistance, and the Agency eventually concluded not to pursue the withdrawal proceedings initiated in 1977 for penicillins and tetracyclines for the nontherapeutic uses (*i.e.*, "growth promotion" uses) for antimicrobial drugs that are considered important to human medicine ("Medically Important Antimicrobials"). *See* Supplemental Declaration of William T. Flynn dated June 1, 2012 ("Second Flynn Decl.") Ex. A at 13-17; Second Flynn Decl. Ex. B at 18-22; Jan. Barcelo Decl. Ex. I at 3-4, Jan. Barcelo Decl. Ex. J at 2-4. FDA therefore formulated an alternative regulatory strategy that would focus first on working with drug sponsors to voluntarily eliminate the injudicious use of such drugs, with the potential for more compulsory regulatory action later, if needed. Jan. Barcelo Ex. I at 4; Jan. Barcelo Decl. Ex. J at 4; *see also* Second Flynn Decl. Ex. C at 7.

FDA publicly announced its new plan in 2010 when it published a draft guidance titled *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, draft Guidance for Industry #209 ("Draft GFI 209"). Second Flynn Decl. Ex. A. Draft GFI 209

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and parasites. Antimicrobial resistance occurs after bacteria are exposed to an antimicrobial drug and continue to survive in the drug's presence. *See* Jan. Barcelo Decl. C at 1.

announced FDA's plan to work with sponsors to voluntarily withdraw approvals for growth-promotion uses, and also to make labeling changes sufficient to require that Medically Important Antimicrobials be used for therapeutic purposes only under the direction of a veterinarian. *See id.* at 17. On April 11, 2012, FDA took another important step to implement its strategy by publishing a final version of Draft GFI 209 (which, accordingly, is now known as GFI 209), and published Draft Guidance for Industry 213 ("Draft GFI 213"), which proposes detailed instructions to guide sponsors on how to withdraw their existing approvals for growth-promotion indications (*i.e.*, using antimicrobial drugs to promote the growth of food producing animals) and transition the remaining therapeutic indications (*e.g.*, using antimicrobial drugs to prevent or treat sickness or disease) to veterinarian oversight. Second Flynn Decl. Exs. B & C.

On December 16, 2011, FDA withdrew the 1977 NOOHs, and explained that it was doing so because of: (1) its decision to pursue other regulatory strategies to achieve the Agency's goals with respect to antimicrobial resistance, (2) the outdated nature of the 1977 NOOHs, and (3) the fact that if, in the future, FDA decides to seek to involuntarily withdraw approval of any antimicrobial drugs for use in animals, FDA would need to prioritize which drugs to focus on first. 76 Fed. Reg. 79697 (Dec. 22, 2011), Ex. L Jan. Barcelo Decl.

B. Plaintiffs' Claims

Plaintiffs began this action by filing a complaint on May 25, 2011, which they amended on July 7, 2011. (Dkt. No. 11.) Plaintiffs brought claims in the amended complaint pursuant to the Administrative Procedures Act and, specifically, 5 U.S.C. § 706(1), seeking to "compel agency action unlawfully withheld or unreasonably delayed." In the claim that is at issue in the instant motion, Plaintiffs alleged that the Government had "unlawfully withheld" further action with respect to the 1977 NOOHs. Specifically, in briefing on the parties' cross-motions for

summary judgment, Plaintiffs originally argued that, because it had issued the 1977 NOOHs, FDA was required to now "withdraw approval" for subtherapeutic uses of the NOOH Products. *See, e.g.*, Plaintiffs' Brief in Support of their Motion for Summary Judgment at 8-9 (Dkt. No. 20). Plaintiffs later conceded that they were not entitled to such relief and instead sought a Court order requiring FDA to update the 1977 NOOHs, publish such updated notices, and then hold hearings on the withdrawals it had proposed in 1977. *See, e.g.*, Plaintiffs' Opposition and Reply Brief in Support of their Motion for Summary Judgment at 3, 20.

C. The Court's March 22 Order

On March 22, 2012, the Court granted Plaintiffs' motion for summary judgment and denied the Government's cross-motion for summary judgment. In granting Plaintiffs' motion, the Court ordered FDA to "initiate withdrawal proceedings" as contemplated by 21 U.S.C. § 360b(e)(1) for the "subtherapeutic" uses of the penicillin and tetracycline classes of drugs (the "Withdrawal Proceedings"). March 22 Order at 54. Specifically, the court ordered FDA to undertake the following actions: "the Commissioner of the FDA or the Director of the CVM must re-issue a notice of the proposed withdrawals (which may be updated) and provide an opportunity for a hearing to the relevant drug sponsors; if drug sponsors timely request hearings and raise a genuine and substantial issue of fact, the FDA must hold a public evidentiary hearing. If, at the hearing, the drug sponsors fail to show that the use of the drugs is safe, the Commissioner must issue a withdrawal order." *Id.*

In reaching that holding, the Court relied on its interpretation of 21 U.S.C. § 360b(e)(1); an FDA regulation promulgated in connection with that statutory provision, 21 C.F.R. § 514.115(b)(3)(ii); and other FDA regulations setting forth hearing procedures, to hold: (1) that FDA subsidiary bureau BVM had the authority to make statutory safety "findings" within the

meaning of 21 U.S.C. § 360b(e)(1), (2) that the 1977 NOOHs reflected such statutory FDA "findings," and (3) that, as a consequence of having made such "findings" in 1977, the Agency was obligated to commence adversarial proceedings to withdraw the applicable drug approvals, even though FDA withdrew the 1977 NOOHs in December 2011. March 22 Order at 49-53.

On May 21, 2012, the Government filed a notice of appeal from the March 22 Order. (Dkt. No. 88).

ARGUMENT

THE COURT SHOULD GRANT A STAY OF THE ORDER PENDING APPEAL

A. Governing Standards

The Court considers four factors when determining whether to grant a stay pending appeal: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *Nken v. Holder*, 556 U.S. 418, 434 (2009) (citation and internal quotation marks omitted); *In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170 (2d Cir. 2007) (citations and internal quotation marks omitted). These factors are not prerequisites to be met, but rather are considerations to be balanced. "[T]he degree to which a factor must be present varies with the strength of the other factors, meaning that more of one [factor] excuses less of the other." *World Trade Ctr.*, 503 F.3d at 170 (alteration in original; citation and internal quotation marks omitted).

"'The necessary 'level' or 'degree' of possibility of success will vary according to the court's assessment of the other [stay] factors.'" *Mohammed v. Reno*, 309 F.3d 95, 101 (2d Cir. 2002) (quoting *Wash. Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843

(D.C. Cir. 1977) (second alteration in original)). "The probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury plaintiff[ ] will suffer absent the stay." *Id.* (quoting *Mich. Coal. of Radioactive Users, Inc. v. Griepentrog*, 945 F.2d 150, 153 (6th Cir. 1991) (alteration in original)). Where the other factors are satisfied, the Government need only demonstrate "a substantial case on the merits," rather than a strong likelihood of success, in order to obtain a stay. *See LaRouche v. Kezer*, 20 F.3d 68, 72-73 (2d Cir. 1994) ("movant need only present a substantial case on the merits when a serious legal question is involved and show that the balance of the equities weighs heavily in favor of granting the stay"); *Ctr. for Int'l Envtl. Law v. Office of U.S. Trade Representative*, 240 F. Supp. 2d 21, 22 (D.D.C. 2003) (same).

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

On appeal, the Government will present substantial arguments that the Second Circuit should reverse or vacate the March 22 Order. As far as the Government is aware, the Court's ruling—that the mere proposal to withdraw a drug and the publication of an NOOH constitutes a statutory "finding" that triggers a nondiscretionary duty requiring FDA to pursue the withdrawal further—is unprecedented. Given the novelty of this holding, the statutory language, and the relevant case law, the Government's appeal will present a "substantial case" that the Court erred in its interpretation of FDA's obligations under 21 U.S.C. § 360b(e)(1) and FDA's related regulations, and erroneously held that BVM's issuance of the 1977 NOOHs reflected final statutory "findings" by the Commissioner pursuant to 21 U.S.C. § 360b(e)(1) that the NOOH Products were not "shown to be safe" and must be withdrawn. The Government will also present substantial arguments that the Court erred when it ruled that the 1977 NOOHs can

provide a basis to require FDA to move forward with the Withdrawal Proceedings, because FDA exercised its discretion to withdraw those notices in December 2011.

This Court erred in holding that the 1977 NOOHs, which BVM issued before drug sponsors were provided an "opportunity for [a] hearing," constituted FDA's statutory "finding" in favor of withdrawal pursuant to 21 U.S.C. § 360b(e)(1).[3] March 22 Order at 29-47. On the contrary, the plain meaning of the statute provides that the Commissioner's statutory finding comes only after the hearing or after a sponsor opts not to request a hearing. The Court's contrary holding contradicts the plain language of section 360b(e)(1). Specifically, in placing the phrase "after due notice and opportunity for hearing" near the beginning of the sentence in section 360b(e)(1), Congress conveyed its intention that any of the events described following that phrase (including the Commissioner's final findings) would occur only "after" sponsors are granted "due notice and opportunity for hearing."[4]

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[3] Under 21 U.S.C. § 360b(e)(1), "[t]he Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application filed pursuant to subsection (b) of this section with respect to any new animal drug if the Secretary finds" that any of the conditions or events enumerated in 21 U.S.C. § 360b(e)(1)(A) through (F) are shown to have occurred. The March 22 Order found that 21 U.S.C. § 360b(e)(1)(B) was the subsection most relevant here. March 22 Order at 23 n.9. That subsection provides for withdrawal if "new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved." 21 U.S.C. § 360b(e)(1)(B).

[4] The Government also has strong arguments that factors on which the Court relied in concluding that the "finding" referred to in section 360b(e)(1) instead occurs before the hearing do not provide support the Court's conclusion. For example, different language in other statutory provisions regarding when the Agency will make "findings" and hold hearings, *see* March 22 Order at 31-33 (looking to 21 U.S.C. § 360b(d) and language in another part of 21 U.S.C. § 360b(e)(1)) must be interpreted in light of the basic principle of statutory construction that "statutory language must be read in context since a phrase gathers meaning from the words around it." *Gen. Dynamics Lands Sys., Inc. v. Cline*, 540 U.S. 581, 598 (2004). Indeed, the fact that the exigency clause of section 360b(e)(1) on which the Court relies clearly contemplates a

To the extent that section 360b(e)(1) contains any ambiguity regarding whether the "finding" described by that provision is to occur before or after the hearing, FDA's interpretation of that provision is entitled to *Chevron* deference. March 22 Order at 35; *see also* Govt's S.J. Br. at 16-18. The Court's failure to accord such deference to FDA's interpretation of section 360b(e)(1) was based solely on its flawed conclusion that the "finding" described in section 360b(e)(1) is the same "finding" described in FDA regulation, 21 C.F.R. § 514.115(b)(3)(ii). *See* March 22 Order at 35-39. Because the regulation describes a "finding" that occurs before a hearing on the proposed withdrawal is held, the Court concluded that so must the statutory "finding." *Id.*

That ruling, however, failed to accord proper deference to FDA's reasonable interpretation of the statutes and its own regulations. Indeed, FDA's longstanding view is that a proposal to withdraw a drug does not equate to the final decision to withdraw the drug.[5] The

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pre-hearing "finding" supports the conclusion that different language used in the portion of section 360b(e)(1) at issue here reflects Congressional intent that the "findings" at issue here occur only after the contemplated hearing.

The Court also relied on an FDCA provision referring to FDA's general "mission." March 22 Order at 33 (citing 21 U.S.C. § 393(b)(1)-(2)). But as the Supreme Court has held, "broad statutory mandate" cannot provide a basis to compel specific agency action. *See Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 66-67 (2004).

[5] That view is reflected in various FDA regulations. Specifically, as FDA regulations reflect, in withdrawal proceedings, CVM and the drug sponsors are adversaries advocating, respectively, in favor of, and against withdrawal, with the Commissioner or an Administrative Law Judge serving as the fact-finder. 21 C.F.R. § 514.200(c) (hearings are required if "genuine and substantial issue of fact precludes . . . withdrawal of approval of the application). This procedure reflects that the issuance by BVM of an NOOH is no more than the first step in a process ultimately aimed at resolving factual issues and possibly making a final finding.

Likewise, although the Commissioner had delegated to BVM the authority to "issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications," 21 C.F.R. § 5.84 (1977), Ex. M to Jan. Barcelo Decl.; *see also* FDA Staff Manual Guidelines § 1410.10(1)(A)(1) (delegation to CVM today), Ex. A to Jan. Barcelo Decl., BVM did not have authority to issue an actual "notice of withdrawal of approval" unless "the opportunity for hearing ha[d] been waived," Jan. Barcelo Decl. Exs. A &M. This authority to withdraw approvals was reserved to the Commissioner, which also reflects FDA's

designation of "findings" at the beginning and end of the drug withdrawal process does not mean that both findings are the same or carry the same significance. The word "finding" used in two different contexts may carry two different meanings, because the word may refer to two different things that are being "found." *See, e.g.*, *Gen. Dynamics Lands Sys.*, 540 U.S. at 582 ("[S]tatutory language must be read in context since a phrase gathers meaning from the words around it."); *Helvering v. Stockholds Enskilda Bank*, 293 U.S. 84, 87 (1934) ("[M]ost words admit of different shades of meaning, susceptible of being expanded or abridged to conform to the sense in which they are used."). Here, the regulation contemplates only a preliminary "finding" that triggers the withdrawal process, and the statute refers to a final "finding" that actually forms a basis to withdraw approval. It is reasonable for FDA to have used this common word differently in the regulation, and FDA's interpretation of its own regulation should receive judicial deference. *See Auer v. Robbins*, 519 U.S. 452, 461-63 (1997) (an "agency's interpretations [of its own regulations] are . . . entitled to deference and are 'controlling unless plainly erroneous or inconsistent with the regulation'").

Indeed, the Court recognized that under its interpretation of 21 U.S.C. § 360b(e)(1), two "findings" are necessary—one before, and one after, the hearing, March 22 Order at 31 n.11—but the Court did not reconcile its view with the statute's reference to only one "finding." It is only logical that, to the extent that there are two required findings, the first would function to commence the withdrawal process (the finding referred to in 21 C.F.R. § 514.115(b)(3)(ii)) and the second would constitute a final order that concludes the process (the finding referred to in 21 U.S.C. § 360b(e)(1)). Accordingly, to the extent that section 360b(e)(1) contains any ambiguity, that ambiguity should be resolved in favor of FDA's interpretation, pursuant to which the

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intention that to the extent the issuance of an NOOH reflects an agency "finding," that "finding" is merely preliminary, and is not the "finding" described in 21 U.S.C. § 360b(e)(1).

"finding" described in section 360b(e)(1) has never occurred and FDA is under no mandatory duty to convene Withdrawal Proceedings now, 35 years after the 1977 NOOHs issued.

FDA will also make a strong showing on appeal that regardless of the effect of the 1977 NOOHs while they were in place, because FDA withdrew those NOOHs in December 2011, *see* 76 Fed. Reg. at 79700, Jan. Barcelo Decl. Ex. L, those withdrawn notices cannot provide a basis to now compel FDA to move forward with the Withdrawal Proceedings.

The Court erred in its ruling that FDA had not effectively withdrawn the 1977 NOOHs (contrary to FDA's December 2011 announcement in the Federal Register that it had) because the Agency's stated reasons for withdrawing those NOOHs did not, in the Court's view, include withdrawal of the scientific "findings" that formed the basis for the 1977 NOOHs. March 22 Order at 49-52. That ruling overlooked FDA's explanation in its December 2011 withdrawal of the 1977 NOOHs that the scientific bases for the NOOHs had were outdated, and any Withdrawal Proceeding would need to be based on contemporary science. 76 Fed. Reg. 79697, 79700 (Dec. 22, 2011), Jan. Barcelo Decl. Ex. L at 4. Indeed, if FDA were to move forward with the Withdrawal Proceedings, it would first need to "determine the Agency's current scientific positions with regard to the microbial food safety of the NOOH Products." Declaration of William T. Flynn dated May 15, 2012 ("First Flynn Decl.") at ¶ 13 (Dkt. No. 86). But in exercising its regulatory discretion, FDA opted not to update the NOOHs and proceed with Withdrawal Proceedings immediately, but instead decided to implement a phased enforcement program that focuses first on voluntary compliance. This is an archetypal exercise of the agency's expert scientific judgment and regulatory discretion, to which the courts should defer. *See Schering Corp. v. FDA*, 51 F.3d 390, 399 (3d Cir. 1995) (FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA's

expertise and merit deference from us"); *see also Henley v. FDA*, 77 F.3d 616, 620 (2d Cir. 1996) ("[T]he FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits of [the drug] involves a high degree of expert scientific analysis."); *Baltimore Gas & Electric Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *Federal Power Comm'n v. Florida Power & Light Co.*, 404 U.S. 453, 463 (1972).

Established principles of agency discretion also underscore why, on appeal, the Government will present a substantial case that FDA's decision not to proceed immediately with adversarial Withdrawal Proceedings should be unreviewable as a "decision[] not to enforce" under *Heckler v. Chaney*, 470 U.S. 821, 828 (1985), and its progeny, and therefore not subject to judicial review. It is well settled that FDA has broad discretion regarding how to enforce applicable requirements in the FDCA. *See, e.g., Chaney*, 470 U.S. at 838 (FDA's decision to not "take various investigatory and enforcement actions" pursuant to the FDCA was exempt from judicial review); *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005) (FDA's decision to allow manufacturers of unapproved drugs two extra years to submit new drug applications was an "exercise of FDA's enforcement discretion" and immune to judicial review); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) (FDA's decision to abstain from action while it considered whether a product was a "new drug" is an exercise of the Agency's unreviewable discretion because "there are no statutory guidelines compelling the agency to investigate or pursue enforcement actions within any specified time frame"), *id.* at 687 (decision to abandon ongoing enforcement proceedings also within FDA's discretion).[6]

[6] *American Public Health Ass'n v. Veneman*, 349 F. Supp. 1311, 1315 (D.D.C. 1972), on which the Court relied in holding the contrary, *slip op.* at 52, was decided thirteen years before *Chaney*, and dealt with a challenge to a different regulatory undertaking by FDA to which specific timeframes applied. 349 F. Supp. at 1313-15.

Indeed, FDA's December 2011 explanation for its decision to withdraw of the 1977 NOOHs makes clear that, in deciding to withdraw those notices and defer Withdrawal Proceedings, the Agency was invoking the same type of discretion that was at issue in *Chaney*. Jan. Barcelo Decl. Ex. L. The Supreme Court's recognition in *Chaney* that agencies have the discretion to allocate resources is particularly relevant here.[7] *See Chaney*, 470 U.S. at 831. FDA has determined that its limited resources are "best spent" by pursuing voluntary reform in the first instance, rather than pursuing inevitably lengthy and expensive withdrawal proceedings, Jan. Barcelo Decl. Ex. I at 3, Ex. J at 2-3 (citing examples), and that pursuing the Withdrawal Proceedings could force FDA to defer and possibly scale back other regulatory efforts pertaining to the drug supply and human health. (Second Flynn Decl. ¶¶ 4, 8, 10-12.) But the Agency cannot be forced to redirect appropriated funds in order to pursue Plaintiffs' own enforcement agenda. *See, e.g.*, *Cobell v. Norton*, 428 F.3d 1070, 1076 (D.C. Cir. 2005) ("judgment about the allocation of scarce resources" is a "classic reason[ ] for deference to administrators"); *Sierra Club v. Whitman*, 268 F.3d 898, 902-03 (9th Cir. 2001) (agency action held unreviewable in part because of need for agency to focus resources where they might be most effective); *see also Natural Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 105 (D.C. Cir. 1979) (agency is "allowed to be master of its own house" because it "alone is cognizant of the many demands on it, its

[7] All of the reasons the *Chaney* Court gave for applying a presumption of non-reviewability apply here, and should operate to protect FDA's ability to decide on the most desirable means of exercising its authority. Those reasons are: (1) more deference is generally due to agency decisions that "involves a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise," 470 U.S. at 831; (2) "when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect," *id.* at 832; and (3) decisions analogous to "the decision of a prosecutor in the Executive Branch not to indict" are generally owed substantial deference. *Id.*

limited resources, and the most effective structuring and timing of proceedings to resolve those competing demands"). These considerations will further enhance FDA's prospects on appeal.[8]

C. The Government Will Be Irreparably Injured Absent a Stay

The Court should also grant a stay because compliance with the March 22 Order would irreparably harm FDA. Compliance would require the Agency to immediately devote substantial resources to Withdrawal Proceedings that the Court of Appeals may determine are unnecessary. In the meantime, FDA would have diverted resources away from other Agency programs that are important to FDA's public health mission, including its new regulatory strategy to address antimicrobial resistance.

One of the most resource-intensive parts of the Withdrawal Proceedings is the initial step—the re-issuance of the NOOHs.[9] (First Flynn Decl. ¶¶ 8-16.) FDA anticipates that the process of updating and reissuing the NOOHs will take 11 to 17 months. (*Id.* ¶ 16.) Accordingly, by the time the appeal is decided, many (if not all) of the resources needed to prepare the revised NOOHs will likely have been expended.

The quantity of potentially wasted resources would be substantial, whether expressed monetarily or in terms of the resulting inability to assign expert personnel to other important

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[8] Moreover, because FDA has now resolved the 1977 NOOHs by withdrawing them, there remains no live dispute between the parties regarding FDA's alleged failure to conclude such proceedings, and Plaintiffs' request for an order compelling FDA to complete the Withdrawal Proceedings should properly have been dismissed as moot. *See*, *e.g.*, *McBryde v. Comm. to Review Circuit Council Conduct and Disability Orders of the Judicial Conference of the United States*, 264 F.3d 52, 55 (D.C. Cir. 2001) ("If events outrun the controversy such that the court can grant no meaningful relief, the case must be dismissed as moot."); *Natural Res. Def. Council, Inc. v. Nuclear Regulatory Comm'n*, 680 F.2d 810,814-15 (D.C. Cir. 1982) (finding a case moot because the court "can hardly order the NRC at this point to do something that it has already done.").

[9] Although the March 22 Order characterizes such an update as optional, *see Slip op.* at 54, FDA has determined that it could not proceed with the Withdrawal Proceedings without first updating those NOOHs. (First Flynn Decl. ¶¶ 9-10.)

FDA work. Reissuing the NOOHs will take the efforts of over a dozen FDA staff, several of whom would be senior scientists spending substantial amounts of time on the project. (*Id.* ¶¶ 11-16.) These employees would be taken away from other duties, including drug review, scientific research, antimicrobial resistance monitoring activities, post-approval drug monitoring activities, and enforcement activities. (*Id.* ¶¶ 6, 11); *see also infra* pp. 16-18.

These diverted resources could not be recaptured if FDA prevails on appeal. On the other hand, if a stay is granted and FDA has the opportunity to pursue its preferred regulatory strategy, revised NOOHs would only be required for whatever drugs (if any) FDA decides warrant withdrawal proceedings after FDA has exhausted its efforts to encourage voluntary reform. Indeed, even if Plaintiffs prevail on the appeal and establish that FDA has a duty to proceed with the Withdrawal Proceedings, such proceedings may not be necessary if, as FDA expects, its voluntary strategy is successful. In such a circumstance there would be no need for FDA to re-issue NOOHs and launch adversarial proceedings because drug sponsors could by then have committed to withdrawing their growth-promotion approvals voluntarily.

FDA also expects that the potentially unnecessary expenditure of resources to reinitiate the Withdrawal Proceedings will compromise FDA's ability to pursue its goals with respect to antimicrobial resistance and animal drug licensing by diverting resources away from those programs, to the detriment of the public health. *See Ark. Peace Ctr. v. Ark. Dep't of Pollution Control*, 992 F.2d 145, 147 (8th Cir. 1993) (finding irreparable harm sufficient to grant a stay pending appeal where the lack of a stay may negatively affect an agency's ability to fulfill its mission, and the "public interest in protecting the environment"); *James River Flood Control Ass'n v. Watt*, 680 F.2d 543, 544 (8th Cir. 1982) (granting a stay pending appeal where

Department of the Interior ("DOI") had shown that without a stay it may suffer irreparable harm because without a stay DOI's efforts to begin a project would be delayed).

In particular, reinitiating the Withdrawal Proceedings will compromise FDA's ability to finalize and implement its current plan to end the use of Medically Important Antimicrobials in animals for growth promotion uses, because allocating resources to the Withdrawal Proceedings will divert CVM's resources away from finalizing and implementing its proposed strategy. (Second Flynn Decl. ¶¶ 4, 8.) If the strategy set forth in GFI 209 and Draft GFI 213 is sidetracked, FDA believes that its ultimate goal of withdrawing growth promotion indications for the approximately 161 Medically Important Antimicrobials will be delayed. (*Id.* ¶ 8.)

Indeed, FDA's proposed strategy, as described in GFI 209 and Draft GFI 213, is designed specifically to reduce the misuse and overuse of antibiotics in animals that are contributing to the development of antimicrobial resistance in the most quick and efficient manner possible. (*Id.* ¶ 7.) This approach was formulated in part in response to the Agency's experience in attempting to withdraw the drug Baytril (an antibiotic drug product in the fluoroquinolone class) for use in poultry because of concerns about antimicrobial resistance. (*Id.* ¶¶ 4-5.) Given the vast time and expense required to withdraw just one drug approval, the Agency concluded that it might not be practical to seek to withdraw involuntarily the remaining approximately 161 individual approved applications covering growth promotion uses for Medically Important Antimicrobials, which includes the 73 NOOH Products. (*Id.* ¶¶ 2, 5); *see also* Second Flynn Decl. Ex. A at 13-17; Second Flynn Decl. B at 18-22; Jan. Barcelo Decl. Ex. I at 3-4; Jan. Barcelo Decl. Ex. J at 2-4. Because FDA determined that such involuntary withdrawal proceedings would take many years to complete, FDA formulated its alternative strategy, which would focus first on eliminating the injudicious use of such drugs voluntarily, with the potential for more compulsory regulatory

action later, if needed. (Second Flynn Decl. ¶ 5); *see also* Second Flynn Decl. Ex. C at7; Jan. Barcelo Ex. I at 4; Jan. Barcelo Decl. Ex. J at 4. If that alternative regulatory strategy is successful, its should result in the withdrawal of the applicable drug approvals for growth promotion within a three-year period after Draft GFI 213 is finalized. (Second Flynn Decl. ¶ 6.); Second Flynn Decl. Ex. C at 7-8.

The public comment period for Draft GFI 213 closes on July 12, 2012, at which point CVM scientists will need to assist in the review and analysis of those comments. Although CVM cannot be sure of the number of comments it will receive, when GFI 209 was first issued as a draft guidance in 2010, FDA received approximately 1,200 distinct comments from individuals or organizations and more than 100,000 comments as part of "write-in" campaigns. (Second Flynn Decl. ¶ 9.) After completing the analysis of those public comments, CVM's scientists would next be involved in the process preparing a final version of the guidance. If this work is delayed, it will slow the completion and implementation of Draft GFI 213, which will, in turn, delay the withdrawal of growth promotion indications for all of the approximately 161 Medically Important Antimicrobials.

CVM also expects that, consistent with GFI 209 and Draft GFI 213, some drug sponsors, in connection with withdrawing their approvals for growth promotion indications, will seek approvals for legitimate new therapeutic indications at the same time. (First Flynn Decl. ¶ 28; Second Flynn Decl. ¶ 12). CVM's dedication of substantial resources to the Withdrawal Proceedings could delay its review of such new animal drug applications. (First Flynn Decl. ¶ 27; Second Flynn Decl. ¶ 12.) FDA is concerned that, "[i]f the review of new drug applications submitted pursuant to GFI 209 and Draft GFI 213 is delayed because CVM personnel are committed to working on Withdrawal Proceedings," drug sponsors may be discouraged from

participating in the proposed voluntary program, which could cripple FDA's enforcement plan. (First Flynn Decl. ¶ 27.)

Finally, the dedication of resources to prepare new NOOHs would also have negative effects on other programs that are important to public health generally, and the issue of antimicrobial resistance specifically. For instance, many of the employees from CVM's Office of Research who would be involved in the Withdrawal Proceedings would be diverted from working on implementing the National Antimicrobial Resistance Monitoring System ("NARMS"), which is a national public health surveillance system that tracks antibiotic resistance in foodborne bacteria. (*Id.* ¶ 26.) Diversion of resources from the NARMS program would delay the preparation of NARMS data reports and the dissemination of important information on antimicrobial resistance. Complying with the March 22 Order also will hinder CVM's ongoing efforts to implement the NARMS Strategic Plan (Second Flynn Decl. ¶¶ 10-11), which includes plans for important enhancements to the design of the program.

Ultimately, because of these various ways in which FDA's regulatory goals will be compromised by the diversion of resources to pursue the Withdrawal Proceedings that may, after the appeal, no longer be required and that the Government would not be able to recoup, the Government will suffer irreparable harm if a stay is not granted.

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

Although the Government would suffer substantial injury without a stay, neither Plaintiffs nor the public as a whole would suffer such injury if a stay is granted. Indeed, the public would benefit from the grant of a stay because FDA—the agency tasked with regulating animal drug safety—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

regulatory program described in GFI 209 and Draft GFI 213. *See supra* p. 16. As described in more detail above, the pursuit of Withdrawal Proceedings now would compromise the Agency's pursuit of that preferred strategy.

One important reason why the grant of a stay would align with the public interest is that FDA's preferred regulatory strategy covers a much broader set of drugs than contemplated by the March 22 Order. The Withdrawal Proceedings would be aimed at withdrawing growth promotion indications for only the 73 NOOH Products, but FDA's preferred strategy as set forth in GFI 209 and Draft GFI 213 would seek to achieve that same goal with respect to all of the approximately 161 Medically Important Antimicrobials (which include the NOOH Products). (Second Flynn Decl. ¶ 4). Furthermore, the unnecessary expenditure of public funds and resources is not in the public interest. *See supra* pp. 14-15; *accord James River*, 680 F.2d at 544-45 (the public interest is served by minimizing "expenditures from the public treasury"); *Ruiz v. Estelle*, 650 F.2d 555, 569 (5th Cir. 1981) ("If the State prevails on appeal, the public is best served by not placing on the State the personnel and monetary burdens of implement[ation of the court's order].").

Plaintiffs are in the same position as members of the public, and therefore will not suffer substantial harm if a stay is granted. While Plaintiffs may argue that a delay of the Withdrawal Proceedings will cause harm to themselves and to the public generally, any such harm will be mitigated by the fact that the strategy set forth in GFI 209 and Draft GFI 213, which FDA is pursuing already, is specifically designed to address and mitigate those very same harms, and is intended to do so with respect to a broader group of drugs than would be the subject of the Withdrawal Proceedings. Accordingly, any purported harm to Plaintiffs caused by deferring

Withdrawal Proceedings is strongly outweighed by the public benefit of permitting FDA to pursue its regulatory goals.

CONCLUSION

For the foregoing reasons, the Court should grant the Government's motion for a stay of 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 the Government's motion for a stay in the United States Court of Appeals for the Second Circuit.

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Respectfully submitted,

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