IN THE UNITED STATES DISTRICT COURT
FOR THE 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,	)	11 CIV 3562 (THK)
	)	ECF Case
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.	)	

OPPOSITION TO THE GOVERNMENT'S MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON THEIR THIRD CLAIM FOR RELIEF

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Dated: April 2, 2012

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INTRODUCTION

Although it concedes that the "injudicious use of antibiotics in animals should stop," the Government now contends that the U.S. Food and Drug Administration (FDA) exercised unreviewable enforcement discretion when it denied plaintiffs' citizen petitions, which urged the agency to withdraw approvals for nontherapeutic uses of medically important antibiotics in livestock. Defendants wrongly conflate two agency functions: (1) FDA's broad discretion to sanction regulated parties for violations of the Federal Food, Drug, and Cosmetic Act (Food and Drug Act) and (2) its statutory obligation to determine which animal drugs are safe for human health and to rescind approval for drugs that are not shown to be safe. This Court has already held that the Food and Drug Act requires FDA to withdraw approval of animal drugs that it finds are not shown to be safe. Because Congress has provided clear standards against which to judge FDA's conduct, the petition denials are subject to judicial review under the Administrative Procedure Act (APA).

The petition denials are not in accordance with law because they rely on reasoning divorced from the text of the Food and Drug Act. Rather than reviewing the scientific evidence petitioners presented and then determining whether the challenged drug uses are safe for human health under the Act, FDA denied the petitions in favor of an unenforceable plea for industry cooperation. This violated the APA. Moreover, the administrative record FDA has tendered reveals not a shred of evidence that efforts to promote voluntary reform will be effective. The lack of such evidence renders the petition denials arbitrary, in further violation of the APA. For these reasons, plaintiffs seek an order vacating the denials and remanding the matter to FDA with instructions to address the petitions promptly on their merits.

ARGUMENT

I. FDA's Denials of the Citizen Petitions Are Subject to Judicial Review

A. No Presumption of Unreviewability Applies

The APA "embodies a 'basic presumption of judicial review.'" *Drake v. FAA*, 291 F.3d 59, 70 (D.C. Cir. 2002) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967)). Nonetheless, review is precluded when the challenged agency action has been "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). In interpreting this provision, the Supreme Court has concluded that "certain categories of administrative decisions, including refusals to take enforcement actions, are presumptively outside the bounds of judicial review." *Drake*, 291 F.3d at 70 (citing *Heckler v. Chaney*, 470 U.S. 821, 831-34 (1985)). A presumption of unreviewability does not apply in this case because proceedings to withdraw approval of animal drugs are neither enforcement actions nor decisions allocating lump-sum appropriations.

1. Proceedings to Withdraw Approval of an Animal Drug Are Not Enforcement Actions Committed to FDA's Discretion

Although the word "enforcement" never appeared in the Government's summary judgment briefing on plaintiffs' First Claim for Relief—seeking to compel FDA to complete withdrawal proceedings for penicillin and tetracyclines in animal feed—the main thrust of the Government's brief on plaintiffs' Third Claim is that proceedings to withdraw approval of an animal drug are "enforcement" actions committed to the agency's discretion. *See* Mem. in Supp. of the Government's Mot. for Summ. J. on Pls.' First Supplemental Compl. and in Opp'n to Pls.' Second Mot. for Summ. J. (Gov't Opp'n Br.) 1-2, 5, 10, 13-16, 27, Mar. 21, 2012 (Dkt. 64). This late-breaking argument fails for two reasons: First, this Court has already held that FDA has a nondiscretionary duty to commence withdrawal proceedings when it finds that a previously approved animal drug is no longer shown to be safe. Second, withdrawal proceedings are

fundamentally different from enforcement actions. In approval and withdrawal proceedings, FDA *prescribes* which drug uses are lawful. It *enforces* those prescriptions, and other substantive requirements of the law, in separate enforcement actions. No enforcement action is implicated here.

a. This Court Has Held that Withdrawal Proceedings Are Not Committed to FDA's Discretion

FDA contends that withdrawal proceedings are entirely discretionary, *see* Gov't Opp'n Br. 16-17 n.13, but this Court has held otherwise: "[T]he statute unambiguously commands the Secretary to withdraw approval of any new animal drug that he finds is not shown to be safe, provided that the sponsor of the animal drug has notice and an opportunity for a hearing." Mem. Op. & Order (Order) 29, Mar. 22, 2012 (Dkt. 70); *see also id.* at 33-34 (holding that the Food and Drug Act "requires the Secretary to issue notice and an opportunity for hearing whenever he finds that a new animal drug is not shown to be safe"). The Court ordered FDA to initiate and conclude withdrawal proceedings for penicillin and tetracyclines in animal feed, in accordance with the agency's previous findings that these drug uses have not been shown to be safe. *Id.* at 54. The Government's argument that withdrawal proceedings are committed to FDA's discretion runs counter to the Court's Order.[1]

b. Withdrawal Proceedings Are Not Enforcement Actions

Additionally, withdrawal proceedings are not enforcement actions. The cases cited by the Government demonstrate that the purpose of an enforcement action is to hold a regulated party accountable for a violation of existing law. This case is different, as FDA itself points out: "There is no allegation that any drugs at issue in this litigation are not new animal drugs that are

[1] Because the citizen petitions covered medically important antibiotics in addition to penicillin and tetracyclines, the Court's Order did not resolve plaintiffs' Third Claim for Relief.

currently sold lawfully pursuant to approved [applications]." Gov't Opp'n Br. 4. The citizen petitions did not ask FDA to penalize drug sponsors for marketing *unapproved* drug products. Rather, they asked the agency to change the law—to make currently *lawful* drug uses unlawful. That is not an enforcement action.

The organization of the Food and Drug Act separates the substantive provisions of the Act from its enforcement provisions. Subchapter V, "Drugs and Devices," sets forth the substantive law concerning the regulation of human drugs, animal drugs, and medical devices—including the provisions for approval and withdrawal of approval of new animal drug applications. *See* 21 U.S.C. §§ 351-360ccc-2 (containing § 360b). Section 355, in Subchapter V, makes it unlawful to introduce unapproved new drugs into interstate commerce. *See id.* § 355(a). Other provisions in Subchapter V define "adulterated" and "misbranded" drugs, *id.* §§ 351-352, and an additional provision deems unapproved new animal drugs to be adulterated. *See id.* § 360b(a)(1) (referring to § 351(a)(5), defining "adulterated").

A separate subchapter, Subchapter III, is entitled "Prohibited Acts and Penalties." *Id.* §§ 331-337. It is Subchapter III that addresses enforcement. For example, section 331 enumerates dozens of specific acts that constitute violations of the statute's substantive requirements, including the introduction into commerce of any article "in violation of section . . . 355." *Id.* § 331(d). Section 331 classifies adulteration, misbranding, and the introduction of an adulterated or misbranded drug into commerce as prohibited acts. *Id.* § 331(a), (b), (k). Subchapter III sets forth various penalties for these prohibited acts, including imprisonment, fines, and civil penalties. *See id.* §§ 332-333.

The Government misapplies the cases it cites in which courts declined to review FDA's exercise of its enforcement discretion. In every one of these cases, the question was whether

FDA could be required to enforce the Food and Drug Act against a party that had allegedly committed a prohibited act under Subchapter III. In *Chaney* itself, prison inmates argued that their states' use of certain drugs "for human execution was the 'unapproved use of an approved drug' and constituted a violation of the [Food and Drug] Act's prohibitions against 'misbranding.'" 470 U.S. at 823-24; *see* 21 U.S.C. § 331(k). In the other FDA cases, the plaintiffs argued that the agency was permitting violations of the Act by allowing drugs—or, in one case, a genetically modified aquarium fish—to be introduced into interstate commerce without approved new drug or new animal drug applications. *See Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1257-58 (D.C. Cir. 2005) (challenging FDA's decision to allow manufacturers of unapproved drugs three additional years to submit new drug applications); *Cutler v. Hayes*, 818 F.2d 879, 882-86, 892 (D.C. Cir. 1987) (challenging FDA's failure to bring enforcement proceedings against manufacturers lacking approved new drug applications for over-the-counter drugs not generally recognized as effective, *see* 21 U.S.C. § 321(p) (defining "new drug" as a drug "not generally recognized . . . as safe and effective")); *Schering Corp. v. Heckler*, 779 F.2d 683, 685 (D.C. Cir. 1985) (challenging FDA's decision temporarily to forgo an enforcement action against a manufacturer distributing unapproved animal drugs); *Int'l Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 6-7 (D.D.C. 2006) (challenging FDA's decision not to pursue action against a manufacturer marketing a genetically modified aquarium fish without an approved new animal drug application).

The Government points to several FDA policy documents that, it says, describe the agency's enforcement discretion. *See* Gov't Opp'n Br. 5 n.7. Like the cases just discussed, these documents uniformly concern agency efforts to correct or sanction *violations* of existing standards. The FDA Regulatory Procedures Manual explains that the agency may issue warning

letters "to correct violations of the statutes or regulations." Ex. B to 2d Decl. of Amy A. Barcelo, at 1, Mar. 21, 2012 (Dkt. 65-2). The FDA Investigations Operations Manual describes voluntary industry actions to address "violative" products or conditions, and it explains that "violative means the product or condition does not comply with the Acts or associated regulations enforced by the Agency." *Id.* Ex. C, at 1 (Dkt. 65-3). Similarly, the Center for Veterinary Medicine (CVM) Program Policy and Procedures Manual describes educational activities undertaken by CVM to increase "compliance with the Federal Food, Drug, and Cosmetic Act." *Id.* Ex. A, at 1 (Dkt. 65-1). These documents are inapposite because the petitions did not ask FDA to sanction unlawful activity by a third party; rather, petitioners asked *FDA* to comply with mandatory duties imposed on *it* by the Food and Drug Act.

The Government also cites cases delineating the enforcement discretion of agencies other than FDA. Like the FDA cases, these all began with a request that the agency take action against a regulated party that was allegedly not complying with its obligations under existing law. In *Riverkeeper, Inc. v. Collins*, 359 F.3d 156 (2d Cir. 2004), the plaintiffs filed a petition under 10 C.F.R. § 2.206, asking the Nuclear Regulatory Commission (NRC) to take "an enforcement action" against a nuclear power plant. 359 F.3d at 158, 163. FDA misinterprets a footnote in *Riverkeeper* to mean that *Chaney*'s presumption of unreviewability applies even when plaintiffs seek relief that is "not purely enforcement relief." 359 F.3d at 166 n.11; *see* Gov't Opp'n Br. 11. The Government reads too much into this footnote, which has no bearing here. The *Riverkeeper* court made no general statement about the kinds of cases to which *Chaney* applies. Rather, after noting that plaintiffs had waived their argument that they sought relief that was "not purely enforcement relief," the court concluded that "*the case before us* is properly construed under *Chaney* as an appeal from the denial of an enforcement action." 359 F.3d at 166 n.11 (emphasis

added); *cf. Nuclear Info. Res. Serv. v. Nuclear Regulatory Comm'n*, 969 F.2d 1169, 1178 (D.C. Cir. 1992) (en banc) (holding that agency action on a petition under 10 C.F.R. § 2.206 is unreviewable only when the petition requests enforcement).

The *Riverkeeper* plaintiffs sought to compel the NRC to enforce regulations that imposed certain requirements on *licensees*. *See Riverkeeper*, 359 F.3d at 159 nn. 1-2 (describing 10 C.F.R. § 73.55, requiring nuclear plant licensees to take measures to protect the plant from radiological sabotage, and 10 C.F.R. § 73.51, requiring licensees to ensure that spent-fuel storage does not present unreasonable safety risks). The statute governing the agency's conduct granted the NRC broad discretion to regulate the possession and use of nuclear material as it deemed "necessary or desirable," *id.* at 163 (quoting 42 U.S.C. § 2201(b)), and plaintiffs themselves did not argue that the statute provided any "'meaningful standard against which to judge the agency's exercise of discretion.'" *Id.* at 166 (quoting *Chaney*, 359 F.3d at 166)). This case is different. Here, the petitions asked FDA to comply with the very specific mandate that the Food and Drug Act imposes on the *agency* to withdraw approval for drug uses that it finds are not shown to be safe. *See infra* pp. 11-13. No part of the relief sought by petitioners is law enforcement against third parties. *Riverkeeper* is inapposite.

The remaining cases cited by FDA all likewise implicate an agency's discretion to sanction a third party for violations of existing law: In *New York Public Interest Research Group v. Whitman*, 321 F.3d 316, 319, 322 (2d Cir. 2003), plaintiffs requested that the Environmental Protection Agency (EPA) issue a Notice of Deficiency (NOD) to New York State because the state had failed adequately to administer its Clean Air Act permitting program. *See* 42 U.S.C. § 7661a(i)(1); *id.* § 7509(b) (setting forth sanctions that EPA may impose on states after issuing a NOD). Similarly, *Sierra Club v. Whitman*, 268 F.3d 898, 901-02 (9th Cir. 2001), involved an

alleged violation of the Clean Water Act, and *Speed Mining, Inc. v. Federal Mine Safety & Health Review Commission*, 528 F.3d 310, 318-19 (4th Cir. 2008), and *Secretary of Labor v. Twentymile Coal Co.*, 456 F.3d 151, 156-57 (D.C. Cir. 2006), both turned on the prosecutorial discretion of the Secretary of Labor to decide whom to cite for a violation of the Federal Mine Safety and Health Act.

Courts have not applied *Chaney* in cases in which plaintiffs sought the withdrawal or suspension of approval of an animal drug, because that type of regulatory action is not enforcement. In *Barnes v. Shalala*, 865 F. Supp. 550, 554 (W.D. Wis. 1994), plaintiffs asserted that FDA should have imposed a labeling requirement when it approved a bovine growth hormone (rbST), and they sought suspension of approval as a remedy. The court found the action reviewable because plaintiffs were "not asking the agency to undertake enforcement actions," such as "investigat[ing] alleged unapproved uses of rbST." *Id.* at 558. They asked "only that the FDA reconsider the necessity of labeling products containing milk from rbST-treated cows." *Id.*; *see also A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1487, 1492 (D.C. Cir. 1995) (reviewing FDA's denial of a citizen petition requesting withdrawal of approval of an animal drug, and remanding to FDA for a fuller explanation of its approval). This Court should reach the same result.

The fact that approval and withdrawal proceedings can be characterized as adjudications does not make them enforcement actions. Regardless of the form they take, these proceedings have a number of legislative aspects. They have future effect, because they establish whether particular animal drugs are approved to be marketed under the Food and Drug Act. They affect others in addition to the drug sponsor: for example, manufacturers of generic drugs may submit "abbreviated" drug applications that reference and rely on already approved applications. *See* 21

U.S.C. § 360b(b)(2), (n). And they result in "regulation[s]" that are published in the Code of Federal Regulations, *see id.* § 360b(i); 21 C.F.R. pts. 520-529, 558, in which only agency pronouncements with "legal effect" may be published. 44 U.S.C. § 1510(a); *see* 1 C.F.R. § 8.1; *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 539 (D.C. Cir. 1986) (Scalia, J.) (explaining that the Code of Federal Regulations is authorized to contain "only documents 'having general applicability and legal effect'" (citing 44 U.S.C. § 1510) (emphasis omitted)). The Government argues that the provision requiring the publication of regulations is "mostly arcane," but it admits that these regulations have a legal impact on animal feed manufacturers. *See* 21 U.S.C. § 360b(m)(1)(C); Gov't Opp'n Br. 22 n.22. These legislative characteristics amply distinguish approval and withdrawal proceedings from enforcement actions, and the Government has cited no case that suggests otherwise.

2. This Is Not a Lump-Sum Appropriation Case

The Government's reliance on *Lincoln v. Vigil*, 508 U.S. 182, 186 (1993), is misplaced. *See* Gov't Opp'n Br. 15-16. There, the Supreme Court held that, "[l]ike the decision against instituting enforcement proceedings, . . . an agency's allocation of funds from a lump-sum appropriation" is presumptively unreviewable. *Id.* at 193. This case does not concern the allocation of funds from a lump-sum appropriation. It concerns FDA's duty to comply with the substantive requirements of the Food and Drug Act.

B. The Petition Denials Are Reviewable Because There Is Law to Apply

1. The Food and Drug Act Provides Law to Apply

Because no presumption of unreviewability applies, the petition denials are presumptively reviewable, *see Abbott Labs.*, 387 U.S. at 140, unless the action requested by the petitions—the withdrawal of approval of animal drugs that present a human health risk—is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This bar to judicial review "is a

'very narrow exception,' which applies only 'in those rare instances where "statutes are drawn in such broad terms that in a given case there is no law to apply."'" *Drake*, 291 F.3d at 70 (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971)). As the D.C. Circuit has explained, "§ 701(a)(2) encodes the principle that an agency cannot abuse its discretion . . . where its governing statute confers such broad discretion as to essentially rule out the possibility of abuse." *Drake*, 291 F.3d at 70.

Courts have found "no law to apply" in cases where the statute at issue gave the agency "virtually unfettered discretion" to act as it did. *Id.* at 71. For example, Drake involved a statute allowing the FAA Administrator to dismiss a complaint against a carrier when she "is of the opinion that the complaint does not state facts that warrant an investigation." 49 U.S.C. § 46101(a)(3). The court found no law to apply because the statute "gives the FAA virtually unbridled discretion over such decisions. The only statutory reference point is the Administrator's own beliefs." 291 F.3d at 72. Similarly, in *Schneider v. Feinberg*, 345 F.3d 135, 148-49 (2d Cir. 2003), the court declined to review compensation calculations made by the Special Master appointed to administer the September 11 Victim Compensation Fund. The court concluded that the governing statute "does not guide or limit the Special Master's discretion on this point: it expressly allows the Attorney General and the Special Master to adopt all substantive and procedural regulations necessary to resolve claims, and places the resolution of claims beyond the reach of judicial review." *Id.* at 149.

In contrast, the Second Circuit exercised judicial review over a challenge to a National Park Service regulation that prohibited seaplanes on Fire Island. *Christianson v. Hauptman*, 991 F.2d 59, 63 (2d Cir. 1993). The court concluded that Congress had conferred on the Park Service a broad, but not limitless, grant of authority to manage the Fire Island National Seashore:

"Congress sought to limit the scope of the Service's authority to the environmental preservation of the area." *Id.* at 62-63. The court thus rejected the notion that the Service had "unfettered authority to manage the area in whatever way it deems appropriate." *Id.* at 63.

The Food and Drug Act provides clear standards by which to judge FDA's denials of the citizen petitions. This Court has held that the Food and Drug Act "requires the Secretary to issue notice and an opportunity for a hearing whenever he finds that a new animal drug is not shown to be safe," Order 33-34 (citing 21 U.S.C. § 360b(e)(1)), and that "the statute unambiguously commands the Secretary to withdraw approval of any new animal drug that he finds is not shown to be safe, provided that the sponsor of the animal drug has notice and an opportunity for a hearing." *Id.* at 29. The Court ordered FDA to initiate and complete withdrawal proceedings for penicillin and tetracyclines in animal feed. *Id.* at 54.

Plaintiffs do not presently seek to compel FDA to withdraw approval of the remaining drugs covered by the petitions. Rather, they ask that FDA confront the petitions on their substantive merits and determine whether, based on the scientific evidence, the challenged drug uses are shown to be safe for human health. *See* Mem. of Law in Supp. of Pls.' Mot. for Summ. J. on Their Third Claim for Relief (Pls.' Opening Br.), at 9, 20, Feb. 21, 2012 (Dkt. 57). The Government contends that there is no judicially manageable standard by which to evaluate FDA's decision not to *begin* reviewing the safety of a previously approved drug. This interpretation of FDA's statutory mandate would grant the agency unfettered discretion to refuse to make formal safety findings and thus avoid triggering the withdrawal process the statute requires. The logic of the Government's argument would place beyond judicial review FDA's failure to act even, as here, in the face of unimpeachable evidence that an approved drug use posed a serious threat to human health. Congress has not granted FDA that unbridled authority.

This Court has already held that "[a]ccording to its statutory mandate, the FDA is responsible for continuously monitoring regulated drugs and reviewing new studies of their effectiveness and safety." Order 33 (citing 21 U.S.C. § 393(b)(1)-(2) (setting forth FDA's mission to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and to "protect the public health by ensuring that . . . human and veterinary drugs are safe and effective")). FDA does not dispute that the challenged drug uses present a human health threat. *See* Gov't Opp'n Br. 1-2, 25-26. Especially in these circumstances, the agency does not have boundless discretion to decide when, if ever, to review the safety of a previously approved drug.

The Supreme Court's decision in *Massachusetts v. EPA*, 549 U.S. 497 (2007), further demonstrates the limits of FDA's discretion in this regard. There, the Court found law to apply in a section of the Clean Air Act providing that the EPA Administrator "shall" prescribe standards "applicable to the emission of any air pollutant from any class or classes of new motor vehicles . . . *which in his judgment* cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare." 42 U.S.C. § 7521(a)(1) (emphasis added); 549 U.S. at 506. The *Massachusetts* Court held that, once the agency had responded to a citizen petition asking it to make such an "endangerment finding," the agency's exercise of discretion was limited to a determination whether the finding was compelled by the available science. *See* 549 U.S. at 532-34. Likewise, the Food and Drug Act provision for withdrawal of approval of animal drugs, 21 U.S.C. § 360b(e)(1), predicates a mandatory action on a scientific finding. When FDA is confronted with a citizen petition that presents scientific evidence showing that

nontherapeutic uses of antibiotics in livestock endanger human health, the agency does not have unbounded discretion to brush the petition aside.[2]

2. *Massachusetts v. EPA* Applies to this Case

The Government offers no persuasive reason why *Massachusetts* should not apply here. Though the Supreme Court confirmed that an agency's "refusal to initiate enforcement proceedings is not ordinarily subject to judicial review," *id.* at 527, this case does not involve an exercise of enforcement discretion. *See supra* pp. 2-9. Just as in *Massachusetts*, plaintiffs' claim arises out of denials of petitions that "the affected part[ies] had an undoubted procedural right to file in the first instance," 549 U.S. at 527, and FDA regulations provide that the denial of a citizen petition is subject to judicial review. *See* 21 C.F.R. §§ 10.25(a), 10.45(d).

The Government makes much of the distinction between rulemaking and adjudication, but it does not explain why the applicability of the Court's analysis in *Massachusetts* should turn on that distinction. The only suggestion the Government offers is that judicial review of an agency's decision whether to initiate rulemaking is "particularly appropriate" because of the "legal" and "infrequent" nature of such a decision. Gov't Opp'n Br. 22 (citing *Massachusetts*, 549 U.S. at 527). As discussed above, however, the decision whether to approve or withdraw approval of an animal drug also has prospective legal effect, *see supra* pp. 8-9, and the Government concedes that withdrawal proceedings are "relatively uncommon." Gov't Opp'n Br.

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[2] FDA's reliance on *New York Public Interest Research Group v. Whitman*, *see* Gov't Opp'n Br. 17, is misplaced for two reasons. First, as noted above, that case involved a request for an enforcement action. *See supra* p. 7. There is no indication that the court would have reached the same result had it not applied a presumption of unreviewability. *See* 321 F.3d at 331 (finding that the conclusion that the statute granted EPA discretion "effectively resolve[d]" plaintiffs' challenge because "an agency's decision not to invoke an enforcement mechanism provided by statute is not typically subject to judicial review"). Second, *Whitman* predates *Massachusetts v. EPA*. To the extent that FDA's interpretation of *Whitman* were correct, it could not have survived *Massachusetts*.

1. Moreover, the Court in *Massachusetts* held that the decision whether to initiate rulemaking in that case depended on a factual, not a legal, determination: whether greenhouse gases "'cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare.'" *See Massachusetts*, 549 U.S. at 506, 532-33 (quoting 42 U.S.C. § 7521(a)(1)). Here, petitioners ask FDA to make a similar determination: whether the challenged drug uses are shown to be safe for human health. The analogy between the animal drug withdrawal provision and the statute at issue in *Massachusetts* does not fail simply because the scientific findings contemplated by the two statutes trigger different consequences. *See* Gov't Opp'n Br. 20. The point is that each statute conditions a mandatory agency action on a scientific finding, thereby limiting the agency's discretion as well as the justifications it may offer for declining to act.

II. The Petition Denials Are Arbitrary, Capricious, and Not in Accordance with Law

A. Even under a Deferential Standard of Review, the Petition Denials Are Invalid under *Massachusetts v. EPA*

The "arbitrary and capricious" standard of review is deferential. Even applying that standard, however, the Supreme Court in *Massachusetts* invalidated a petition denial very like the denials before this Court. The Supreme Court concluded that the Clean Air Act provision at issue, by predicating mandatory action on a scientific finding, directed the agency to "exercise discretion within defined statutory limits." *Massachusetts*, 549 U.S. at 533. Because the agency denied the petition based on reasons that fell outside of those limits, the Court found the denial "arbitrary, capricious, . . . or otherwise not in accordance with law." *Id.* at 534.

This Court should reach the same conclusion. The Food and Drug Act "unambiguously commands the Secretary to withdraw approval of any new animal drug that he finds is not shown to be safe." Order 29 (citing 21 U.S.C. § 360b(e)(1)). When it is confronted with a citizen petition presenting evidence that an approved drug use is not shown to be safe, the agency cannot

rely on voluntary measures in lieu of making the finding (or, on the merits, determining not to make the finding) that triggers the withdrawal process. In these circumstances, the agency's discretion to decide whether to initiate withdrawal proceedings is limited to a scientific determination whether the challenged drug uses are shown to be safe for human health. "To the extent that this constrains agency discretion to pursue other priorities . . . , this is the congressional design." *Massachusetts*, 549 U.S. at 533. Here, FDA denied the petitions without addressing the scientific evidence petitioners presented. This violated the APA.

B. FDA Admits that the Challenged Drug Uses Pose a Threat to Human Health

The Government asks this Court to defer to FDA's "evaluation of scientific information within the agency's area of technical expertise," Gov't Opp'n Br. 24, but the agency offered no scientific reasons for denying the petitions. In fact, every statement FDA has made about the science supports *granting* the petitions.

The Government admits that "the phenomenon of antimicrobial resistance exists," that "antimicrobial resistance poses a threat to public health," that "the overuse of antimicrobial drugs in food-producing animals can contribute to the development of antimicrobial resistance," and that "FDA should be involved in mitigating the risks posed by antimicrobial resistance." *Id.* at 2. FDA "has acknowledged that it has significant concerns about the potential public health consequences of misusing and overusing" antibiotics in livestock. *Id.* at 1. The agency has "made clear that it does not consider the use of medically important antibiotics for 'growth promotion' in animals to be in the interest of public health." *Id.* at 2. FDA "agrees that the injudicious use of antibiotics in animals should stop." *Id.* at 25. The Government even concedes that plaintiffs' argument that "FDA's pronouncements convey agreement with the premise of the petitions" is "true in a general sense." *Id.* at 26.

The administrative record contains similar statements, in addition to the scientific studies underlying them. In 2003, CVM reported that "[s]cientific evidence demonstrates that the use of antimicrobial drugs in food-producing animals can result in the development of resistant bacteria. The resistant bacteria can then be transferred to humans through food." The report continues: "Resistance to the antimicrobial drugs needed to treat human illness is a serious public health threat, whether the resistance develops from inappropriate use of antibiotics in people, use of antimicrobials in food-producing animals, or other sources." Administrative Record, at FDA 3067. The petitions cover antibiotics that FDA has categorized as "critically important" or "highly important" to human medicine. *See* Ex. K to Decl. of Jennifer A. Sorenson (Sorenson Decl.), at 2, Oct. 5, 2011 (Dkt. 33-11).

The Government's litigation position presents this paradox: FDA asks this Court to defer to the agency's scientific judgment because that is its area of expertise. Gov't Opp'n Br. 24-25. But the evidence proves that FDA's scientific judgment is that the nontherapeutic use of antibiotics in livestock is not shown to be safe for human health. This is precisely what the petitions say. If the Court were to defer to FDA's scientific judgment, the Food and Drug Act would require the agency to *grant* the petitions and commence withdrawal proceedings. Thus, the Government's own argument for deference underscores plaintiffs' claim that the petition denials were arbitrary.

The agency's answer is that it has selected voluntary measures as "the best path to pursue." *Id.* at 26. But that is not the path Congress has chosen. FDA's refusal to make findings about whether the drug uses covered by the petitions are "shown to be safe" for human health, 21 U.S.C. § 360b(e)(1)(B), is arbitrary, capricious, and not in accordance with law.

C. FDA Has Offered No Evidence that Voluntary Measures Will Be Effective

Even if FDA's reliance on voluntary measures were a legitimate basis under the statute for denying the petitions, the petition denials would still be arbitrary and capricious because the agency has offered no evidence to support its rationale. Given the opportunity, FDA has not pointed to a single document in a 3,317-page administrative record to justify its stated belief that voluntary measures will be effective. The Government devoted only three sentences in its brief to plaintiffs' argument that such evidence is required, contending simply that FDA need not provide any evidence, because its "attempts at voluntary reform" are "only a first step." Gov't Opp'n Br. 27. Besides conveying even less faith in voluntary measures than the agency has previously professed, *see* Pls.' Opening Br. 16, the Government's casual dismissal of plaintiffs' request for evidence disregards FDA's obligation to explain the "factual basis for its decision," rather than resting on "mere speculation." *Detsel by Detsel v. Sullivan*, 895 F.2d 58, 63-64 (2d Cir. 1990) (quoting *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626-27 (1986) (plurality opinion)).

The Government also implies that FDA intends to take some steps that are not voluntary: "FDA[] plans to regulate the Citizen Petition Drugs' remaining therapeutic indications by labeling them 'VFD' [Veterinary Feed Directive] for use only under the supervision of a licensed veterinarian." Gov't Opp'n Br. 25. But FDA has made clear, both in the petition denials and in previous briefing in this case, that the agency will not *require* drug sponsors to adopt the VFD label; rather, sponsors will have the option *voluntarily* to change the status of their products. Ex. A to Decl. of Mitchell S. Bernard (Bernard Decl.), at 4, Feb. 21, 2012 (Dkt. 59-1) ("FDA intends to work with sponsors who approach FDA and are interested in working cooperatively with the Agency . . . to transition medically important antimicrobials currently approved for over-the-counter use in food-producing animals to a marketing status that involves veterinary oversight . . . ."); Mem. in Supp. of the Government's Mot. for Summ. J. and in Opp'n to Pls.'

Mot. for Summ. J., at 9, Jan. 9, 2012 (Dkt. 41) ("FDA is now working with sponsors to voluntarily change the status of medically important antimicrobial drugs currently approved for use in feed from 'over the counter' to 'veterinary feed directive' ('VFD') status."). As with the other components of FDA's "attempts at voluntary reform," the Government has presented no evidence that its efforts to encourage drug sponsors voluntarily to opt for VFD status will be effective in protecting public health.

The Government asserts that "FDA has been actively involved in the area of antimicrobial resistance for over 40 years." Gov't Opp'n Br. 2. In that time, the volume of antibiotics used annually in U.S. livestock has quadrupled, from 7.3 million pounds in 1970 to 13,067,100 kilograms, or 28.8 million pounds, in 2009. *See* Antibiotic and Sulfonamide Drugs in the Feed of Animals, 38 Fed. Reg. 9811, 9812 (Apr. 20, 1973), Sorenson Decl. Ex. D (Dkt. 33-4); Sorenson Decl. Ex. P, at tbl.1 (Dkt. 33-16). Livestock antibiotic use outstrips human antibiotic use by a four-to-one ratio. *See* Pls.' Statement of Undisputed Material Facts in Supp. of Mot. for Summ. J. ¶ 12, Oct. 6, 2011 (Dkt. 21). During the last four decades, as the nontherapeutic use of antibiotics in livestock has proliferated, so have the scientific studies demonstrating the link between such use and the diminished efficacy of these same antibiotics to treat human infections. *See* Order 2-3. In light of these facts, FDA cannot avoid the obligation to provide a factual basis for the petition denials by labeling its voluntary reform efforts a "first step." Gov't Opp'n Br. 27.

FDA's failure to offer evidence to support its reliance on voluntary measures underscores the arbitrary and capricious nature of the petition denials. *See Detsel*, 895 F.2d at 63-64. The Government's citation to summary accounts on FDA's website of three occasions on which the agency persuaded drug sponsors voluntarily to discontinue sales of different animal drugs, in

different circumstances, does not demonstrate that the same approach is likely to be effective here. *See* Gov't Opp'n Br. 6 n.8. Given the magnitude of the use of antibiotics in livestock, the pharmaceutical industry's economic interest in maximizing that use, livestock producers' economic interest in promoting weight gain and feed efficiency, and the skepticism of the industry groups that submitted public comments on FDA's Draft Guidance 209, there is no reason to believe that FDA's attempts at voluntary reform will be successful. The Government has offered none.[3]

CONCLUSION

For the reasons detailed above and in their opening brief, plaintiffs urge the Court to invalidate the petition denials and remand the matter to FDA with instructions promptly to address the petitions on their merits and determine whether the challenged drug uses are shown to be safe for human health.

Dated: April 2, 2012

Respectfully submitted,

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[3] For the reasons set forth in their accompanying Motion to Complete the Administrative Record, plaintiffs request an order that the administrative record be completed with the industry comments filed as Exhibits C, D, and E to the Bernard Declaration (Dkt. 59).

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