UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

Alliance of Nurses for Healthy Environments, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants.	No. 8:23-cv-00176-DLB

DEFENDANTS' MEMORANDUM IN SUPPORT OF THEIR MOTION TO DISMISS

OF COUNSEL:

SAMUEL R. BAGENSTOS
General Counsel
U.S. Department of Health and Human Services

MARK RAZA
Chief Counsel
Food and Drug Administration

WENDY VICENTE
Deputy Chief Counsel, Litigation

LESLIE COHEN
Associate Chief Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Ave.
White Oak 31, Room 4532
Silver Spring, MD 20993-002
Leslie.Cohen@FDA.hhs.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

HILARY K. PERKINS
Assistant Director

GABRIEL I. SCHONFELD
ISAAC C. BELFER
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice

P.O. Box 386
Washington, DC 20044-0386
(202) 353-1531 (Schonfeld)
(202) 305-7134 (Belfer)
(202) 514-8742 (fax)
Gabriel.I.Schonfeld@usdoj.gov
Isaac.C.Belfer@usdoj.gov

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INTRODUCTION

Antimicrobial drugs are crucial tools of human and veterinary medicine, used to treat a wide variety of infections caused by microorganisms (*e.g.*, bacteria, viruses, fungi, and parasites) in both people and animals. But because microorganisms are living things that evolve in response to their environments, the use of those drugs—in both humans and animals—can contribute to the emergence of strains that are resistant to treatment. Like Plaintiffs, the U.S. Food and Drug Administration ("FDA") believes that antimicrobial resistance is a serious public health problem and that it is important to take steps to combat it. The parties disagree, however, about how FDA should pursue that goal.

This case arises out of FDA's careful, science-based efforts to promote the judicious use of medically important antibiotics (those antimicrobials—such as penicillin—that are active against bacteria)[1] for the treatment, control, and prevention of disease in food-producing animals.[2] With great success, FDA has sought the voluntary

[1] This memorandum uses the umbrella term "antimicrobials" in discussing FDA's efforts to combat drug resistance, because those efforts are not limited to antibiotics alone. But for purposes of this case—where all of the medications specifically at issue are antibiotics, *see* Compl. ¶ 43—the terms are interchangeable. *See, e.g.*, FDA, *Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* at 4 n.2 (April 3, 2012) ("*Guidance #209*"), https://perma.cc/24AY-VJLQ. "The term 'medically important antimicrobial drugs' generally refers to antimicrobial drugs that are important for therapeutic use in humans." *Id.* at 3 n.1. "Judicious [use] means that unnecessary or inappropriate use should be avoided." *Id.*

[2] Importantly, Plaintiffs seek relief only as to the approval of these drugs for the *prevention* of infection and disease. "Disease prevention involves the administration of an antimicrobial drug to animals, none of which are exhibiting clinical signs of disease,

cooperation of drug manufacturers, livestock and poultry producers, and veterinarians to ensure that medically important antibiotics are administered to food-producing animals only under veterinary supervision and when necessary to protect the animals' health. FDA has explained that such uses—including for disease prevention—are appropriate, that veterinary oversight is an important mechanism to mitigate the risk that antibiotic use will contribute to resistance, and that encouraging voluntary adoption of those principles is the most practical way to ensure that medically important antibiotics are used as judiciously as possible.

Plaintiffs are four advocacy organizations that disagree with FDA's approach. They ask the Court to second-guess FDA's expert judgment, and require it to instead adopt Plaintiffs' preferred approach—completely withdrawing certain antibiotics' approvals for *preventative* use in food-producing animals. Suing under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, *et seq.*, they assert a single claim for relief challenging FDA's denial of a Citizen Petition that requested that the agency

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in a situation where disease is likely to occur if the drug is not administered." *Guidance #209*, *supra* n.1, at 21 n.5.

Plaintiffs do *not* challenge the approval of any medically important antimicrobial for the *treatment* or *control* of infection and disease. "Treatment" covers administration of a drug "to animals diagnosed (based on clinical signs or other appropriate diagnostic methods) with the indicated disease." FDA, *Concept Paper: Potential Approach for Defining Duration of Use for Medically Important Antimicrobial Drugs Intended for Use In or On Feed* at 5 (Jan. 8, 2021), https://perma.cc/8BRG-AJFJ. "Control" describes administration "to a group of animals once a proportion of the animals in the group have been diagnosed (based on clinical signs or other appropriate diagnostic methods) with the indicated disease." *Id.* at 6.

initiate the process necessary to effectuate such withdrawals. For two independent reasons, however, this Court lacks subject matter jurisdiction over Plaintiffs' claim.

First, Plaintiffs do not have Article III standing to challenge FDA's denial of the Citizen Petition either in their own right or on behalf of their members. *See infra* Part I. Plaintiffs lack organizational standing because FDA's approach to the use of antibiotics in food-producing animals has no tangible effect on Plaintiffs' day-to-day operations, and their mere abstract disagreement with federal policy cannot support standing to sue. Plaintiffs likewise cannot sue on behalf of their members because—to the extent the Complaint identifies them at all—Plaintiffs allege only that their members have a speculative fear of hypothetically, at an unknown time in the future, contracting an unknown infection, resistant to an unknown antibiotic, which may or may not ever be prescribed (or even considered) as part of their hypothetical treatment. Nor can Plaintiffs sue based on actions their members are voluntarily taking in the present (*e.g.*, buying meat and poultry raised without antibiotics) based on these speculative concerns about the future. Those measures are in no way fairly traceable to FDA, and Plaintiffs have not plausibly alleged that they could be redressed by a favorable ruling from this Court.

Second, this Court lacks jurisdiction because the action requested in the Citizen Petition is committed to FDA's discretion by law. *See infra* Part II. An agency's discretionary enforcement decisions are not subject to review under the APA, *see* 5 U.S.C. § 701(a)(2), and the Second Circuit has already held—in a decision three of four Plaintiffs are estopped from disputing—that FDA has complete discretion regarding

initiation of the withdrawal proceedings at issue in this case. *See Nat. Res. Def. Council v. FDA* ("*NRDC II*"), 760 F.3d 151 (2d Cir. 2014). This Court should adopt the Second Circuit's persuasive reasoning with regard to all the Plaintiffs and dismiss their claim as unreviewable under the APA.

BACKGROUND

A. FDA's Authority to Regulate Animal Drugs

Just like it does for human drugs, FDA oversees the safety and efficacy of animal drugs used in the United States. *See generally* 21 U.S.C. § 360b. New animal drugs may be marketed only with FDA's approval, *see id.* § 360b(a)(1)-(3), which the agency grants only to products that satisfy the rigorous standards of the Federal Food, Drug, and Cosmetic Act ("FDCA"), *see id.* § 360b(d).[3] FDA will approve a new animal drug only if scientific evidence shows that, when used according to its labeling, the drug will be safe and effective for the animal receiving it, *see id.* § 360b(d)(1)(A), (B), (D), (E), as well as safe for humans, *see id.* § 360b(d)(2).

FDA exercises continuing oversight of approved animal drugs and—if the science warrants it— may withdraw or modify its approval by following procedures set out in the FDCA and its implementing regulations. *See id.* § 360b(e)(1). As relevant here, FDA will withdraw an animal drug's approval if the agency finds, "after due notice and opportunity for hearing to the applicant," that new evidence "shows that such drug is

[3] Certain new animal drugs may qualify for legal marketing under other provisions of the FDCA, such as those governing conditional approval. *See* 21 U.S.C. § 360ccc. Those provisions are not at issue here.

not shown to be safe . . . under the [approved] conditions of use." *Id.* § 360b(e)(1)(B). Notably, FDA has discretion under the FDCA whether to initiate proceedings to withdraw an animal drug's approval. *See infra* Part II.

B. FDA's Risk-Based Approach to the Judicious Use of Veterinary Antibiotics in Food-Producing Animals

FDA considers human safety when it decides whether to approve a new animal drug for use in food-producing animals. *See* 21 U.S.C. § 360b(d)(2). For antimicrobial drugs such as antibiotics, evaluating the risk that use in such animals will contribute to resistance is one part of that human safety review.[4] FDA also considers resistance risk as part of its ongoing safety oversight of approved antimicrobials. *Guidance #209*, *supra* n.1, at 19.

Under FDA's longstanding interpretation of the FDCA, an animal drug is "safe" for humans if there is "reasonable certainty of no harm to human health" from the proposed use of the drug in food-producing animals according to its label. *Guidance #152*, *supra* n.4, at 2; *Guidance #209*, *supra* n.1, at 18; *see also Withdrawal of Approval of The New Animal Drug Application for Enrofloxacin in Poultry* at 99-100, FDA Docket No. 2000N-1571 (July 27, 2005), https://perma.cc/LB6P-VRG4 (Part 1),

[4] *Guidance #209*, *supra* n.1, at 18; FDA, *Guidance for Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern* at 6 (Oct. 23, 2003) ("*Guidance #152*"), https://perma.cc/ZNP7-SKL7. A proposed revision to Guidance #152 was released for public comment in December 2022. *See* FDA, *Draft Guidance for Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to their Microbiological Effects on Bacteria of Human Health Concern* (Jan. 2023) ("*Draft Guidance #152*"), https://perma.cc/MCG3-N44F.

https://perma.cc/7WAV-W4ZR (Part 2). In 2003, FDA issued guidance on the "risk assessment" approach it will typically use in applying the "reasonable certainty of no harm" standard to the issue of antimicrobial resistance. *See generally Guidance #152*, *supra* n.4.

FDA's risk-based approach considers (1) the "probability that resistant bacteria are present in [the] target animal as a consequence of drug use," (2) the "probability for humans to ingest [the] bacteria in question from the relevant food commodity," and (3) the "probability that human exposure to resistant bacteria results in an adverse health consequence." *Id.* at 6. Each of these three factors is ranked as "High, Medium, or Low." *Id.* "FDA then uses the overall risk estimation ranking [derived from these three factors], along with other relevant data and information . . . to determine whether [a] drug is approvable under specific risk management conditions [set out in its labeling]."*Id.*

"FDA's [approach] is premised on the concept that increasing the exposure of bacterial populations to antimicrobial drugs increases the risk of generating resistance to those . . . drugs." *Guidance #209*, *supra* n. 1, at 18. Therefore, FDA has explained that "[u]sing medically important antimicrobial drugs *as judiciously as possible* is key to minimizing resistance development and preserving . . . effectiveness." *Id.* at 20 (emphasis added).[5]

[5] *See supra* n.1 (defining "medically important antimicrobial" and "judicious use").

Based on this approach, FDA has for more than a decade recommended two key limitations on the use of medically important antimicrobials in food-producing animals. ***First***, such uses "should be limited to those . . . that are considered necessary for assuring animal health." *Id.* at 21-22. Medically important antimicrobials should be used for "treatment, control, or prevention of specific diseases" under circumstances where disease is actually present or likely to occur, not for "enhancing the production of animal-derived products." *Id.* at 21 & n.5. ***Second***, such drugs should be used only under "veterinary oversight or consultation." *Id.* at 22.[6]

At FDA's urging, affected manufacturers have voluntarily implemented these limits with respect to *all* medically important antimicrobials administered via a food-producing animal's water or feed.[7] This implementation was completed in January 2017, and consisted of the voluntary withdrawal of dozens of new animal drug applications—either in full or with respect to their indications for production enhancement—and the voluntary conversion of hundreds of applications from over-

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[6] *See also* FDA, *Guidance for Industry #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* (Dec. 2013), https://perma.cc/JUM9-5SU9 (guidance on voluntary supplementation of approved new animal drug applications to align with FDA's judicious use principles).

[7] FDA, *FDA Announces Implementation of GFI #213, Outlines Continuing Efforts to Address Antimicrobial Resistance* (Feb. 17, 2017) ("*Guidance #213 Implementation Announcement*"), https://perma.cc/LD9M-NGVA?type=image. In order to voluntarily implement the new use requirements contemplated by *Guidance #213*, a manufacturer submits a supplemental application memorializing those requirements in revised labeling. The new requirements become mandatory upon FDA approval of the supplemental application. *See generally* 21 C.F.R. § 514.8(c).

the-counter to either prescription or "veterinary feed directive" status (both of which legally require veterinary oversight). *See Guidance #213 Implementation Announcement*, *supra* n.7. "As a result of these changes, [the antimicrobials FDA has identified as medically important] cannot be used for production (e.g., growth promotion) purposes and may only be used [in an animal's food or water] under the authorization of a licensed veterinarian." *Id.*

As demonstrated by recent proposed revisions to its guidance on the subject, FDA continues to refine and expand its voluntary, risk-based approach to assuring judicious use of antimicrobials in animals.[8] Its current priorities include the voluntary modification of existing approvals to ensure that all medically important antibiotics used in animal feed or water are labeled with a defined duration of use, the voluntary conversion to prescription status of over-the-counter medically important antibiotics administered via other routes (*e.g.*, by injection), and the collection of additional data on veterinary use of medically important antimicrobials in the United States.[9]

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[8] In particular, FDA has proposed to revise Guidance #152 to place even greater emphasis on a drug's importance in contemporary human medicine. *See* FDA, *Notice of Availability of Draft Guidance: Evaluating the Safety of Antimicrobial New Animal Drugs With Regard to Their Microbiological Effects on Bacteria of Human Health Concern*, 87 Fed. Reg. 77619, 77620 (Dec. 19, 2022); *Draft Guidance #152*, *supra* n.4, at 4 (proposing criteria for ranking drugs as "Important," "Highly Important," or "Critically Important" to human medicine).

[9] *See generally* FDA, *FDA Delivers Progress Update on 5-Year Veterinary Stewardship Plan, Publishes Report about Antimicrobial Sales, Use, and Resistance Data in Animal Agriculture* (June 30, 2022), https://perma.cc/6UMP-NH6W; FDA, *Guidance for Industry #263: Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over the Counter* (June 10, 2021), https://perma.cc/56LQ-ZK6T.

C. The Citizen Petition Submitted by Several Plaintiffs and FDA's Denial

Plaintiffs are advocacy organizations that disagree with FDA's voluntary, risk-based approach. *See* Compl. ¶¶ 15-21. Three Plaintiffs (all except Alliance of Nurses for Healthy Environments ("Alliance of Nurses")) presented their views to FDA in a Citizen Petition which they filed in 2016 and supplemented in 2020. *See* Ex. A (2016 Petition); Ex. B (2020 Petition Supplement)[10]; *see also* 21 C.F.R. § 10.25(a) ("An interested person may petition [FDA] to . . . revoke a[n] . . . order, or to take . . . any other form of administrative action."); *id.* § 10.30 (procedures for submission and consideration of citizen petitions). The Citizen Petition argued that the current prevalence of antibiotic use in livestock and poultry production is unsafe for humans, Ex. A at 13-20, 24-32, and that as long as FDA allows medically important antibiotics to be administered for animal disease prevention, it will not reduce their overall usage to what Plaintiffs regard as a safe level, *id.* at 33-38.[11] The Citizen Petition asked FDA to "use informal hearing procedures to withdraw [approval for those disease prevention] uses,"[12] *id.* at 38-40, with respect to certain medically important antibiotics, *id.* at 4.

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[10] Citations to "Ex. __" refer to the exhibits to the Declaration of Gabriel I. Schonfeld filed contemporaneously with this memorandum.

[11] FDA disagrees with Plaintiffs' characterization of disease prevention uses as "subtherapeutic." *See, e.g.*, Compl. ¶ 52. Disease prevention is a *therapeutic* use because it involves situations where disease is likely to occur if a drug is not administered. *See Guidance #209*, *supra* n.1, at 21 n.5. Preventative uses are directed at a specifically identified disease, and the decision to administer a drug is made by veterinarians. *See id.* at 21.

[12] The Citizen Petition also requested that FDA revoke the same drugs' approval for growth promotion uses. That request was mooted by the subsequent voluntary

FDA denied the Citizen Petition in 2021. *See* Ex. C. The agency first described its statutory discretion to initiate (or not initiate) proceedings to withdraw drug approvals. *Id.* at 5-6. It then explained that while FDA "generally agree[d] with [the petitioners'] description of how the use of antimicrobials (in both human and animal medicine) can contribute to the development and proliferation of . . . resistant bacteria," *id.* at 4—and moreover that the studies cited in the Citizen Petition "provide[d] important information to consider," *id.* at 9—the agency would not begin withdrawal proceedings in response.

FDA gave several reasons for its conclusion that such proceedings were not warranted. It explained that the agency's voluntary approach had already resulted in the withdrawal of approval of medically important antimicrobials for production use, and the bringing of all remaining administrations via water or feed under veterinary oversight. *Id.* at 6-7. Moreover, FDA's guidances had provided veterinarians (who are legally prohibited from prescribing drugs for off-label use in animal feed, *see* 21 U.S.C. § 360b(a)(4)(A); 21 C.F.R. § 530.11(b)) with a framework to judiciously limit their own prescribing practices. *Id.* at 11, 13. And finally, support from major veterinary organizations showed that those clinicians would prescribe based on that framework. *Id.* at 13-15.

The agency further emphasized that it did not share the petitioners' focus on "setting overall targets for reductions in antimicrobial sales." *Id.* at 8. Rather, FDA "has

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withdrawal of all such indications, and Plaintiffs do not pursue it further here. *See* Ex. C at 3; Compl. ¶¶ 42, 44, 46-47, 50.

focused [its] efforts on supporting judicious use of antimicrobials in animals for therapeutic purposes and under the oversight of licensed veterinarians." *Id.* FDA recognized that levels of "antimicrobial sales and use" are expected to fluctuate up and down over time based on a variety of factors unrelated to FDA's actions. Rather than impose arbitrary limits on "changes in antimicrobial use from year-to-year," FDA explained that it had chosen steps that would help assure that those fluctuations "are appropriate to changes in animal health and populations" by facilitating "addition[al] . . . veterinary oversight." *Id.*

D. Plaintiffs' Complaint and Alleged Injuries

Plaintiffs' sole claim for relief asserts that FDA's denial of the Citizen Petition violated the APA's prohibition on arbitrary and capricious agency action. Compl. ¶¶ 61-64; *see also* 5 U.S.C. § 706(2)(A). The Complaint alleges that FDA did not respond to evidence of drug resistance associated with the preventive use of antibiotics, and failed to explain how enhanced veterinary oversight helps to protect human (rather than animal) health. Compl. ¶¶ 49-52.

Plaintiffs allege that FDA's denial of the Citizen Petition caused two categories of injury: (1) organizational injury to Food Animal Concerns Trust ("FACT"), *id.* ¶ 59, and (2) health, economic, and recreational injuries to unidentified members of Alliance of Nurses, National Resources Defense Council, Inc. ("NRDC"), and Public Citizen (collectively, the "Membership Organizations"), *id.* ¶¶ 16, 19, 21, 53-57.[13] Plaintiffs also

[13] FACT is not a membership organization. *See* Compl. ¶ 17; https://www.foodanimalconcernstrust.org (last accessed May 24, 2023).

assert the *interests* of several named members of the Membership Organizations, without alleging any *harm* to those interests. *See id.* ¶¶ 16, 19, 21.

LEGAL STANDARD

Both Article III standing and the APA's exclusion of actions committed to agency discretion from judicial review are properly raised under Fed. R. Civ. P. 12(b)(1) because they go to this Court's subject matter jurisdiction. *See, e.g.*, *Beck v. McDonald*, 848 F.3d 262, 269 (4th Cir. 2017) (standing); *Angelex Ltd. v. United States*, 723 F.3d 500, 505-06 (4th Cir. 2013) (APA reviewability). Subject matter jurisdiction is a threshold issue that must be addressed before reaching the merits. *See, e.g.*, *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94-95 (1998).

Plaintiffs bear the burden of establishing jurisdiction. *See, e.g.*, *Beck*, 848 F.3d at 269. Plaintiffs must meet that burden "in the same way as any other matter on which the[y] . . . bear the burden of proof, i.e., with the manner and degree of evidence required at the [current] stage[] of the litigation." *Id.* at 270 (quotations omitted). Thus, at the motion-to-dismiss stage, facial challenges to jurisdiction turn on whether "the allegations in the Complaint, taken as true, are sufficient to establish standing under the plausibility standard of Rule 12(b)(6)." *Evans v. Am. Collection Enter.*, — F. Supp. 3d —, 2022 WL 3923394, at *3 (D. Md. Aug. 31, 2022) (quotations omitted); *Beck*, 848 F.3d at 270 ("In a facial challenge, the defendant contends that a complaint simply fails to allege facts upon which subject matter jurisdiction can be based." (quotations omitted)).

ARGUMENT

This Court lacks subject matter jurisdiction for two independent reasons. ***First***, Plaintiffs lack Article III standing to challenge FDA's denial of the Citizen Petition. *See infra* Part I. No Plaintiff alleges that it, or a member whose rights it is entitled to assert, will imminently suffer an injury that is fairly traceable to FDA's action and redressable through this litigation. ***Second***, this Court lacks subject matter jurisdiction because the decision whether to initiate proceedings to withdraw approval of a new animal drug application is committed to FDA's discretion by law, *see* 5 U.S.C. § 701(a)(2), and therefore excluded from judicial review under the APA, *see infra* Part II. Congress directed FDA to withdraw approval of a new animal drug application when, after a hearing, it *decides* that the drug is unsafe, but provided no instructions for how and when the agency should *initiate that decisionmaking process*. *Id.* Instead, FDA has discretion in whether and when to initiate withdrawal proceedings, and because the FDCA contains no standards against which the exercise of that discretion can be measured, the APA makes its exercise unreviewable as a matter of law.

I. Plaintiffs Lack Article III Standing to Sue.

To establish "the irreducible constitutional minimum of standing," Plaintiffs must plausibly allege that they have suffered (1) an injury in fact, (2) that is fairly traceable to FDA's denial of the Citizen Petition, and (3) that will likely be redressed by a favorable decision. *See, e.g.*, *Lujan v. Defs. Of Wildlife*, 504 U.S. 555, 560-61 (1992). Satisfying the injury-in-fact requirement requires showing "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent,

not conjectural or hypothetical." *Id.* (quotations omitted). Threatened future harm can support standing only if it is "imminent," meaning that it is "*certainly impending*" and that "allegations of *possible* future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (quotations omitted).

Because Plaintiffs are organizations rather than natural persons, they attempt to "allege standing based upon two distinct theories." *See Nat'l Fed'n of the Blind, Inc. v. Wal-Mart Assocs., Inc.*, 566 F. Supp. 3d 383, 394-95 (D. Md. 2021) (quotations omitted). FACT asserts it has "organizational standing"—standing "derive[d] from injury the organization itself has suffered." *CASA de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 945-46 (D. Md. 2020); *see also Nat'l Fed'n of the Blind*, 566 Supp. 3d at 394 ("Organizational standing permits a group to allege standing on its own behalf for injuries directly inflicted on the organization." (quotations omitted)). The Membership Organizations, by contrast, claim "associational" (sometimes called "representational" or "representative") standing "to sue as . . . representative[s] of [their] members who have been harmed." *Nat'l Fed'n of the Blind*, 566 F. Supp. 3d at 395 (quotations omitted).

Neither theory of standing is satisfied here. ***First***, FACT has not shown organizational standing because its only claimed harm—its voluntary "diversion" of resources to education and advocacy opposing antibiotic uses it would prefer FDA simply preclude—cannot support standing as a matter of law. *See infra* Part I.A. ***Second***, the Membership Organizations have not shown associational standing because the Complaint fails to identify any specific member who faces a certainly impending injury that would be fairly traceable to FDA and redressable by this Court. *See infra* Part I.B.

Because no Plaintiff has satisfied the requirements of Article III standing, the Court should dismiss the Complaint for lack of subject matter jurisdiction.

A. FACT Has Not Alleged an Organizational Injury.

Binding precedent precludes FACT's theory of organizational standing—that FDA's refusal to withdraw approval of antibiotics for animal disease prevention has caused FACT to spend resources working against that practice. *See* Compl. ¶ 59. The Fourth Circuit has held that the "mere expense" of education and advocacy efforts undertaken in response to government action with which an organization disagrees "does not constitute an injury in fact." *Lane v. Holder*, 703 F.3d 668, 674-75 (4th Cir. 2012); *see also CASA de Md., Inc. v. Trump*, 971 F.3d 220, 238-39 (4th Cir. 2020) ("[A] plaintiff's voluntary expenditure of resources to counteract governmental action that only indirectly affects the plaintiff does not support standing.") (citation omitted)), *vacated on grant of reh'g en banc*, 981 F.3d 311 (4th Cir. 2020).[14] If the law were otherwise, *any* group with an abstract objection to federal policy "could bootstrap standing by expending . . . resources" to vindicate its contrary views. *Lane*, 703 F.3d at 675 (citation omitted). Finding standing on that basis would flatly contradict the settled rule that "an organization's abstract concern with [the] . . . subject [of] . . . an adjudication" cannot

[14] Because it was automatically vacated by the full court's grant of rehearing *en banc*, *see* 4th Cir. Local R. 35(c), the panel opinion in *CASA* is not binding on this Court. However, because the *CASA* appeal was voluntarily dismissed prior to the *en banc* court's decision on the merits, the panel opinion may still be relied on as persuasive authority. *See, e.g.*, *Crowson v. Washington County Utah*, 983 F.3d 1166, 1187 n.10 (10th Cir. 2020); *Nat'l Black Police Ass'n v. District of Columbia*, 108 F.3d 346, 354 (D.C. Cir. 1997) (noting that decisions vacated on non-merits grounds "remain 'on the books'" so that "future courts will be able to consult [their] reasoning").

substitute for the concrete injury required by Article III. *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 39-40 (1976).

Put another way, this is not a case where agency action has injured "a group's ability to *operate* as an organization," rather than "its theoretical ability to *effectuate* its objectives in its ideal world." *CASA*, 971 F.3d at 239; *see also Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919-21 (D.C. Cir. 2015) (explaining that standing requires showing "that the defendant's conduct perceptibly impaired the organization's ability to provide services"). "[A] diversion-of-resources injury does not count for Article III purposes where the only 'service' impaired is pure issue-advocacy." *Int'l Acad. of Oral Med. & Toxicology v. FDA*, 195 F. Sup. 3d 243, 257 (D.D.C. 2016) (quotations omitted).

That is especially true where—as here—there is no allegation that the government has interfered with the organization's ability to operate as an advocate. *Id.* at 258. FDA's decision not to adopt FACT's preferred policy "has no impact whatsoever on [FACT's] *ability* to gather information, collect and present data, communicate its belief that [the use of antibiotics in food-producing animals for disease prevention] is unsafe, or otherwise convince pertinent actors that [such use should be eliminated]." *Id.* Simply put, FACT's theory of organizational injury "is essentially an argument that [it] cannot allocate [those] issue advocacy expenses in the way it would prefer, which is insufficient to establish standing." *Ams. for Safe Access v. DEA*, 706 F.3d 438, 458 (D.C. Cir. 2013).

FACT is free to disagree (including through the citizen petition process) with FDA's risk-based approach to antimicrobial stewardship, and to spend time and money

"raising awareness," "monitoring government . . . activity," and "pressuring companies" to adopt more restrictive limits than FDA has imposed. Compl. ¶ 59. But it cannot use its own "decision[] to voluntarily spend money to combat the effects of [FDA's] policy" as a springboard to challenge that policy in federal court. *CASA*, 971 F.3d at 240.

B. Alliance of Nurses, NRDC, and Public Citizen Have Not Plausibly Pled Standing to Sue on Behalf of Their Members.

An organization has associational standing to sue on behalf of its members when (1) at least one identified member of the organization would have standing to sue in his or her own right, (2) the interests the litigation seeks to protect are germane to the organization's purpose, and (3) the lawsuit would not require the participation of the organization's individual members. *Lane*, 703 F.3d at 674 n.6. The Membership Organizations' attempt to establish this theory of standing fails at the first step—they do not plausibly allege that any of their identified members would have standing to sue on their own behalves.

The Complaint's attempt to make this showing fails for three reasons. ***First***, none of the three Membership Organizations *both* identifies a member *and* alleges how that specific member has been or will be injured by FDA's denial of the Citizen Petition. *See infra* Part I.B.1. ***Second***, even if they were linked to a specific member, the purported health, economic, and recreational injuries described in the Complaint would still rest on alleged harms that are too speculative to support standing. *See infra* Part I.B.2. ***Third***, even if Plaintiffs had alleged a cognizable injury to their members' economic and

recreational interests, their argument for standing on those grounds would still fail because there is no fairly traceable connection between FDA's denial of the Citizen Petition and those members' consumption and recreation habits, and because any order by this Court would not redress those members' self-inflicted harms. *See infra* Part I.B.3.

1. The Membership Organizations Fail to Connect Their General Allegations of Potential Harm to any Identified Member.

Associational standing "demands specific allegations establishing that at least one *identified member* ha[s] suffered or [will] suffer harm" sufficient to support standing. *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 264-65 (quotations and additional emphasis omitted). Merely describing a theory of harm is not enough—the Complaint must identify the specific member for whom such harm is certainly impending. *Chamber of Com. of U.S. v. EPA*, 642 F.3d 192, 199-200 (D.C. Cir. 2011); *see also Md. Shall Issue, Inc. v. Anne Arundel County*,—F. Supp. 3d —, 2023 WL 2599548, at *6 (D. Md. Mar. 21, 2023) (refusing to "confer associational standing" based on allegation that "unidentified members will suffer harm"). The reverse is true as well: "merely *naming* an individual member, without illustrating why such individual has standing . . . in his or her own right . . . , falls short of what is required." *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 267 (quotations omitted). The Membership Organizations lack standing because the Complaint does not show a connection between any of the members it names and any of the alleged injuries it describes.

The Complaint identifies members of each Membership Organization, but offers only the broadest generalities as to how those specific individuals might be affected by

FDA's denial of the Citizen Petition. Merely asserting that a named member has "health, recreational, aesthetic, and other interests" in reducing antibiotic use, *see* Compl. ¶¶ 16, 19, 21, is insufficient to allege an injury in fact, *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 265-66.

The D.C. District Court's decision in *International Academy of Oral Medicine* is illustrative. In that case, an association of dentists and dental students (among other plaintiffs) challenged FDA's regulatory classification of mercury-containing dental amalgam. *Id.* at 248. Broadly speaking, that organization alleged that FDA's decision not to ban or further restrict the use of mercury amalgam would cause dental students to be exposed to mercury because their schools were required to teach amalgam installation and removal as a condition of accreditation. *Id.* at 265. The court held the organization lacked standing because it alleged only that the sole dental student it identified "would be susceptible to the risk of future [mercury] injuries described in the Plaintiffs' . . . papers." *Id.* at 265-66.

The Complaint's allegations here are even more deficient. As to the members they actually name, the Membership Organizations do not allege any injuries, only each individual's name and one-word descriptions ("health," "recreational," and/or "aesthetic") of his or her "interests in reducing the use of antibiotics." Compl. ¶¶ 16, 19, 21. The Complaint does not allege anything else about the named members' circumstances. Nor does it plead that any of the named members' alleged interests actually have been or will be harmed.

Moreover, to the extent the Complaint offers more detail about *any* purported harms, those allegations refer only to "Plaintiffs' members" as the injured parties without reference to any specific individual (or even a specific Membership Organization). *Compare id.* ¶¶ 16, 19, 21, *with id.* ¶¶ 53-57. The Membership Organizations cannot establish standing by naming a handful of members on the one hand, listing a smattering of injuries on the other, and leaving the Court and Defendants to guess which dots to connect. "Without [more] specificity, the Court cannot police the critical boundar[ies] of its own Article III powers." *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 265-66.

2. Even if Allegations of Injury were Linked to Specific Members of the Plaintiff Organizations, They Would Still Be Too Speculative to Support Standing.

The Membership Organizations allege that their members have suffered or will suffer three kinds of harm: (1) increased health risk from antibiotic-resistant disease, (2) economic harm based on steps taken to limit or avoid exposure to meat and poultry raised with antibiotics, and (3) recreational harm based on the decision to avoid outdoor activities in landscapes allegedly contaminated with waste from livestock and poultry. For multiple reasons, even if these theories were alleged as to identified members (they are not, *see supra* Part I.B.1), they still would not satisfy the constitutional requirement of injury-in-fact.

Health Risk. The Membership Organizations allege that some of their (unidentified) members are at risk of contracting antibiotic-resistant illnesses, either by

eating contaminated meat or poultry products or (in the case of medical practitioners[15]) from contact with their infected patients.[16] Compl. ¶¶ 53, 55, 56. This speculative fear of contracting an unspecified illness, resistant to an unidentified antibiotic, at some unknown point in the future, cannot support standing because on its face it is not "certainly impending." *See, e.g.*, *Clapper*, 568 U.S. at 410-14. To the contrary, Plaintiffs' underexplained theory of health injury rests on an "attenuated chain of possibilities," like that in *Clapper*, which the Supreme Court has held does not support standing. *Id.* at 410.

To unpack that claim, Plaintiffs speculate (1) that veterinarians—"independent decisionmakers" not before the court, who prescribe medications based on "their [own professional] judgment," *id.* at 413-14—will prescribe antibiotics improperly (*i.e.*, for growth promotion), and in irresponsible quantities; (2) that this over-use will cause the emergence of a resistant strain of bacteria in the animals who ingested the drug; (3) that

[15] If the Membership Organizations seek to sue on behalf of their medical provider members' *patients*, *see* Compl. ¶ 55, they lack standing to do so because they have not shown that those patients could not sue on their own behalves. *See Powers v. Ohio*, 499 U.S. 400, 410-11 (1991). Furthermore, to the extent those organizations allege that their medical provider members are harmed by having to adjust their treatment approach to account for antibiotic resistance, *see* Compl. ¶ 55, they do not describe a cognizable injury-in-fact. Physicians are not harmed when they select a treatment that is, in their medical judgment, most appropriate to a patient's condition.

[16] To the extent the Membership Organizations seek to establish standing by claiming that FDA's decision will raise the United States' overall incidence of antibiotic-resistant disease—without pointing to a specific pathway through which their members in particular might be exposed to resistant bacteria—their suit presents a non-justiciable generalized grievance common to all members of the public. *See Griffin v. Dep't of Lab. Fed. Credit Union*, 912 F.3d 649, 654-55 (4th Cir. 2019).

at least one of Plaintiffs' members will be exposed to that resistant strain; (4) that those exposures will actually cause illness in Plaintiffs' members; and (5) that this illness will be more severe or expensive to treat than that which could be caused by a strain of the same bacteria without resistance to the same antibiotic or whose resistance was caused by a use (*e.g.*, treatment) to which Plaintiffs do not object. Notably, despite the longstanding use of antibiotics for disease prevention by American farmers over many decades, *see* Compl. ¶ 29, Plaintiffs do not allege that *any* of their members have *ever* contracted a resistant infection of this kind. *See Animal Welfare Inst. v. Vilsack*, 2022 WL 16553395, at *8 (W.D.N.Y. Oct. 31, 2022) (fact that plaintiffs did "not claim to have encountered [allegedly dangerous bacteria] in their prior decades of consuming and preparing poultry" weighed against standing based on risk of future exposure).

As the Second Circuit concluded in a prior suit brought by NRDC, the Membership Organizations have no standing to sue based on their fear of "unspecified bacteria or microbes" that may never develop antibiotic resistance and that Plaintiffs' "members may not ever come into contact with." *See Nat. Res. Def. Council v. FDA* ("*NRDC I*"), 710 F.3d 71, 86 (2d Cir. 2013). Because this chain of speculation cannot establish the "certainly impending" injury to their members' health that Article III requires, Plaintiffs lack standing to sue based on their fear of drug-resistant infections.

Economic Harm. The Membership Organizations also allege that in response to the health concerns discussed above, some number of their (unidentified) members are reducing their meat and poultry consumption, or else expending time and money to purchase food derived from animals raised without antibiotics. *See* Compl. ¶ 53. This

theory fails along with the first, because expenses incurred to mitigate a risk of disease that is not itself "certainly impending" cannot transform Plaintiffs' speculative fear of that risk into a present injury in fact. *See, e.g.*, *Clapper*, 568 U.S. at 415-18.

Recreational Harm. The Membership Organizations also allege that they have (unidentified) members who live near livestock production facilities, and "avoid swimming, fishing, and other [recreational] activities because they are concerned about exposure to drug-resistant bacteria." Compl. ¶ 54. These cursory allegations cannot support standing because they are devoid of facts that might show those members are changing their behavior in response to a genuine risk, rather than a mere speculative fear, of such exposure. *See id.* The Complaint is silent, for example, on whether any farming operation near any member uses antibiotics to prevent animal disease, or whether resistant bacteria attributable to such use are actually present in the would-be recreational environment. To survive a motion to dismiss for lack of standing, the Complaint must include more than "naked assertions devoid of further factual enhancement." *Ashcroft v. Iqbal*, 556 U.S. 662, 677-78 (2009) (quotations omitted).

3. The Economic and Recreational Injuries Alleged in the Complaint Are Neither Fairly Traceable to FDA's Challenged Actions Nor Redressable by This Court.

"To satisfy standing's causation requirement, the alleged injury must be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court." *DiCocco v. Garland*, 52 F.4th 588, 592 (4th Cir. 2022) (alterations and quotations omitted). The claimed harm must also be redressable: it must be "likely, as opposed to merely speculative, that the

injury will be redressed by a favorable decision." *Doe v. Va. Dep't of State Police*, 713 F.3d 745, 755 (4th Cir. 2013) (quotations omitted). Traceability and redressability are "two facets of a single causation requirement," *Allen v. Wright*, 468 U.S. 737, 754 n.19 (1984), and are best addressed jointly in cases where, as here, "they rise or fall together," *see Friends for Ferrell Parkway, LLC v. Strasko*, 282 F.3d 315, 323 n.1 (4th Cir. 2002). The Membership Organizations have the burden to show traceability and redressability, *see, e.g.*, *Marshall v. Meadows*, 105 F.3d 904 (4th Cir 1997), and have failed to do so with respect to their members' alleged economic and recreational injuries.

First, the Membership Organizations have not alleged facts sufficient to show that FDA's denial of the Citizen Petition is the cause of their members' voluntary (and allegedly burdensome) food-purchasing decisions. Compl. ¶ 53. Those organizations allege that some of their members fear antibiotic-resistant illness, and in response have opted to either "reduce[] their meat consumption or . . . buy [more expensive and harder to find] meat from animals raised without antibiotics." *Id.* But the Membership Organizations have not shown that such members face greater economic harm traceable to antibiotic resistance than they would if the Citizen Petition were granted.

Granting the Citizen Petition would not end either the use of antibiotics in commercial meat production, *see id.* ¶ 30 ("This litigation and the underlying Petition . . . do not concern targeted, short-term uses of antibiotics to treat animals that are sick."), or the accompanying risk that meat and poultry from animals treated with antibiotics may contain resistant bacteria, *see id.* ¶ 31 (alleging causal link between the use of antibiotics and the development of resistance). Even if FDA adopted Plaintiffs'

preferred policy, that would not *eliminate* the risk of foodborne antibiotic-resistant illness, which Plaintiffs' members have allegedly structured their behavior to avoid. Nor does the Complaint allege facts showing that Plaintiffs' members would actually change their behavior if the risk were merely reduced as a consequence of lower overall levels of antibiotic usage—the greatest possible redress a judgment against FDA could even indirectly provide. Absent such allegations, there is no basis to conclude that FDA's challenged approach to antibiotic stewardship is the cause of the economic burdens Plaintiffs' members allegedly seek to avoid, or that an order requiring FDA to commence withdrawal proceedings would redress those alleged harms.

Second, the Membership Organizations have not plausibly alleged that their members' alleged decisions not to fish, swim, or otherwise recreate in unspecified environments allegedly contaminated with animal waste, *see id.* ¶ 54, is traceable to FDA's denial of the Citizen Petition, which at most affects whether *some portion of the waste came from food-producing animals administered antibiotics for disease prevention*. In short, the Membership Organizations do not identify any member who would be willing to fish, swim, or otherwise recreate in or near waters contaminated with animal waste if the waste did not contain or contained less antimicrobial resistant bacteria in particular. "[U]nreasonable inferences" get no credit at the pleading stage, *Martin v. Duffy*, 858 F.3d 239, 248 (4th Cir. 2017), "[a]nd there comes a point where this Court should not be ignorant as [a] judge[] of what [it] know[s] as [a person]," *see Watts v. Indiana*, 338 U.S. 49, 52 (1949) (Frankfurter, J.).

FDA has no role in regulating the disposal of animal waste, and land or water that is allegedly contaminated today will remain as such no matter what FDA does or could conceivably be ordered to do. This Court need not draw the patently implausible inference either that FDA's approval of antibiotics for preventative use in animals caused the alleged contamination near Plaintiffs' members' homes, or that any judgment from this Court could redress their reluctance to fish, swim, or otherwise recreate in such surroundings. There simply is no plausible reason to believe that these allegedly contaminated environments would become recreational attractions but for FDA's decision to deny the Citizen Petition.

In sum, the Membership Organizations have not established associational standing because they have not shown that any identified member faces an injury in fact that is fairly traceable to FDA's denial of the Citizen Petition or redressable by this Court. Likewise, for the reasons described in Part I.A, *supra*, FACT has not shown an organizational injury that supports standing. The Complaint should therefore be dismissed for lack of subject matter jurisdiction.

II. The Administrative Procedure Act Does Not Authorize Review of FDA's Discretionary Decision Not to Initiate Drug Withdrawal Proceedings.

The APA does not permit judicial review of "agency action [that] is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). This Court lacks jurisdiction because Plaintiffs' claims fall squarely within that exclusion.

A decision is committed to agency discretion where the statute authorizing the agency to exercise discretion provides "no judicially manageable standards . . . for

judging how and when" it should do so. *Heckler v. Chaney*, 470 U.S. 821, 830-31 (1985). "In determining whether a meaningful standard for reviewing agency discretion exists, courts consider the particular language and overall structure of the statute in question, as well as the nature of the administrative action at issue." *Speed Mining, Inc. v. Fed. Mine Safety and Health Rev. Comm'n*, 528 F.3d 310, 317 (4th Cir. 2008) (quotations omitted) (collecting cases and emphasizing that "the Supreme Court and other courts have found numerous administrative decisions unreviewable" under § 701(a)(2)).

FDA's denial of the Citizen Petition is unreviewable under the APA because—as the Second Circuit held in rejecting a closely related suit brought by NRDC, Public Citizen, and FACT—"the decision [under the FDCA] whether to institute or terminate a [withdrawal] hearing . . . is a discretionary determination left to the prudent choice of the FDA." *NRDC II*, 760 F.3d at 174-75.

Like this case, *NRDC II* arose out of FDA's decision to deny citizen petitions that sought withdrawal of certain antibiotics' approvals for use in animal feed for growth promotion and disease prevention. *NRDC II*, 760 F.3d at 153. Public Citizen, NRDC, and FACT sued FDA in response. Those plaintiffs alleged—as they do in this case—that the denial was arbitrary and capricious because FDA (1) did not respond to the scientific data offered in the petitions, and (2) had chosen a cooperative, voluntary approach it believed would obtain results faster and more efficiently than years-long formal withdrawal proceedings. *Id.* at 173. In the plaintiffs' view, FDA was statutorily required to initiate such proceedings once it had reason to suspect a human safety issue, and

could decline to move forward only if it made a definitive judgment that the drug in question was safe. *Id.*

The Second Circuit disagreed. It rejected an interpretation of the FDCA that would deny FDA the "considerable discretion" that federal agencies presumptively possess "to choose their own enforcement priorities" and "to decide, for prudential reasons, whether to initiate [enforcement] action or not" in light of the agency's limited resources and numerous "other . . . priorities." *Id.* at 170-71. The court held that while the statute constrained the FDA's "*remedial* discretion" by directing withdrawal of any drug formally found to be unsafe after a hearing, the agency "retain[ed] the [*enforcement*] discretion to institute or terminate [withdrawal] proceedings" based on its own "prudential judgment" about the tradeoffs involved, *id.* at 171-72, 175 (emphasis added).

Under basic principles of collateral estoppel, NRDC, Public Citizen, and FACT—each of which was an active litigant before the Second Circuit—may not contest that court's holding that whether and when to commence withdrawal proceedings is a matter for FDA's discretion. Collateral estoppel (sometimes termed "issue preclusion") "preclude[s] relitigation of both issues of law and issues of fact if [they] were conclusively determined in a prior proceeding." *United States v. Stauffer Chem. Co.*, 464 U.S. 165, 170-71 (1984). The elements of collateral estoppel are (1) that the present and prior proceedings raised the same issue; (2) that both proceedings were between the same parties; (3) that the prior proceeding was litigated to a final judgment; and (4) that

the issue in question was essential to reaching that prior judgment. *See, e.g.*, *Baker v. Raimondo*, 2021 WL 1381560 (E.D. Va. Mar. 30, 2021).

Each of those elements is satisfied here as to NRDC, Public Citizen, and FACT. ***First***, both this case and *NRDC II* present the issue of whether a decision to initiate or not initiate withdrawal proceedings under 21 U.S.C. § 360b(e) is a discretionary choice for FDA, or one that may be compelled by private parties in litigation. ***Second***, NRDC, Public Citizen, and FACT were also parties to *NRDC II*. ***Third***, *NRDC II* ended in a final judgment on the merits for FDA. And ***fourth***, that judgment was necessarily and explicitly based on the Second Circuit's holding that FDA has unfettered discretion under section 360b(e) to commence or decline commencement, according to its own priorities, of proceedings that may lead to a finding that requires withdrawal of an animal drug's approval. *NRDC II*, 760 F.3d at 172-76 (concluding that this decision "is a discretionary [one] left to the prudent choice of the FDA," and deciding the case "[o]n that basis").

Although Alliance of Nurses was not a party to *NRDC II*, it cannot avoid the Second Circuit's sound reasoning. This Court should adopt the Second Circuit's statutory analysis, and find on that basis that Plaintiffs' claim is unreviewable because it falls within the APA's exception for actions committed to agency discretion by law.

As explained above, the Fourth Circuit has held that whether Congress has provided a "meaningful standard" by which to review agency discretion under the APA turns on both the "language and . . . structure of the statute in question," and the "nature of the administrative action at issue." *Speed Mining*, 528 F.3d at 317. Both

considerations indicate that the decision to initiate withdrawal proceedings under section 360b(e) is fully committed to FDA's discretion.

The language and structure of the FDCA vest FDA with enforcement discretion unconstrained by any judicially manageable standards. *NRDC II*, 760 F.3d at 170-72, 174-75. Section 360b(e) provides only that a new animal drug approval shall be withdrawn "if [FDA] finds" the drug is unsafe after notice and a hearing. 21 U.S.C. § 360b(e)(1). Nothing in that text "limits the considerations that the FDA may take into account in deciding whether to initiate the [withdrawal] hearing process," or "mandate[s] that . . . FDA take any action until and unless certain findings are made after a hearing." *Id.* at 174-75. In *Heckler*'s terms, the statute specifies what FDA should do "*if* [the agency] finds," 21 U.S.C. § 360b(e)(1) (emphasis added), that certain facts have "been established," but provides no standards by which courts could judge FDA's decision to begin (or not) "proceedings designed to discover the[ir] existence." *Heckler*, 470 U.S. at 837.

Moreover, the nature of the action at issue here—declining to commence an adversary adjudication to determine whether an application's approval should be withdrawn for failure to conform to the FDCA—is similar to other "refusals to institute investigative or enforcement proceedings," *id.* at 838, that courts have held are unreviewable, *see, e.g.*, *Sierra Club v. Larson*, 882 F.2d 128, 129-30, 131-32 (4th Cir. 1989) (decision to obtain compliance with conditions of federal funding through informal cooperation rather than by initiating adjudication); *Drake v. FAA*, 291 F.3d 59, 70-71

(D.C. Cir. 2002) (decision to dismiss, without adjudicatory hearing, a pilot's complaint that airline violated federal regulations).

Like those decisions, FDA's here "involve[d] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Heckler*, 470 U.S. at 831. FDA assesses not only the safety record of the medications at issue, but also "whether agency resources are best spent on this [priority] or another, whether the agency is likely to succeed if it acts [through a time-consuming adversary proceeding], whether [that] particular enforcement action [would] . . . best fit[] the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all." *Id.* FDA "is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32. That is why, as the Fourth Circuit has explained, the exercise of agency "enforcement discretion is an area in which the courts have traditionally been most reluctant to interfere." *Speed Mining*, 528 F.3d at 318 (quotations omitted); *see also NRDC II*, 760 F.3d at 171 ("Ordinarily, administrative discretion is at its zenith when an agency decides whether to initiate enforcement proceedings.").

In sum, Plaintiffs have raised a classic challenge to FDA's exercise of enforcement discretion, which is unreviewable under the APA. Indeed, there is nothing else for them to challenge—this case at bottom presents a disagreement over the FDA's discretionary choice of method to pursue a goal that all parties share. FDA and Plaintiffs both believe that responsible limitations on antibiotic use in food-producing animals are a crucial part of the broader battle against drug-resistant illness. FDA has concluded that the

most efficient way to pursue that goal, consistent with the FDCA's mandate to protect human health, is to encourage drug sponsors voluntarily to seek approval to align their applications with FDA's risk-based model of judicious use.

To promote sound administration and protection of the public health, Congress has given FDA latitude to pursue an informal approach rather than institute adversary enforcement proceedings. Plaintiffs disagree with how FDA has used that discretion, but the FDCA leaves no question that the choice is FDA's to make. Plaintiffs' Complaint should be dismissed because the APA bars review of suits that challenge a pure exercise of agency discretion.

CONCLUSION

For the foregoing reasons, the Court should dismiss the Complaint for lack of subject matter jurisdiction.

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Respectfully submitted,

/s/ Gabriel I. Schonfeld

GABRIEL I. SCHONFELD
ISAAC C. BELFER
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
PO Box 386
Washington, DC 20044-0386
(202) 353-1531 (Schonfeld)
(202) 305-7134 (Belfer)
(202) 514-8742 (fax)
Gabriel.I.Schonfeld@usdoj.gov
Isaac.C.Belfer@usdoj.gov