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-176-DLB

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Antibiotic resistance—the ability of bacteria to evade the drugs designed to defeat them—is on the rise, threatening our ability to treat common diseases. Each year, more than 2.8 million antibiotic-resistant infections occur in the United States, contributing to an estimated 162,000 deaths annually. This public health crisis is fueled in significant part by the misuse and overuse of medically important antibiotics in industrial livestock and poultry facilities. The U.S. Food and Drug Administration (FDA) has long recognized that administering low doses of antibiotics to entire herds or flocks contributes to the proliferation of resistant strains of bacteria that sicken people. Even so, FDA refuses to withdraw approval of these unsafe drug uses.

Health advocates filed a petition in 2016 asking FDA to halt disease-prevention uses of medically important antibiotics in livestock and poultry. FDA denied the petition in 2021 without responding to the petition's core argument that eliminating these antibiotics uses is necessary to safeguard human health. Plaintiffs—a coalition of nurses and consumer rights, environmental, health, and animal welfare groups—now challenge FDA's decision under the Administrative Procedure Act (APA) as arbitrary and capricious.

FDA's Motion to Dismiss insists this Court cannot review the agency's decision for three reasons: (1) that Plaintiffs lack standing, (2) that the petition denial is an unreviewable exercise of FDA's discretion, and (3) that Plaintiffs are estopped from bringing their claim. Each argument fails.

First, the Complaint pleads facts sufficient to establish Plaintiffs' standing. The Complaint identifies members of Alliance of Nurses for Healthy Environments (Alliance of Nurses), Public Citizen, and Natural Resources Defense Council (NRDC) who suffer concrete harms to their health, recreational, and economic interests. It ties those injuries directly to FDA's

refusal to ban preventive uses of antibiotics in livestock and the consequent development of drug-resistant bacteria. The Complaint also explains that FDA's unlawful petition denial has forced Plaintiff Food Animal Concerns Trust (FACT) to divert organizational resources from other projects central to FACT's mission and impedes FACT's ability to operate. These injuries would be redressed if the Court ordered FDA to grant the petition. The Complaint, read with all reasonable inferences in favor of Plaintiffs, easily establishes Article III standing. Standing is further demonstrated by the attached declarations.

Second, the APA empowers courts to set aside final agency actions that are arbitrary and capricious. FDA's decision to deny the petition fails to grapple with the central issue: prophylactic use of antibiotics in livestock contributes to the mounting public health threat of antibiotic resistance. FDA discusses *animal* health, but nowhere in the decision does FDA respond to the petition's primary point that, to protect *human* health, the agency must halt all preventive uses of antibiotics in livestock. Whether FDA arbitrarily failed to "consider an important aspect of the problem" is a garden-variety APA claim that courts routinely adjudicate. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983).

Finally, Plaintiffs' challenge to FDA's 2021 petition denial is not estopped by a decision on a different challenge to a different denial of a different citizen petition. The claim alleged in this case has never been litigated, and the record at issue has never been reviewed to determine whether FDA's decision to deny the citizen petition was arbitrary and capricious.

For these reasons, the Court should deny FDA's Motion to Dismiss.

BACKGROUND

A. The misuse and overuse of antibiotics in livestock contribute to the proliferation of antibiotic-resistant superbugs, threatening human health

Meat producers routinely administer antibiotics to livestock and poultry to compensate for the cramped, dirty conditions common to factory farms. Complaint ¶ 3, ECF No. 1. Today, approximately two-thirds of all antibiotics sold in the United States are for use in food-producing animals. *Id.* Entire herds or flocks are given antibiotics over extended periods of time, not to treat individual sick animals, but to stave off diseases that tend to occur because of overcrowding, poor nutrition, and waste management problems. *Id.* This low-dose, long-term antibiotics use is particularly conducive to the development and spread of drug-resistant bacteria. *Id.* ¶¶ 29-30.

When an antibiotic is introduced to a population of bacteria, the "weaker" bacteria that are susceptible to low doses of the drug die off, but "stronger" bacteria resistant to the drug are left behind and continue to multiply. *See id.* ¶ 31. This process of natural selection increases the proportion of resistant bacteria in the population. *Id.* Bacteria exposed to antibiotics can also develop mutations that make them resistant, and in some cases more likely to cause hard-to-treat diseases in humans. *Id.* ¶ 32.

Antibiotic resistance spreads between different types of bacteria and threatens the effectiveness of a wide range of drugs. *See id.* ¶ 33. When a bacterial cell develops resistance to a particular antibiotic, that resistance multiplies in two primary ways: through the exponential growth of that bacteria and as different types of bacteria trade genes. *See id.* The use of any one drug may select for groups of genes that provide resistance not only to the original drug but also to other drugs. *Id.* In practical terms, this means the use of one antibiotic can cause multiple species of bacteria to develop multidrug resistance, and by extension, lead to infections in humans for which there are few or no effective treatments. *See id.*

Drug-resistant bacteria move from animals to people through multiple pathways, including when people eat tainted meat. *Id.* ¶¶ 34-35. These bacteria include common sources of foodborne illness in humans, such as Salmonella, Campylobacter, and E. coli. *Id.*

B. FDA has long recognized that routine use of antibiotics in livestock imperils human health

FDA regulates antibiotics in animal feed as "new animal drugs" under the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 360b; *see also id.* § 393(d)(2) (delegating authority to FDA). If FDA finds new evidence that a drug is not shown to be safe, it must withdraw existing approval of that drug use. *Id.* § 360b(e)(1)(B). An animal drug is "safe" for human health if "there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals." FDA, *Guidance for Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs* (Oct. 23, 2003) ("Guidance #152"), https://tinyurl.com/yc4maj4d.

FDA has known for at least five decades that use of antibiotics in animal feed poses a serious public health risk. Compl. ¶ 38. In the early 1970s, an FDA task force recommended that antibiotics used in human medicine be prohibited from use in animal feed unless drug manufacturers met certain safety criteria. *Id.* ¶ 39 (citing 37 Fed. Reg. 2444 (Feb. 1, 1972)). In the following years, FDA proposed to withdraw its approval of most preventive uses of penicillin and tetracyclines in animals, because those uses were not shown to be safe for human health. *Id.* ¶ 40. Despite decades of further studies that failed to establish safety, FDA did not withdraw the drug use approvals. *Id.*

Meanwhile, scientific evidence that routine use of antibiotics in livestock is dangerous for people continued to mount. *See id.* ¶ 33. For example, a 2014 study found that intestinal bacteria in pigs exposed to an antibiotics cocktail acquired resistance not only to the drugs in the cocktail

(such as penicillin), but also to other types of antibiotics (such as aminoglycoside). *See* Ex. A to Decl. of Gabriel I. Schonfeld, ECF No. 16-3 ("Petition"), at 25. A study of hospital patients in Iowa found that patients who live near large swine facilities are nearly twice as likely to carry MRSA (methicillin-resistant Staphylococcus aureus), which causes infections resistant to many drugs used to treat ordinary staph infections. *Id.* at 27-28. In short, FDA's decision to allow vast quantities of medically important antibiotics to be used in livestock, in lieu of safe strategies to improve animal health (such as improving hygiene and relieving overcrowding), is spurring the antibiotic resistance crisis, making diseases in humans harder to treat.

C. FDA's non-binding guidance documents

In 2011, advocacy groups, including some of the Plaintiffs in this lawsuit, sued FDA, arguing that FDA's 1977 notices seeking comments on proposed withdrawal of certain antibiotics used in animals triggered a statutory requirement for the agency to hold a formal hearing to withdraw the drug approvals. *NRDC v. FDA*, 760 F.3d 151, 153, 156 (2d Cir. 2014). The appeals court rejected plaintiffs' interpretation of the statute as well as plaintiffs' claim that FDA failed to adhere to the sole governing statutory criteria: whether the approved antibiotic uses were "shown to be safe." *Id.* at 175.

In 2012, during the pendency of that lawsuit, FDA issued Guidance #209.[1] Compl. ¶ 41. The guidance suggested that livestock facilities administer medically important antibiotics (1) only when necessary to ensure the animals' health, and not for growth promotion (where antibiotics are used to help livestock grow faster on less feed); and (2) only with veterinary

[1] FDA, *Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (Apr. 13, 2012) ("Guidance #209"), https://www.fda.gov/media/79140/download.

oversight. *Id.* (citing Guidance #209 at 21-22). Like other FDA guidance documents, it was not legally binding.

In 2013, FDA issued Guidance for Industry #213,[2] asking pharmaceutical companies to voluntarily remove growth-promotion uses from labels of medically important antibiotics and change the use conditions of over-the-counter products to require veterinary oversight, such as a veterinary feed directive (a prescription filled by an animal feed mill). *Id.* ¶ 42 (citing Guidance #213, at 4, 6-7). Guidance #213 also recommended the "voluntary adoption of judicious use principles," in which veterinarians authorize the use of antibiotics in feed after evaluating factors such as animal stress from overcrowding and transport, whether there is evidence of drug efficacy, and whether there is a reasonable alternative to administering antibiotics. *Id.* In the following years, the industry ceased growth-promotion uses. *Id.* Disease-prevention uses, however, continue at high levels. *See id.*

Following the issuance of the Guidances, antibiotics sales dropped in 2016 and 2017. *Id.* ¶ 46. But the downward trend did not continue—since 2017, sales have gone back up. *Id.* In 2020, six million kilograms of antibiotics were sold for use in livestock, reflecting an eight-percent increase from 2017 sales. *Id.* This is nearly *double* the amount of antibiotics sold for human use. *See* Univ. of Minn., Ctr. for Infectious Disease Res. & Policy, *U.S. lagging Europe in efforts to cut antibiotics in livestock* (Dec. 2, 2022), https://tinyurl.com/28hzhpvn (noting that 3.3 million kilograms of antibiotics were sold for human use in 2019—at the time, the most

[2] 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) ("Guidance #213"), https://www.fda.gov/media/83488/download.

recent data available on human antibiotics sales in the United States). [3] And intensity of use—measured by adjusting raw antibiotic sales by the size of the animal population likely to have received those antibiotics—remains alarmingly high. *See* Petition at 7; NRDC, *Issue Brief: U.S. Livestock Industries Persist in High-Intensity Antibiotic Use* 6-7 (Nov. 2022), https://tinyurl.com/3u8jrm4b (showing that intensity of antibiotics use in cattle, pig, and turkey increased between 2017 and 2020). This is not the "great success," FDA Mem. 1, that the agency claims.

D. The 2016 citizen petition and 2020 supplement, and FDA's 2021 denial

Any interested person may petition FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a); *see* 5 U.S.C. § 553(e). FDA "may grant or deny such a petition, in whole or in part," and "take other action as the petition warrants." 21 C.F.R. § 10.30(e)(3).

In 2016, advocacy groups, including Plaintiffs FACT, NRDC, and Public Citizen, and co-counsel Earthjustice, filed a petition with FDA asking the agency to withdraw approval of uses of certain medically important antibiotics in livestock and poultry for disease-prevention purposes. Compl. ¶ 43. The petition explained that FDA's voluntary program to reduce antibiotics use would not adequately reduce use and protect human health. While antibiotics are no longer used for growth-promotion purposes, antibiotics administered for disease prevention pose the same risks—it entails low doses administered to entire herds or flocks for extended periods of time. *Id.* ¶ 44; *see* Petition at 5-6, 33-37; *supra* pp. 3-4.

[3] To prop up the agency's narrative that its voluntary program is effective, FDA cites documents that post-date the petition denial. *See* Defs.' Mem. in Support of their Mot. to Dismiss, ECF No. 16-1, at 5 n.4 & 8 nn.8-9 ("FDA Mem."). In response, Plaintiffs refer the Court to recent data and analysis showing that antibiotics use in food-producing animals remains dangerously high.

In 2020, the advocacy groups supplemented the 2016 petition with new studies and reports. Compl. ¶ 47; *see* Ex. B to Schonfeld Decl., ECF No. 16-4. The supplement to the petition acknowledged that growth-promotion uses had been phased out and focused only on disease-prevention uses. Compl. ¶ 47. It pointed out that by authorizing continued prophylactic use of antibiotics, FDA exposes more animals and thus more bacteria to the drugs, elevating the risk that resistance will develop and spread. *Id.*

FDA denied the petition in February 2021. *Id.* ¶ 48. The agency "generally agree[d]" that antibiotics use "can contribute to the development and proliferation of antimicrobial resistant bacteria." *Id.* ¶ 49; *see* Ex. C to Schonfeld Decl., ECF No. 16-5 ("FDA Denial"), at 4. FDA disclaimed, however, any goal of reducing antibiotic use, stating that it "has not focused on setting overall targets for reductions in antimicrobial sales or use." FDA Denial at 8. Instead, FDA focused on "the judicious use of antimicrobials" under veterinary oversight "for the treatment, control, or prevention" of disease. Compl. ¶ 51 (citing FDA Denial at 3). A use is "judicious," according to FDA, if it is not "unnecessary or inappropriate." *Id.* (citing Guidance #209 at 3). In other words, the guidepost for FDA's antibiotics stewardship is that judicious uses of antibiotics in animals comprise uses that are not injudicious.

The agency asked veterinarians to consider a number of factors in determining whether animals are at risk of developing a disease, including, for example, "inadequate ventilation"; "stress of animal transport"; the drug's efficacy in animals; whether use is consistent with "accepted veterinary practice" and "linked to a specific [disease-causing] agent"; and whether "reasonable alternative[]" treatments exist. *See* FDA Denial at 3 (quoting Guidance #213 at 7), 11. However, these factors relate to "the health of food-producing *animals*," *id.* at 11 (emphasis

added), not whether continued use of antibiotics in this manner—low doses administered to whole herds or flocks over lengthy periods—is safe for *human* health. Compl. ¶ 51.

STANDARD OF REVIEW

The APA gives any person "suffering legal wrong because of agency action, or adversely affected by agency action," the right to federal judicial review. 5 U.S.C. § 702. The Court must "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A); *see also Defs. of Wildlife v. N.C. Dep't of Transp.*, 762 F.3d 374, 393 (4th Cir. 2014). An agency acts arbitrarily if it "entirely fail[s] to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43.

On a motion to dismiss, the court assumes as true all well-pleaded facts and draws all reasonable inferences in favor of the plaintiff. *Nemet Chevrolet, Ltd. v. Consumeraffairs.com, Inc.*, 591 F.3d 250, 253 (4th Cir. 2009).

ARGUMENT

I. Plaintiffs Have Standing to Challenge FDA's Petition Denial

To show Article III standing, a plaintiff must have an injury in fact that is traceable to the defendant's actions and redressable by the court. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). An organization has "associational standing to sue on behalf of [its] members when [its] members would otherwise have standing to sue in their own right."[4] *Sierra Club v. U.S. Dep't of the Interior*, 899 F.3d 260, 282 (4th Cir. 2018) (quoting *Friends of the Earth, Inc. v. Laidlaw*

[4] FDA does not contest that Alliance of Nurses, NRDC, and Public Citizen satisfy the other two prongs of associational standing. The health, recreational, and other interests alleged are germane to the organizations' purposes, Compl. ¶¶ 15, 18, 20, and individual members do not need to participate in the lawsuit to assert the APA claim or seek relief. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *see* Decl. of Katie Huffling (Alliance of Nurses); Decl. of Gina Trujillo (NRDC); Decl. of Robert Weissman (Public Citizen).

Env't Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000)) (internal quotation marks omitted). An organization can also show standing when a defendant's action "impair[s] [plaintiff's] ability to carry out its mission through frustration of that mission and a consequent drain on its resources." *People for the Ethical Treatment of Animals, Inc. v. Tri-State Zoological Park of W. Md., Inc*., 843 F. App'x 493, 496 (4th Cir. 2021) (per curiam).[5]

To defeat a motion to dismiss for lack of jurisdiction under Federal Rule 12(b)(1), a plaintiff need only show that "the allegations in the Complaint, taken as true, are sufficient to establish standing under the plausibility standard of [Fed. R. Civ. P.] 12(b)(6) . . . ." *Evans v. Am. Collection Enter.*, 624 F. Supp. 3d 593, 598 (D. Md. 2022). The Court has the "power to allow or to require the plaintiff" to make "further particularized allegations" supporting standing, by amending the complaint or filing affidavits. *Warth v. Seldin*, 422 U.S. 490, 501 (1975); *see also, e.g.*, *Ctr. for Biological Diversity v. U.S. Int'l Dev. Fin. Corp.*, 585 F. Supp. 3d 63, 70 (D.D.C. 2022). The Court can therefore consider the declarations filed with this memorandum. *See infra* pp. 11-13. When assessing standing, the court must "assume that on the merits the plaintiffs would be successful in their claims." *Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 924 (D.C. Cir. 2008) (quoting *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003)) (crediting plaintiff's claim that the Coast Guard's ocean traffic rules would increase the chance of ship strikes that harm whales).

[5] Although the *Tri-State Zoological* panel did not select the case for publication, this Court may still consider the 2021 decision. *See* 4th Cir. R. 32.1 (disfavoring citation of unpublished opinions issued *before* January 1, 2007).

A. Members of Alliance of Nurses, NRDC, and Public Citizen credibly allege injury to their health, recreational, and economic interests

The Complaint pleads facts that directly link the overuse of antibiotics in livestock with the rise in antibiotic resistance that harms human health. The Complaint also identifies individuals from each of the three Plaintiff organizations as examples of members who are harmed by the proliferation of antibiotic-resistant bacteria. FDA objects to Plaintiffs' associational standing on two grounds: (1) there are too many "dots to connect" between allegations of harm and identified members, FDA Mem. 18-20, and (2) even if the allegations were sufficiently specific, the claimed injury is too speculative, *id.* at 20-23. Neither argument has merit.

1. The Complaint details harms and identifies injured members

As alleged in the Complaint, Plaintiffs' members suffer cognizable harms to their recreational, health, and economic interests. Plaintiffs' members who live near intensive livestock facilities "avoid swimming, fishing, and other activities" because of feared "exposure to drug-resistant bacteria" in animal waste runoff. Compl. ¶ 54; *see also id.* ¶ 36 (noting that resistant bacteria may spread "through air, dust, animal waste, or insects and rodents that pass through these facilities"). Plaintiffs' members also include nurses who are "at higher risk of contracting resistant infections." *Id.* ¶ 55. Other members are exposed to drug-resistant bacteria through eating "meat and poultry products contaminated with bacteria resistant to antibiotics," and they "spend more time or money . . . to buy meat from animals raised without antibiotics." *Id.* ¶ 53. These are the "health, recreational, aesthetic, and other injuries" that Plaintiffs' members seek to vindicate. *See id.* ¶¶ 16, 19, 21.

In addition to the facts alleged in the Complaint, the attached declarations further link individual members with specified injuries. The proliferation of drug-resistant bacteria harms

Plaintiffs' members' recreational interests. For example, NRDC member Dennis Haller lives in Decorah, Iowa, near intensive swine facilities where "[t]housands of hogs" are "fed a lot of antibiotics." Decl. of Dennis Haller ¶¶ 2, 4. Manure from these facilities is applied as fertilizer in fields near his home, and when it rains, or when waste storage lagoons leak, animal waste contaminates the groundwater and nearby streams. *Id.* ¶¶ 5-6. Mr. Haller enjoys trout fishing, but he does so less often to limit his exposure to antibiotic-resistant bacteria from animal waste runoff in the water. *Id.* ¶¶ 8-9. This is a quintessential form of injury in environmental cases. *See, e.g.*, *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 156 (4th Cir. 2000) (en banc) (finding injury in fact based on avoiding use of lake because of fears of pollution).

FDA's denial of the citizen petition also harms the health of Plaintiffs' members. David Buchheit, an Alliance of Nurses member, serves patients with drug-resistant infections and is "very aware of the serious threats posed by antibiotic-resistant bacteria." Decl. of David Buchheit ¶ 5. He treats patients with MRSA, which "can spread easily from patient to patient and to hospital staff from skin-to-skin contact and from surfaces." *Id.* Mr. Buchheit is at higher risk of "acquir[ing] some highly resistant bacterial infection"—for example, from "changing bandages on a patient's wounds." *Id.* ¶ 11. Another Alliance of Nurses member, Dr. Kathryn Murphy, has forty years of clinical experience and has provided care for children who require hospitalization and surgery for drug-resistant infections. Decl. of Dr. Kathryn Murphy ¶¶ 2-5. Dr. Murphy worries about heightened exposure to antibiotic-resistant bacteria that threaten her health and the health of her sister, who is immune compromised. *Id.* ¶¶ 6-7. And Public Citizen member Scott Nelson has "chronic medical conditions" that leave him "immune compromised and require frequent visits to medical facilities," increasing his vulnerability to bacterial

infections. Decl. of Scott L. Nelson ¶ 3; *see also* Haller Decl. ¶ 10 (stating that he is delaying necessary knee surgery because he fears acquiring a resistant infection). In sum, Plaintiffs' members' allegations of health harms are amply supported.

Plaintiffs' members have also incurred costs to avoid unwanted exposure to antibiotic-resistant bacteria. Mr. Haller had to install a deeper drinking water well, which cost thousands of dollars more, because shallower sources of water near his home were already contaminated by nearby swine operations. Haller Decl. ¶ 7 (expressing concern that even the deeper aquifer will become contaminated). Mr. Nelson buys meat labeled as antibiotic-free, "although such meat usually is more expensive and is sometimes difficult to find." Nelson Decl. ¶ 5; *see* Murphy Decl. ¶ 8; Haller Decl. ¶ 11; *cf.* Decl. of Dr. Jay Graham ¶ 22 ("As bacterial populations in . . . animals adapt to new antibiotic selective pressures, the prevalence of antibiotic-resistant bacteria present on meat and poultry products will increase and likely transfer to consumers."). And Mr. Buchheit spends extra money on shoes he wears only to work at the hospital, to avoid inadvertently carrying pathogens home and exposing his family and himself to antibiotic-resistant bacteria. Buchheit Decl. ¶ 10. These added costs are a basis for standing. *See Hutton v. Nat'l Bd. of Exam'rs in Optometry, Inc.*, 892 F.3d 613, 622 (4th Cir. 2018).

FDA's objection amounts to a critique of the Complaint's structure, which lays out health, recreational, and economic injuries to Plaintiffs' members in one section, Compl. ¶¶ 53-58, and names in a different part the individuals who are examples of members harmed by FDA's petition denial, *id.* ¶¶ 16, 19, 21. It is not difficult to "connect the dots," *see* FDA Mem. 20, between the harms specified and the named individuals who are exemplars of members who suffer the harms. The former are explained in the section titled "FDA's denial of the Petition

harms Plaintiffs and their members," Compl. ¶¶ 53-60, and the latter are identified in the section describing "Plaintiffs," *id.* ¶¶ 15-24. The declarations further link harms to specific members.

FDA relies on inapposite cases. *See* FDA Mem. 18-20. For example, the plaintiffs in *International Academy of Oral Medicine & Toxicology v. FDA*, 195 F. Supp. 3d 243 (D.D.C. 2016), largely "ma[d]e no affirmative case" that they "ha[d] standing under *any* theory," *id.* at 253. The jurisdictional defect was not that the complaint "nam[ed] a handful of members" in one section and "listed a smattering of injuries" in another, *see* FDA Mem. 20, but that the plaintiffs failed to identify a single member who had standing, even after multiple rounds of briefing. *Int'l Acad. of Oral Med.*, 195 F. Supp. at 263-65 (the relief sought would not redress the alleged harm, and plaintiffs did not "unavoidably face" exposure because of available alternatives). The other cases FDA cites are also unpersuasive. *See Chamber of Com. of U.S. v. EPA*, 642 F.3d 192, 199-200 (D.C. Cir. 2011) (faulting one plaintiff for "not identif[ying] a single member who was or would be injured" by challenged action); *Md. Shall Issue, Inc. v. Anne Arundel County*, No. 22-cv-00865 (SAG), 2023 WL 2599548, at *6 (D. Md. Mar. 21, 2023) (finding on summary judgment that plaintiff did not submit any affidavit showing that any member's ability to buy a gun was affected by the county's distribution of pamphlets promoting mental health resources).

Plaintiffs easily meet the pleading standard for standing. Indeed, the Complaint goes well beyond "general factual allegations of injury" and provides detailed facts outlining the many harms Plaintiffs' members suffer stemming from Defendant's petition denial. *See, e.g.*, *Hutton*, 892 F.3d at 620 (noting that "general factual allegations of injury resulting from the defendant's conduct may suffice" because, on a motion to dismiss, courts "presume that general allegations

embrace those specific facts that are necessary to support the claim" (quoting *Lujan*, 504 U.S. at 561)).[6]

2. Plaintiffs' health, recreational, and economic injuries are cognizable

Plaintiffs' allegations of recreational, health, and economic harm are grounded in their exposure to antibiotic-resistant bacteria, increased risk of contracting a resistant infection, and steps taken to mitigate those risks. These allegations show concrete and imminent harm that satisfies the injury-in-fact requirement.

a. Recreational interests

Plaintiffs "adequately allege injury . . . when they aver that they use the affected area and are persons for whom the aesthetic and recreational values of the area will be lessened by the challenged activity." *Laidlaw*, 528 U.S. at 183 (cleaned up). A litigant "does not have to await the consummation of threatened injury to obtain preventive relief." *Gaston Copper*, 204 F.3d at 160 (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). This is particularly true in the context of threatened environmental injury. *Id.*; *see Mountain States Legal Found. v. Glickman*, 92 F.3d 1228, 1234 (D.C. Cir. 1996) (injury to recreational and aesthetic interests from increased risk of wildfire); *cf. Hutton*, 892 F.3d at 622 (recognizing standing based on "substantial risk of harm").

As set forth in the Complaint, Plaintiffs' members include people "who live in areas with industrial livestock facilities" and "avoid swimming, fishing, and other activities because they are concerned about exposure to drug-resistant bacteria from animal waste that contaminates the water and air." Compl. ¶ 54. Mr. Haller's declaration adds further detail. He lives in a hilly

[6] On summary judgment, a plaintiff must present affidavits or other evidence of specific facts to establish standing. *See, e.g., Laidlaw*, 528 U.S. at 183. Plaintiffs meet that standard as well.

region of Iowa, and when it rains, animal waste containing bacteria is carried from nearby swine operations into local streams. Haller Decl. ¶ 6. The state regularly issues advisories against using the waterways because of high bacterial count. *Id.* ¶ 8. This prevents Mr. Haller from fishing as often as he would like. *Id.* ¶ 9.

FDA insists that Plaintiffs must further allege that "certain resistant bacteria attributable" to specific antibiotics used at nearby facilities are "actually present in the would-be recreational environment." *See* FDA Mem. 23. The Fourth Circuit has rejected a similar contention that plaintiffs living downstream of a smelting facility needed to show the chemical content of the affected river or negative changes to the ecosystem. *Gaston Copper*, 204 F.3d at 158-59. Article III "does not require such proof," *id.* at 159, and FDA's demand for such specificity raises the standing bar too high.[7] *See, e.g.*, *Laidlaw*, 528 U.S. at 183 (finding injury where declarant avoided canoeing near facility "because he was concerned that the water contained harmful pollutants"); *accord Congaree Riverkeeper, Inc. v. Carolina Water Serv., Inc.*, 248 F. Supp. 3d 733, 746-47 (D.S.C. 2017) (concluding that members who use the affected river and avoid the section near a wastewater discharge pipe have standing).

b. Health harms

Standing may be based on a "substantial risk" that the harm will occur. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153 (2010)). In the context of food and drug safety suits, a "sufficiently

[7] The demand for evidence linking the use of a specific antibiotic to the presence of a resistant bacterial strain, FDA Mem. 22, is especially disingenuous given FDA's failure to collect detailed data on antibiotics use. To illustrate the agency's opaque practices, FDA has in the past refused to share certain aggregated antibiotics sales and distribution data, claiming it reveals trade secrets. *Gov't Accountability Project v. FDA*, 206 F. Supp. 3d 420, 426 (D.D.C. 2016) (rejecting FDA's claim of Freedom of Information Act exemptions from disclosure).

serious risk of medical harm—not the anticipated medical harm itself," is a cognizable injury. *Baur v. Veneman*, 352 F.3d 625, 641 (2d Cir. 2003). Courts frequently consider whether plaintiffs have shown a "credible threat" that takes the health injury from the realm of the conjectural to the concrete. *See, e.g.*, *NRDC v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013) (quoting *Covington v. Jefferson County*, 358 F.3d 626, 641 (9th Cir. 2004) (finding "credible threat" of health harm because EPA's approval of nanosilver for use as a pesticide "increases the odds" that plaintiffs will be exposed to the substance in clothing and other textiles); *NRDC v. FDA*, 710 F.3d 71, 81 (2d Cir. 2013) ("[T]he injury contemplated by exposure to a potentially harmful product is not the future harm that the exposure risks causing, but the present exposure to risk."); *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 572, 575 (6th Cir. 2005) (finding standing based on increased risk of harm in a medical device case).

In cases asserting health harms, courts have looked to authoritative studies confirming the danger and whether a plaintiff's exposure to a harmful substance is linked to the contested government action. For example, the plaintiff in *Baur* challenged government policy that increased his risk of contracting mad cow disease. 352 F.3d at 628-29. In finding standing, the court relied on government reports of health hazards and on plaintiff's allegation that a policy permitting human consumption of downed cattle heightened plaintiff's risk of contracting a serious disease. *Id.*at 637-39. Similarly, in a challenge to agency failure to regulate certain chemicals used in children's toys, the court credited government findings on potential health harms and rejected the defendant's argument that plaintiffs were not injured because manufacturers had voluntarily stopped using some of the chemicals. *NRDC v. U.S. Consumer Prod. Safety Comm'n*, No. 16-cv-9401 (PKC), 2017 WL 3738464, at *5 (S.D.N.Y. Aug. 18, 2017) (finding a continued "credible risk of personal harm from potential exposure").

The presence of intermediary steps or intervening actors leading to the alleged harm does not categorically make the injury "speculative." *Contra* FDA Mem. 21-22. In *Bennett v. Spear*, for instance, the fact that a third party not before the court had several options for responding to the challenged agency decision—including options that would not harm plaintiffs—did not defeat standing. 520 U.S. 154, 167-68 (1997) (noting, at the pleading stage, that "it is easy to presume specific facts" supporting plaintiffs' allegations of injury); *accord U.S. Consumer Prod. Safety Comm'n*, 2017 WL 3738464, at *5 (reasoning that even though manufacturers had voluntarily ceased using the contested chemicals, that decision could change). *Bennett* made another important distinction: while injury cannot be wholly based on "the independent action of some third party not before the court," this "does not exclude injury produced by determinative or coercive effect upon the action of someone else." 520 U.S. at 169 (cleaned up).

FDA focuses on *Clapper*'s analysis of whether an injury is "certainly impending," FDA Mem. 21 (citing *Clapper*, 568 U.S. at 410-14), but ignores the other half of the formulation: standing can be "based on a 'substantial risk' that harm will occur," and plaintiffs do not need to "demonstrate that it is literally certain that the harms they identify will come about."[8] *Clapper*, 568 U.S. at 414 n.5 (quoting *Monsanto*, 561 U.S. at 153); *see Monsanto*, 561 U.S. at 153-55 (finding that alfalfa farmers established that agency's deregulation decision would increase the likelihood that the farmers' crops would be contaminated by genetically engineered alfalfa genes, forcing them to take steps to mitigate the harm); *Clean Wisc. v. EPA*, 964 F.3d 1145, 1156

[8] *Clapper* can also be distinguished on the facts. There, plaintiffs' injury turned on a complex matrix of hypotheses—plaintiffs' harm was concrete and redressable only if the government invoked the challenged statute and not a different authority or method of surveillance, and if the judge overseeing surveillance requests did not follow constitutional safeguards, and so on. *Clapper*, 568 U.S. at 410-11. By contrast, FDA does not dispute that it is the sole agency with authority to allow or ban the use of antibiotics in livestock. Compl. ¶¶ 4, 58.

(D.C. Cir. 2020) (explaining that "[a]dverse health effects . . . constitute Article III injuries, even if a [plaintiff] merely asserts realistic health concerns instead of providing medical evidence").

FDA also misreads a Second Circuit decision concerning the regulation of two chemicals used in antibacterial hand soap: triclosan and triclocarban, *see* FDA Mem. 22 (citing *NRDC v. FDA*, 710 F.3d at 86). That case supports Plaintiffs' theory of injury. The court found that NRDC *did* establish standing by presenting evidence that (1) triclosan may be harmful, (2) a member declarant is exposed to the chemical, and (3) FDA's failure to regulate triclosan allows it to enter the market without confirmation of safety. *NRDC v. FDA*, 710 F.3d at 82. The court's reference to "unspecified bacteria," *id.* at 86, which FDA quotes out of context, FDA Mem. 22, pertained only to triclocarban, the other chemical at issue—and NRDC had conceded that it did not present evidence of members' exposure to triclocarban. *See* 710 F.3d at 86. Likewise, *Animal Welfare Inst. v. Vilsack*, No. 20-cv-6595 (CJS), 2022 WL 16553395, at *8 (W.D.N.Y. Oct. 31, 2022), which FDA cites, FDA Mem. 22, does not support FDA's argument here. In that case, the court held that the plaintiffs had not established a possibility of exposure to pathogens and that the agency's inspection program likely prevented contaminated meat from entering the market. 2022 WL 16553395, at *8.

In minimizing the health risks to Plaintiffs' members as "speculative," FDA Mem. 23, FDA also misunderstands the empirical data and microbiology principles that underpin these risks. *See* Graham Decl. ¶¶ 15-18, 23, 32-25. As set forth in the Complaint and in the declaration of Dr. Jay Graham, an environmental microbiologist and Director of the Master of Public Health Program in Environmental Health Sciences at UC Berkeley, the use of one antibiotic can cause bacteria to develop resistance to other antibiotics, and to transfer those resistance genes to other bacteria species. Compl. ¶ 33; Graham Decl. ¶¶ 15-18. Regardless of which antibiotics are used

at any one facility, that use can exert selective pressure favoring antibiotic-resistant bacteria, and those bacteria then pass along multidrug-resistance genes to other species and genera of bacteria, amplifying the health risks to Plaintiffs' members. *See* Graham Decl. ¶ 23 (tetracycline in animal feed caused chickens to develop tetracycline-resistant bacteria within one week, and the bacteria tested had multidrug-resistance genes capable of transferring resistance to a wide range of other bacteria); *see also id.* ¶¶ 32-36. Thus, even if Plaintiffs' members do not need to be treated by a particular antibiotic used at any one facility, the use of that antibiotic can still compromise the efficacy of other antibiotics that Plaintiffs' members do need for treatment. *See id.* ¶¶ 17-18, 23-24, 35-37 (discussing multidrug-resistant bacteria and explaining that "[o]nce antibiotic resistance develops in one community, it can easily spread to other locations and establish itself in healthcare facilities"); Murphy Decl. ¶ 9 ("We are running out of effective antibiotics to treat infections, putting all our lives at risk. We should be taking all steps possible to prevent the continued development and spread of resistant strains of bacteria.").

In sum, Plaintiffs have demonstrated the requisite injury: a credible risk of contracting an antibiotic-resistant infection.[9] Public health authorities, including FDA and the U.S. Centers for Disease Control, agree that the use of medically important antibiotics to prevent disease in livestock contributes to the proliferation of antibiotic-resistant bacteria. Compl. ¶ 34; *see* Petition at 18-20; FDA Denial at 4. Plaintiffs' members are exposed to resistant pathogens via meat products, healthcare facilities, and environmental pathways, and consequently face higher risk of contracting a drug-resistant infection. Compl. ¶¶ 53-55; Haller Decl. ¶¶ 9-11; Buchheit Decl.

[9] These are not generalized grievances. *Contra* FDA Mem. 21 n.16. The Complaint alleges pathways by which Plaintiffs' members are exposed to drug-resistant bacteria, and the declarations provide further factual support. *Supra* pp. 12-13; *see, e.g.*, *Gaston Copper*, 204 F.3d at 157 (finding that plaintiff who lived near polluting facility had a "particularized" injury).

¶¶ 9, 10-12; Murphy Decl. ¶¶ 6-8; Nelson Decl. ¶¶ 3, 5; Donne Decl. ¶¶ 3, 5; *see also* Graham Decl. ¶¶ 21-22 & fig.2 (depicting environmental and community spread). This increased risk of disease is an injury in fact. *See, e.g.*, *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751, 759-60 (S.D.W. Va. 2009), *aff'd in part, dismissed in part*, 636 F.3d 88 (4th Cir. 2011) (plaintiffs had a cognizable "interest in safe drinking water" and their "alleged significantly increased risk of future disease" was a cognizable injury).

c. Economic injury

FDA suggests that because some of Plaintiffs' members have "structured their behavior to avoid" the risk of contracting a drug-resistant infection, they lack standing. FDA Mem. 25. Quite the opposite—spending additional money to avoid a reasonably feared harm is a "classic form of injury-in-fact." *Talbert v. Am. Water Works Co.*, 538 F. Supp. 3d 471, 482 (E.D. Pa. 2021) (buying water filters to avoid drinking contaminated water constitutes economic harm (internal quotation marks omitted)); *see also Hutton*, 892 F.3d at 622 (noting that "the Court has recognized standing to sue on the basis of costs incurred to mitigate or avoid harm when a substantial risk of harm actually exists"). Because Plaintiffs face a sufficiently serious risk of health harm, *see supra* pp. 12-13, 19-20, costs incurred to avoid that harm also constitute injury in fact. *See Hutton*, 892 F.3d at 622 (recognizing "standing to sue on the basis of costs incurred to mitigate or avoid harm when a substantial risk of harm actually exists"); *see also United States v. Students Challenging Regul. Agency Procs. (SCRAP)*, 412 U.S. 669, 689 n.14 (1973) (explaining that the monetary injury need not be large—"an identifiable trifle is enough").

Some of Plaintiffs' members "spend more time or money than they otherwise would" to avoid exposure to antibiotic-resistant bacteria. Compl. ¶ 53; *see* Buchheit Decl. ¶ 10 (cost of shoes); Haller Decl. ¶ 11 ("We pay approximately $10 a pound for organic ground beef that will

not have drug-resistant bacteria; by comparison, conventionally raised beef at the local supermarket is about half that price."); Decl. of Stephanie Donne ¶ 5 ("I try to buy for myself and my family only meat that is labeled as organic or antibiotic-free, although such meat usually is more expensive."); Murphy Decl. ¶ 8 (similar); Nelson Decl. ¶ 5 (similar). Plaintiffs' members reasonably incur these expenses to avoid a substantial risk of harm from exposure to drug-resistant bacteria. This provides a separate ground for injury in fact.

B. These harms flow from FDA's refusal to ban preventive uses of antibiotics in livestock and are redressable by the Court

Traceability and redressability are "two facets of a single causation requirement." *See Allen v. Wright*, 468 U.S. 737, 754 n.19 (1984) (internal quotation marks omitted). The requirement ensures that there is a genuine nexus between a plaintiff's injury and a defendant's alleged illegal conduct. *See Gaston Copper*, 204 F.3d at 159. The causation element of standing "does not require the challenged action to be the sole or even immediate cause of the injury." *Sierra Club*, 899 F.3d at 284 (explaining that without defendant's grant of a right-of-way, "the pipeline could not have been authorized in its currently proposed form" that allegedly injures plaintiffs' aesthetic and recreational interests); *see Bennett*, 520 U.S. at 168-71 (holding that injuries were fairly traceable to agency's decision even though another agency had leeway in deciding how to proceed in light of the decision).

Plaintiffs' harms are traceable to FDA's petition denial and redressable by this Court. FDA regulates the use of antibiotics in livestock. *See* 21 U.S.C. § 360b. If FDA grants the petition and withdraws approval for disease-prevention uses of medically important antibiotics in animal feed, veterinarians and meat producers will not be able to lawfully use antibiotics for these purposes. As a result, "the prevalence of bacteria in livestock with resistance to those drugs would stop increasing and would likely decrease." Compl. ¶ 58; *see also* Petition at 31-32 (citing

empirical evidence that restricting certain antibiotic uses in livestock has reduced the prevalence of resistant bacteria); Graham Decl. ¶ 23 (citing 2020 study showing that "reduction in use [of colistin in livestock] was followed by a steep decline in colistin resistance in bacteria found in livestock, meat products and humans"). Plaintiffs' members would then "face a reduced risk of contracting a drug-resistant infection" from eating contaminated meat, recreating in rivers near livestock facilities, and through other pathways. Compl. ¶ 58; *see, e.g.*, Buchheit Decl. ¶ 13 (withdrawing the challenged antibiotics uses "would directly benefit me" by helping to "address the impact on my health" of "the development and spread of antibiotic-resistant bacteria"); Haller Decl. ¶ 13 ("I would feel tremendously better about the safety of the groundwater, rivers, and streams around my home. I would go fishing more and enjoy it more because I would be less worried about my exposure to drug-resistant bacteria."); *accord* Graham Decl. ¶ 23.

FDA contends that granting the petition "would not end . . . the use of antibiotics" in meat production or "eliminate the risk" of foodborne pathogens altogether. FDA Mem. 24-25 (emphasis omitted). The agency also argues that withdrawing antibiotics uses now would not clean up already contaminated waters. *Id.* at 26. Courts have squarely rejected such reasoning that makes "the erroneous assumption that a small incremental step, because it is incremental, can never be attacked in a federal judicial forum." *Massachusetts v. EPA*, 549 U.S. 497, 524 (2007). Accepting FDA's premise "would doom most challenges to regulatory action" because agencies "do not generally resolve massive problems in one fell regulatory swoop." *Id.* That there might be other sources of food contamination, FDA Mem. 25, or other reasons why people may avoid using a river, *id.* at 26, does not defeat the redressability prong of standing. Plaintiffs here allege a nexus between FDA's unlawful action and the spread of drug-resistant bacteria that harms Plaintiffs' members' health and hampers their ability to enjoy the surrounding

environment. Granting the petition would ameliorate these harms. *See supra* pp. 11-13. Article III does not require more to satisfy traceability and redressability. *See Gaston Copper*, 204 F.3d at 163 (finding that injunctive relief against facility's continuing and threatened future permit violations would redress plaintiffs' injuries).

Moreover, FDA underestimates the benefit to Plaintiffs' interests of withdrawing disease-prevention uses of antibiotics. "Approximately two-thirds of medically important antibiotics sold in the United States . . . are sold for use in food-producing animals," Compl. ¶ 3, and a "significant percentage" of those drugs "are administered flock- or herdwide" in an attempt to prevent disease, *id.* ¶ 29; *see also* Petition at 35-36 (noting that disease prevention uses represent the "lion's share of routine antibiotic use in livestock production"); Graham Decl. ¶¶ 19, 31. Just as EPA regulation of motor-vehicle emissions affects the pace of greenhouse gas increases that contribute to climate change, *Massachusetts*, 549 U.S. at 523-24, FDA action here—eliminating prophylactic uses of medically important antibiotics in livestock—affects the development and spread of resistant bacteria. It is therefore not an "[u]nreasonable inference[]," FDA Mem. 25 (internal quotation marks omitted), that halting a substantial portion of antibiotics use in livestock will redress the harms to Plaintiffs' members.

For these reasons, Alliance of Nurses, NRDC, and Public Citizen have standing.

C. FDA's denial of the citizen petition impedes FACT's operations[10]

Plaintiff FACT's mission is to improve the welfare of farm animals, address public health problems from the production of meat, milk, and eggs, and broaden opportunities for family

[10] Because the membership-organization Plaintiffs have standing, the Court need not reach the question of FACT's standing. *See, e.g., Bostic v. Schaefer*, 760 F.3d 352, 370 (4th Cir. 2014) ("[T]he presence of one party with standing is sufficient to satisfy Article Ill's case-or-controversy requirement." (quoting *Rumsfeld v. Forum for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 52 n.2 (2006))).

farmers. Compl. ¶ 17; *see* Decl. of Steven Roach ¶¶ 4-5. FDA's petition denial forces FACT to expend limited resources to combat antibiotics overuse by raising public awareness of the problem and pressuring companies to adopt practices that are more protective than what FDA requires. Compl. ¶ 59; Roach Decl. ¶ 10. This thwarts FACT's ability to allocate funds and staff time to other programs central to its mission, including "researching links between regenerative agriculture and food safety, and ensuring more equitable access to healthy food." Compl. ¶ 59; Roach Decl. ¶ 11, 13-14. FDA's decision also impedes FACT's ability to carry out its mission of protecting animal and human health. Roach Decl. ¶ 12. The drain on FACT's resources and interference with its operations is "more than simply a setback to [FACT's] abstract social interests." *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982).

FACT's injury is not mere "budgetary choice[]" untethered to "actions taken by [the agency]." *Lane v. Holder*, 703 F.3d 668, 675 (4th Cir. 2012) (internal quotations omitted). FDA's reliance on *Lane* is misplaced. Plaintiffs in *Lane* were a Second Amendment rights group and individual gun purchasers. *Id.* at 670, 673. The law at issue regulated firearm dealers who, in turn, charged a transfer fee to people buying out-of-state guns. *Id.* at 670, 674. The court concluded that purchasers' "minor inconveniences" stemmed from laws that did not apply directly to them. *Id.* at 672-74 (discussing theory of "injury based on restriction of distribution channels"). This is distinct from the harms that FACT alleges. *Cf. Tri-State Zoological*, 843 F. App'x at 497 (distinguishing *Lane*).

Post-*Lane*, courts within this Circuit have affirmed that "a plaintiff has suffered an organizational injury if the challenged policy or practice frustrated both its purpose and caused a drain on its resources." *Id.* at 496. In one such case, PETA—an organization dedicated to preventing animal cruelty—alleged that defendant's Endangered Species Act violations forced

PETA to divert resources, reducing the group's ability to engage in mission-related campaigns against other zoos. *Id.* at 496-97. The court held that this dual showing of "frustration of [PETA's] mission and a consequent drain on its resources" established standing. *Id.*; *see also Nat'l Fed'n of the Blind v. U.S. Dep't of Educ.*, 407 F. Supp. 3d 524, 533 (D. Md. 2019) (finding that plaintiffs "alleged a need to expend more resources than usual to assist their members in a specific fashion that is core to their mission of advancing equal access to education, and have asserted that it will be more burdensome to do so" because of the challenged law). District courts within this Circuit have applied *Tri-State Zoological*'s reasoning to find organizational injury in other cases. *See, e.g.*, *PETA v. Tabak*, No. 21-cv-2413 (PX), 2023 WL 2599573, at *3 (D. Md. Mar. 21, 2023) (concluding that government funding of animal-involved research forced plaintiff to devote resources on education, letter-writing, and public pressure campaigns at the expense of other projects, which is "precisely the sort of mission-driven diversion of resources" sufficient to show organizational injury); *Defs. of Wildlife v. Boyles*, 608 F. Supp. 3d 336, 343-44 (D.S.C. 2022) (holding that "diversion of resources for investigation, research, education, and public advocacy" focused on one species impeded organization's advocacy for other species, which established harm for standing).

The cases that FDA cites are readily distinguished. *See* FDA Mem. 15-16 (relying on *CASA de Maryland, Inc. v. Trump*, 971 F.3d 220, 239 (4th Cir. 2020), *reh'g en banc granted*, 981 F.3d 311 (4th Cir. 2020) (challenged rule did not impair CASA's ability to provide services to immigrants); *Food & Water Watch v. Vilsack*, 808 F.3d 905, 920 (D.C. Cir. 2015) (plaintiff did not show that its "operational costs [were] beyond those normally expended" (internal quotation marks omitted)); and *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 257 (organizational plaintiff did not identify "any specific projects that [it] had to put on hold or otherwise curtail"

(alteration in original) (internal quotation marks omitted))). *CASA* was vacated by the grant of rehearing en banc. *See* 4th Cir. Local R. 35(c). And *CASA* is not persuasive—in contrast to the plaintiff there, FACT shows that FDA's decision impedes the organization's ability to operate. By allowing the continued misuse and overuse of antibiotics in livestock, FDA's petition denial "increases the risk of antimicrobial resistance," which "impedes FACT's ability to carry out its mission of protecting animal and human health." Roach Decl. ¶ 12. Unlike plaintiffs in *Food & Water Watch* and *International Academy*, FACT details the "considerable resources" it commits to ameliorating the effects of FDA's decision. *Id.* ¶ 11. Among other steps, FACT works with corporations to reduce antibiotics use, publishes reports on food companies' practices relating to antibiotic use policies at major restaurant chains, and improves consumer awareness by penning opinion pieces on the dangers of FDA's inaction on antibiotics misuse in livestock. *Id.* ¶¶ 10-11. This diversion of staff time and resources has forced FACT to place other important projects on the back burner, including filing a citizen petition to ban the use of a carcinogenic swine feed additive, efforts to reduce Salmonella contamination by improving farm practices, and programs to promote food equity. *Id.* ¶ 13.

FDA's dereliction of its statutory duty to regulate animal drugs for human safety "divert[s]" FACT's resources "away from other mission-based projects," *Boyles*, 608 F. Supp. 3d at 342, and frustrates FACT's mission, *Tri-State Zoological*, 843 F. App'x at 496. This establishes FACT's organizational injury.

II. FDA's denial of the citizen petition is final agency action reviewable by this Court

Plaintiffs' claim that FDA's petition denial was arbitrary and capricious is well within the proper scope of judicial review. *See, e.g.*, *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1487, 1491-92 (D.C. Cir. 1995) (remanding FDA decision to deny citizen petitions challenging the

approval of growth-promotion drug used in chickens); *Henley v. FDA*, 77 F.3d 616, 618-19 (2d Cir. 1996) (upholding FDA denial of petition concerning health warnings on drug labels). The question Plaintiffs present—whether FDA "failed to consider an important aspect of the problem" highlighted in the record before the agency—is of a type that courts routinely consider. *See, e.g.*, *Ohio River Valley Env't Coal., Inc. v. Kempthorne*, 473 F.3d 94, 97, 103 (4th Cir. 2006) (internal quotations omitted) (reviewing federal agency approval of state plan governing surface coal mining); *New England Anti-Vivisection Soc'y v. Goldentyer*, No. 20-cv-2004 (JRR), 2023 WL 2610867, at *1-3 (D. Md. Mar. 23, 2023) (reviewing challenge to Department of Agriculture denial of petition to promulgate standards for protecting primates used in research).

In denying the citizen petition, FDA failed to address Plaintiffs' argument and evidence that halting the use of antibiotics for disease prevention in livestock is necessary to protect public health. Courts regularly adjudicate challenges to analogous agency mistakes by applying established standards developed through decades of caselaw. *See State Farm*, 463 U.S. at 43 (laying out grounds for courts to invalidate agency actions); *A.L. Pharma*, 62 F.3d at 1486, 1491 (FDA's petition denial arbitrarily failed to explain contrary scientific evidence); *Henley*, 77 F.3d at 619 (applying arbitrary and capricious standard in reviewing FDA denial of petition); *cf. NRDC v. FDA*, 598 F. Supp. 3d 98, 110 (S.D.N.Y. 2022) (discussing scope of record in APA review of petition denial). Judicial review of whether FDA ignored key points in the petition does not require the court to second-guess FDA's expert judgment on matters like agency rulemaking priorities or the safety record of various drugs. *Contra* FDA Mem. 31.[11]

[11] Even if Plaintiffs' claim is interpreted as a challenge to a decision not to withdraw antibiotics uses (as opposed to a decision to deny a petition without addressing key points), an FDA decision with respect to drug use withdrawal is reviewable in court, subject to the standards set

FDA mischaracterizes the petition denial as an "enforcement" decision "committed to agency discretion by law," and claims the court has no "judicially manageable standards" to apply here. FDA Mem. 26, 30 (citing 5 U.S.C. § 701(a)(2)). But a final decision on a citizen petition is not equivalent to a choice of whether to prosecute or enforce a criminal or civil action. Rather, it is one for which "a statute . . . set[s] clear guidelines for determining" whether the petition should be granted or denied. *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). Specifically, the APA provides "judicially manageable standards," *id.* at 830, by instructing courts to invalidate final agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Here, FDA acted arbitrarily because it failed to consider an important aspect of the problem, *see State Farm*, 463 U.S. at 43—the question of human safety. FDA's decision to deny the citizen petition is precisely the type of agency action for which the APA provides judicial review. *See, e.g.*, *Henley*, 77 F.3d at 619; *A.L. Pharma*, 62 F.3d at 1487; *cf. Pfizer, Inc. v. FDA*, 753 F. Supp. 171, 174-75 (D. Md. 1990) (reviewing challenge under 5 U.S.C. § 706(2)(A) to FDA denial of citizen petition).

FDA cites a handful of cases that address agency actions that are prosecutorial, FDA Mem. 26-31, all of which are easily distinguished. In *Heckler*, plaintiffs asked FDA to "take various investigatory and enforcement actions" relating to off-label uses of drugs in lethal injections. *Heckler*, 470 U.S. at 823-24. The court in *Speed Mining* held that the agency had discretion whether to cite a mine owner, the independent contractor, or both entities for safety violations. *Speed Mining, Inc. v. Fed. Mine Safety & Health Rev. Comm'n*, 528 F.3d 310, 314 (4th Cir. 2008). And *Sierra Club v. Larson*, 882 F.2d 128, 130 (4th Cir. 1989), involved agency

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forth in the Food, Drug, and Cosmetic Act and implementing regulations. *See* 21 U.S.C. § 360b(h) (providing for judicial review of FDA decision not to approve a drug or to withdraw approval).

discretion to withhold federal highway funds. These are all enforcement choices; in contrast, Plaintiffs challenge FDA's final decision denying a citizen petition that seeks withdrawal of the agency's drug approvals, which is not an enforcement decision.

FDA also misses the mark in relying on a Second Circuit ruling concerning a different FDA decision on antibiotics in animal feed. *See* FDA Mem. 27. The court in that case did not hold that FDA's decision was "unreviewable." *See id.* at 31. Rather, the court disagreed with plaintiffs on the merits: It concluded that the statute did not compel initiation of formal withdrawal proceedings given FDA's preliminary safety findings, *NRDC v. FDA*, 760 F.3d at 153, and that FDA's decision to deny two citizen petitions was not arbitrary and capricious, *id.* at 172-73. FDA misconstrues the Second Circuit's holding, claiming the court found that "the agency retain[ed] the [*enforcement*] discretion to institute or terminate [withdrawal] proceedings." FDA Mem. 28. This is a surprising misreading— it adds a key word, "enforcement"—and italicizes the added word for emphasis. *Compare* FDA Mem. 28, *with NRDC v. FDA*, 760 F.3d at 171-72 (noting that FDA is not required to hold hearings "whenever FDA officials have scientific concerns" about drug safety issues). FDA also takes plaintiffs' argument and the court's analysis out of context. The Second Circuit did not hold that FDA has unfettered "enforcement discretion" in withdrawing drug use approval. The actual holding was narrower: that the statutory mandate to withdraw a drug use approval, 21 U.S.C. § 360b(e)(1), comes into play only *after* FDA has "made a final determination" that the drug poses a threat to human safety. *NRDC v. FDA*, 760 F.3d at 171-72. The court found that FDA's 1970s Federal Register notices questioning the safety of the antibiotics uses was not a "final determination" triggering a duty to hold a hearing and withdraw the drug use approvals. In short, the case did *not*

find that FDA's denial of a citizen petition is unreviewable—instead, it reviewed that decision. *Id.* at 175 (crediting FDA's reasoning for pursuing a voluntary compliance program).

The law is clear: this Court can review FDA's decision to deny a citizen petition seeking withdrawal of drug use approvals under the APA's well-established standard of review.

III. Plaintiffs' APA suit based on FDA's 2021 decision is not estopped

The assertion that Plaintiffs are estopped from challenging FDA's 2021 denial of the 2016 petition, FDA Mem. 28-29, is a nonstarter. Collateral estoppel prevents relitigation of issues of law and fact if they were "conclusively determined in a prior action." *United States v. Stauffer Chem. Co.*, 464 U.S. 165, 170-71 (1984). The issues presented in this case were not determined in any prior case.

The present lawsuit asserts that FDA's 2021 decision is arbitrary and capricious because it "failed to consider an important aspect of the problem" presented in the 2016 petition: to safeguard human health, FDA must significantly reduce the vast quantity of antibiotics used in livestock by halting the herd- and flock-wide use of antibiotics for disease prevention. Compl. ¶ 63 (Claim for Relief); *see also id.* ¶¶ 7-9, 50-52. The case makes neither the same legal claim nor challenges the same agency action at issue in *NRDC v. FDA*, 760 F.3d at 153. The questions before the Second Circuit in 2014 were (1) whether FDA had already made a human safety finding and was therefore required by statute to initiate withdrawal proceedings, and (2) if FDA had discretion to consider non-statutory factors in deciding two citizen petitions filed in 1999 and 2005. *Id.* at 155-56, 174-75 (considering plaintiff's argument, based on *Massachusetts v. EPA*, that FDA could not weigh factors other than human safety in deciding whether to initiate withdrawal proceedings). These are not the same issues of law or fact presented in this case.

* * *

Plaintiffs are harmed by FDA's petition denial and have standing to bring this case. The APA enables the Court to review final agency actions, including FDA's decision to deny a citizen petition, and to set aside the decision if it is arbitrary and capricious. And Plaintiffs are not estopped from challenging FDA's new decision based on a distinct administrative record, and through a different legal theory. The Court should adjudicate the merits of this case.

CONCLUSION

The Court should deny Defendants' Motion to Dismiss and order the parties to meet and confer and, within 14 days of the Court's order, submit a proposed schedule for summary judgment briefing.

Respectfully submitted,

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