IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ALLIANCE OF NURSES FOR HEALTHY ENVIRONMENTS, *et al.*,	*	
Plaintiffs,	*	
v.	*	**Civ. No. DLB-23-176**
U.S. FOOD & DRUG ADMINISTRATION, *et al.*,	*	
Defendants.	*	

MEMORANDUM OPINION

In 2021, the U.S. Food and Drug Administration ("FDA") denied a petition from several public health and environmental organizations to withdraw approval of the use of certain antibiotics for the prevention of disease in livestock and poultry. Three of the organizations that filed the petition, joined by another organization that did not, sued FDA and three related government defendants for violating the Administrative Procedure Act, 5 U.S.C. § 701 *et seq.* ("APA"). The defendants moved to dismiss the case for lack of subject matter jurisdiction, primarily on the ground that the plaintiffs lacked Article III standing. The defendants are correct: The plaintiffs do not have standing to bring this case. The motion to dismiss for lack of subject matter jurisdiction is granted. The case is dismissed.

I. Background

Some bacteria cause disease. ECF 1, ¶ 1. We depend on antibiotics to kill them. *Id.* But some of the bacteria that cause disease have evolved to defeat these antibiotics. *Id.* ¶¶ 1, 31–33. These antibiotic-resistant bacteria threaten public health. *Id.* ¶ 1. Each year, in the United States alone, they cause more than 2.8 million infections and kill as many as 162,000 people. *Id.*

One reason bacteria have become dangerously resistant to antibiotics is that antibiotics are used too much, for too little cause. *Id.* Since the 1950s, livestock producers have been adding low doses of antibiotics to the feed of otherwise healthy animals to prevent them from developing diseases. *Id.* ¶ 29. Roughly two-thirds of the antibiotics we rely on to protect human health are used to protect food-producing animals from infection. *Id.* This long-term, preventative administration of antibiotics to whole herds and flocks is more likely to generate antibiotic-resistant bacteria than short-term, targeted treatment for animals that are sick already. *Id.* ¶¶ 29–30.

Antibiotic-resistant bacteria from food-producing animals can infect humans in a variety of ways. *Id.* ¶¶ 35–36. People can get sick from contaminated meat. *Id.* ¶ 35. They can get sick from encountering infected livestock. *Id.* These bacteria can spread through the air, dust, animal waste, insects, or rodents. *Id.* ¶ 36. And once one person is infected, that person can spread the bacteria to more people. *Id.*

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, authorizes FDA to regulate the agricultural use of antibiotics. *Id.* ¶ 4 (citing 21 U.S.C.§ 360b). The statute requires FDA to withdraw approval of an animal drug if the drug is not shown to be safe for its approved uses. *Id.* ¶ 4 (citing 21 U.S.C. § 360b(e)(1)); *id.* ¶ 26. The FDA Commissioner has delegated some of the responsibility for administering this provision to the Director of FDA's Center for Veterinary Medicine. *Id.* ¶ 27. An FDA guidance document—"Guidance for Industry No. 152"—specifies that an animal drug is safe if "there is reasonable certainty of no harm to human health from the proposed use of the drug in food-producing animals." *Id.*

In 2016, Food Animal Concerns Trust ("FACT"), Natural Resources Defense Council, Inc. ("NRDC"), Public Citizen, and Earthjustice petitioned FDA under 21 C.F.R. § 10.25(a) to ban the

use of specific medically important antibiotics—macrolides, lincosamides, penicillins, streptogramins, tetracyclines, aminoglycosides, and sulfonamides—for disease prevention in livestock and poultry. *Id.* ¶¶ 2, 5. That regulation authorizes any interested person to petition FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." *Id.* ¶ 28 (quoting 21 C.F.R. § 10.25(a)). The petitioners cited scientific evidence that this use of antibiotics contributes to the development of antibiotic-resistant bacteria that harm human health. *Id.* ¶ 5. After several years of silence from FDA, the petitioners submitted a supplement to their petition, which included new evidence that beef, pork, and turkey production routinely involves administering antibiotics to entire herds of animals—and that this routine, large-scale use of antibiotics in food-producing animals is not safe for humans. *Id.* ¶¶ 6, 47.

In February 2021, FDA denied the petition. *Id.* ¶¶ 7, 48. Although FDA acknowledged the risk antibiotic-resistant bacteria pose to public health, FDA decided it would "support[] judicious use" of antibiotics rather than withdraw approval. *Id.* ¶¶ 7, 49–51. FDA's guidance on judicious use directs veterinarians to consider carefully how the use of these drugs can impact animal health. *Id.* ¶¶ 7, 42. But FDA's guidance does not address how the use of these drugs in animals can impact human health. *Id.* ¶ 8. FDA did not respond to the petitioners' argument that withdrawing approval of the use of medically important antibiotics for disease prevention in livestock is essential to protecting human health. *Id.*

On January 24, 2023, Alliance of Nurses for Healthy Environments ("Alliance of Nurses"), FACT, NRDC, and Public Citizen brought this case against FDA, FDA Commissioner Robert M. Califf, FDA's Center for Veterinary Medicine, and its Acting Director, Tracey H. Forfa. ECF 1. The plaintiffs claim that the defendants' denial of the petition was arbitrary and capricious, in violation of the APA, 5 U.S.C. § 706(2)(A). ECF 1, ¶ 9. Alliance of Nurses, NRDC, and Public

Citizen allege that the denial of the petition impairs the health, recreational, economic, and aesthetic interests of individual members of these organizations. *Id.* ¶¶ 53–58.[1]

David Buchheit is a member of Alliance of Nurses. ECF 24-1, ¶¶ 1–3. As a travelling nurse, he moves frequently to serve communities with high medical needs. *Id.* ¶ 3. At the time Buchheit filed his declaration, he was working at St. Luke's South Hospital in Overland Park, Kansas. *Id.* ¶ 4. At the start of a typical shift, he reviews nurses' reports and patient logs for isolation orders for patients who tested positive for antibiotic-resistant bacteria (among other things). *Id.* Then Buchheit makes his rounds, which include administering medication to patients and coordinating care. *Id.* "Quite frequently," patients are admitted for one illness but also have an existing wound. *Id.* ¶ 5. He "often" finds that these patients are carrying antibiotic-resistant bacteria that threaten to infect the wound and complicate treatment. *Id.* Antibiotic-resistant bacteria are now so prevalent that some hospitals where he has worked do "surveillance testing": taking nasal swabs of patients who do not even have symptoms of a resistant infection. *Id.* ¶ 6. When one of his patients tests positive for antibiotic-resistant bacteria that spread through contact, he takes a range of measures to protect himself from infection. *Id.* He washes or sanitizes his hands before and after visiting the patient and wears gloves while interacting with them. *Id.* He also dons a disposable gown before contact with the patient and doffs it afterwards. *Id.* And he sanitizes surfaces with bleach because alcohol-based cleaners will not kill certain resistant bacteria, like clostridium difficile. *Id.* When one of Buchheit's patients tests positive for a resistant bacterium that can transmit through the air, the patient is isolated in a negative-pressure room that prevents the pathogens from entering the hospital corridors. *Id.* He enters the room wearing a powered air purifying respirator system, which

[1] Initially, the plaintiffs alleged that FDA's denial of the petition harmed FACT as an organization. ECF 1, ¶ 59; *see also* ECF 24-8 (declaration of Steven Roach). FACT subsequently dismissed its claims. ECF 31.

delivers filtered air into his mask with a fan. *Id.* These protective protocols take time, preventing him from seeing patients as efficiently. *Id.* ¶ 7. Buchheit takes precautions to protect his family from antibiotic-resistant bacteria he encounters at work: He buys special shoes that he wears only for work, and as soon as he gets home, he changes his scrubs and washes them. *Id.* ¶ 10. But he knows that no matter what he does, he cannot eliminate the risks to himself and to others entirely. *Id.* ¶¶ 11–12. Buchheit also reports seeing more patients prescribed "broad-spectrum antibiotics" like vancomycin at the outset of their care. *Id.* ¶ 8. Broad-spectrum antibiotics have the power to combat a range of infectious bacteria. *Id.* Before, these drugs might have been reserved for patients with severe medical conditions. *Id.* Now, Buchheit sees vancomycin being prescribed "routinely, in part because bacteria are becoming resistant to other, more narrow-spectrum antibiotics." *Id.* This happens despite the fact that vancomycin can be administered only through an IV and patients taking it must be monitored carefully to prevent kidney and hearing damage. *Id.* Buchheit "fear[s] we are moving into a post-antibiotic world where many infections will be very resistant to every kind of antibiotic." *Id.* ¶ 9.

Kathryn Murphy is a member of Alliance of Nurses who has been a nurse for 40 years. ECF 24-6, ¶¶ 1–2. Her sister is immunocompromised, and Murphy worries about getting her sick. *Id.* ¶ 6. Over her decades of clinical practice, Murphy has seen an uptick in the use of tougher antibiotics with more serious side effects because the rise of antibiotic-resistant bacteria has made it harder to tell which antibiotics will be effective. *Id.* ¶ 4. For much the same reason, providers also often prescribe a patient multiple antibiotics at the outset of their treatment. *Id.* Murphy's work exposes her to "superbugs" like methicillin-resistant staphylococcus aureus ("MRSA"). For instance, she has taken care of children with MRSA-infected wounds. *Id.* ¶¶ 5–7. "Simple, everyday common activities expose [her] to superbugs like MRSA" too, like going to the gym for

physical therapy, buying groceries, and eating meat. *Id.* ¶¶ 7–8. To mitigate her risk of exposure to antibiotic-resistant bacteria, she buys organic meat when she can, even though it costs her more and is harder to find. *Id.* ¶ 8. But she "can't completely avoid exposure to resistant bacteria" and worries about how those with less knowledge or less money can protect themselves. *Id.* Ending the use of antibiotics to prevent disease in food-producing animals "would address an important source of resistant bacteria," and thereby "directly benefit [her], [her] patients, and [her] community." *Id.* ¶ 10.

Stephanie Donne is a member of Public Citizen. ECF 24-2, ¶ 1. Concerned that the use of antibiotics to prevent disease in animals increases the risk she and her family members will contract a serious infection and lowers the effectiveness of treatment, Donne has reduced the amount of meat she eats, and she pays more for meat labelled organic or antibiotic-free. *Id.* ¶¶ 3–5.

Scott L. Nelson is a member of Public Citizen as well. ECF 24-7, ¶ 1. He has chronic medical conditions that leave him immunocompromised. *Id.* ¶ 3. As a result, he frequently has to go to medical facilities for treatment. *Id.* To avoid the risk of antibiotic-resistant bacteria, Nelson has reduced the amount of meat he eats. *Id.* ¶ 5. And when he does buy meat, he chooses antibiotic-free options, even when they are more expensive, harder to find, or unavailable in the cuts he prefers. *Id.*

Dennis Haller belongs to NRDC. ECF 24-4, ¶ 1. For decades, he has lived in Decorah, Iowa, a town near a number of concentrated animal feeding operations ("CAFOs"). *Id.* ¶¶ 2–4. CAFOs confine thousands of food-producing animals in tight quarters. *Id.* ¶ 4. Because confinement puts these animals at heightened risk of disease, they are "fed a lot of antibiotics." *Id.* CAFOs store the manure from these animals in large "lagoons." *Id.* ¶ 5. Nearly every week, these

lagoons leak animal waste into nearby streams and rivers. *Id.* ¶¶ 5–8. The Iowa Department of Natural Resources often issues warnings against recreational use of local waterways because of their high bacteria count. *Id.* ¶ 8. And because the groundwater is just 20 feet below the surface, bacteria from this animal waste runoff has contaminated the local water supply. *Id.* ¶ 7. So when Haller and his wife installed a drinking water well in 1998, they "had to install a much deeper well to reach the Jordan Aquifer, which is about 400 to 500 feet below the surface." *Id.* The project cost them $10,000. *Id.* Today, a project like that would cost around $35,000. *Id.* In addition, local farmers spread manure from the CAFOs on crop fields within "a mile or two" of Haller's home. *Id.* ¶ 5. There is so much manure in the area that Haller "can smell it from miles away, no matter which direction the wind is blowing." *Id.* Haller likes to go fishing at South Pine Creek, a trout stream five miles from his home. *Id.* ¶ 9. But now, worried about the risk of exposure to antibiotic-resistant bacteria, Haller fishes there less. *Id.* When he does fish in the area, he wears waders, tries to avoid contact with the water, and handles fish more carefully, reminding himself not to rub his eyes or touch his face. *Id.* What's more, Haller has been postponing knee replacement surgery because he worries the surgery will result in an infection from antibiotic-resistant bacteria like MRSA. *Id.* ¶ 10. Nor is that all. In December 2020, Haller contracted an infection after getting a thistle in his thumb. *Id.* Fortunately, the infection responded to treatment with penicillin. *Id.* Finally, Haller reports that he and his wife pay more to buy organic meat and eggs to avoid the risk of exposure to drug-resistant bacteria. *Id.* ¶ 11.

On May 24, 2023, the defendants moved to dismiss the complaint under Rule 12(b)(1) for lack of subject matter jurisdiction. ECF 16. The next day, they filed a corrected motion to dismiss. ECF 17. The plaintiffs opposed the motion. ECF 24. The defendants replied. ECF 25.

On December 13, 2023, the Supreme Court granted petitions for writs of certiorari in *Food & Drug Administration v. Alliance for Hippocratic Medicine* and *Danco Laboratories, LLC v. Alliance for Hippocratic Medicine* and consolidated the cases. *Food & Drug Admin. v. All. for Hippocratic Med.*, No. 23-235, 2023 WL 8605746 (Mem) (Dec. 13, 2023). The threshold question presented was whether the plaintiff physicians and physicians' associations had Article III standing to challenge two FDA changes to the approved conditions of use of mifepristone, a pregnancy-ending drug. *See* Pet. for Writ of Cert. at I, *All. for Hippocratic Med.*, No. 23-235. On February 21, 2024, this Court found that the Supreme Court's ruling was "highly likely to affect the resolution of this case" and exercised its discretion to stay the case to await the ruling. ECF 28.

On June 13, 2024, the Supreme Court issued its ruling. *Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367 (2024). On June 27, the parties filed supplemental briefs on what *Alliance for Hippocratic Medicine* means for this case. ECF 29 & 30.

II. Standard of Review

"Federal courts are courts of limited jurisdiction," possessing "only that power authorized by Constitution and statute." *Robb Evans & Assocs., LLC v. Holibaugh*, 609 F.3d 359, 362 (4th Cir. 2010) (quoting *Kokkonen v. Guardian Life Ins. Co.*, 511 U.S. 375, 377 (1994)). "A motion to dismiss based on lack of subject matter jurisdiction pursuant to Rule 12(b)(1) raises the question of whether the Court has the competence or authority to hear the case." *Davis v. Thompson*, 367 F. Supp. 2d 792, 799 (D. Md. 2005). The plaintiff, as the party asserting jurisdiction, bears the burden of establishing it. *Robb Evans*, 609 F.3d at 362. Where, as here, the defendants contest subject matter jurisdiction "by contending that, even assuming that the allegations are true, the complaint fails to set forth facts upon which jurisdiction is proper"—a facial challenge to jurisdiction—the plaintiff "is afforded the same procedural protections as he would receive under

a Rule 12(b)(6) consideration[.]" *Durden v. United States*, 736 F.3d 296, 300 (4th Cir. 2013) (quoting *Kerns v. United States*, 585 F.3d 187, 192 (4th Cir. 2009)) (internal quotation marks omitted). Dismissal for lack of subject matter jurisdiction is proper "where a claim fails to allege facts upon which the court may base jurisdiction." *Davis*, 367 F. Supp. 2d at 799 (citing *Crosten v. Kamauf*, 932 F. Supp. 676, 679 (D. Md. 1996)). On a Rule 12(b)(1) motion, "the court may look beyond the pleadings and the jurisdictional allegations of the complaint and view whatever evidence has been submitted to determine whether in fact subject matter jurisdiction exists." *Stahlman v. United States*, 995 F. Supp. 2d 446, 451 (D. Md. 2014) (quoting *Khoury v. Meserve*, 268 F. Supp. 2d 600, 606 (D. Md. 2003), *aff'd*, 85 Fed. App'x 960 (4th Cir. Jan. 23, 2004)); *see also Warth v. Seldin*, 422 U.S. 490, 501 (1975) ("For purposes of ruling on a motion to dismiss for want of standing . . . it is within the trial court's power to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff's standing.").

III. Discussion

None of the plaintiffs has standing to bring this case.

Under Article III of the United States Constitution, "judicial Power" extends only to cases or controversies. U.S. Const., art. III, § 2, cl. 1; *TransUnion, LLC v. Ramirez*, 594 U.S. 413, 423 (2021). There is a case or controversy only if the plaintiff has standing to assert their claim. *TransUnion*, 594 U.S. at 423. The standing doctrine serves a vital purpose: limiting the "role of the courts in a democratic society." *All. for Hippocratic Med.*, 602 U.S. at 380 (quotation omitted). "By limiting who can sue," standing requirements "allow[] issues to percolate and potentially be resolved by the political branches in the democratic process." *Id.* (citations omitted).

To establish standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion*, 594 U.S. at 423 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992)). To satisfy the causation requirement, "the injury has to be fairly traceable to the challenged action of the defendant." *Lujan*, 504 U.S. at 560 (cleaned up).

The plaintiff organizations, Alliance of Nurses, NRDC, and Public Citizen, assert standing on behalf of their members. *See S. Walk at Broadlands Homeowners' Ass'n, Inc. v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 182 (4th Cir. 2013). To assert standing on behalf of its members—associational standing—an organization "must allege that '(1) its own members would have standing to sue in their own right; (2) the interests the organization seeks to protect are germane to the organization's purpose; and (3) neither the claim nor the relief sought requires the participation of individual members in the lawsuit.'" *Id.* at 184 (quoting *Md. Highways Contractors Ass'n, Inc. v. Maryland*, 933 F.2d 1246, 1251 (4th Cir. 1991)).

A. Causation

The plaintiffs lack standing because they have not established that the FDA action they challenge likely causes or will cause the injuries they allege. The causal chain linking their members' alleged injuries to FDA's actions is too speculative, attenuated, or both.

The Supreme Court spelled out why in its recent ruling in *Alliance for Hippocratic Medicine*. *Alliance for Hippocratic Medicine* concerned two FDA changes to the approved conditions of use of mifepristone, an abortion drug. *All. for Hippocratic Med.*, 602 U.S. at 372–74. Each change "made it easier for doctors to prescribe and pregnant women to obtain mifepristone." *Id.* at 373. The plaintiffs, pro-life "doctors and associations," claimed these changes

violated the APA. *Id.* The plaintiffs advanced three theories of standing. *Id.* at 386. As relevant here, one of their theories concerned economic injuries to the physicians who belonged to the plaintiff associations. *Id.* at 390. On this theory, FDA's relaxation of its mifepristone regulations likely would increase the number of women who would use the drug, thereby increasing the number of women who would experience complications from using the drug, thereby increasing the number of women with complications from the drug who would present in the emergency room, thereby increasing the likelihood that some of the physician-members would have to treat such women, thereby compelling them to divert resources from other patients, exposing the physicians to liability for that treatment and driving up the cost of their malpractice insurance. *Id.*

The Supreme Court held that this chain of causation linking FDA's actions to the alleged injuries was "too speculative or otherwise too attenuated to establish standing." *Id.* at 393. The Court began by distinguishing cases where the plaintiffs challenge regulations that apply to them from cases where the plaintiffs challenge regulations that apply to others. "Government regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements." *Id.* at 382. "By contrast, when (as here) a plaintiff challenges the government's 'unlawful regulation (or lack of regulation) of someone else,' 'standing is not precluded, but it is ordinarily substantially more difficult to establish.'" *Id.* (quoting *Lujan*, 504 U.S. at 562). Typically, that is because "unregulated parties may have more difficulty establishing causation—that is, linking their asserted injuries to the government's regulation (or lack of regulation) of someone else." *Id.* (citations omitted).

The reason is that when the plaintiff is not the object of the regulation at issue, "causation 'ordinarily hinges on the response of the regulated (or regulable) third party . . . and perhaps on the response of others as well.'" *Id.* at 383 (quoting *Lujan*, 504 U.S. at 562). Yet there is standing

only if "the line of causation between the illegal conduct and injury—the links in the chain of causation—[is not] too speculative or too attenuated." *Id.* If the connection is too speculative—that is, "where it is not sufficiently predictable how third parties would react to government action or cause downstream injury to plaintiffs"—then the plaintiffs cannot establish causation. *Id.* If the connection is too attenuated—that is, "the government action is so far removed from its distant (even if predictable) ripple effects"—then the plaintiffs cannot establish causation either. *Id.* In "suits by unregulated parties against the government," "the causation inquiry can be heavily fact-dependent"—a "question of degree." *Id.* at 384.

The doctors and medical organizations before the Court were neither prescribers nor users of the regulated drug. So they came before the Court as "unregulated parties who seek to challenge FDA's regulation *of others*"—making it particularly difficult for them to show that FDA's actions caused their alleged injuries. *Id.* at 385. Instead of advancing a short and simple causal story, the plaintiffs advanced a "complicated causation theor[y]" that failed to adequately "connect FDA's actions to the plaintiffs' alleged injuries in fact." *Id.* at 386. In addition, the plaintiffs' "claim that the doctors will incur those [economic] injuries as a result of FDA's 2016 and 2021 relaxed regulations lack[ed] record support and [was] highly speculative." *Id.* at 390. The plaintiffs had not identified even a single instance where they actually had suffered the economic injuries they alleged. *Id.* at 391. And they offered no "persuasive evidence or reason to believe that the future will be different." *Id.* So the causal chain linking their alleged injuries to FDA's actions was too speculative to secure standing.

But that was not all. The Court also held that even if the plaintiffs had made those showings, the causal connection between FDA's actions and the plaintiffs' alleged injuries would have been too attenuated. *Id.* at 391–93. "[V]irtually all drugs come with complications, risks, and side

effects," the Court observed. *Id.* at 392. "Approval of a new drug may therefore yield more visits to doctors to treat complications or side effects." *Id.* If healthcare providers had standing on the basis of these attenuated consequences, then "any doctor or healthcare provider [could] challenge any FDA decision approving a new drug." *Id.* The Court "decline[d] to start the Federal Judiciary down that uncharted path." *Id.* Instead, the Court concluded that "there is no Article III doctrine of 'doctor standing' that allows doctors to challenge general government safety regulations" or the approval of new drugs. *Id.* at 391. Or as the Court put it at the outset of its opinion, "a plaintiff's desire to make a drug less available *for others* does not establish standing to sue." *Id.* at 374.

The causal story the plaintiffs advance here to link their injuries to FDA's denial of their petition is comparably speculative and attenuated. Here, as there, the plaintiffs have sued FDA to make a drug less available for others. *See id.* Here, as there, the members of the plaintiff associations do not assert injuries as users or prescribers of the drugs they want FDA to restrict. *See id.* at 385. Instead, they assert injuries as "unregulated parties who seek to challenge FDA's regulation *of others*." *Id.* And here, as there, the plaintiffs' bid to link their alleged injuries to FDA's actions depends on a long and uncertain causal chain broken up by the choices of independent actors. The heart of the plaintiffs' theory is that FDA's authorization of veterinarians to prescribe and administer certain antibiotics for the prevention of disease in food-producing animals increases the likelihood that veterinarians actually will prescribe and administer these antibiotics to more food-producing animals, increasing the likelihood that food-producing animals develop antibiotic-resistant bacteria, increasing the likelihood these antibiotic-resistant bacteria enter the food and water supply, increasing the likelihood that members of the plaintiff organizations are exposed to these antibiotic-resistant bacteria, thereby causing the plaintiffs' members some injury.

The precise ultimate injuries the plaintiffs' members identify vary. Some allege health injuries, like an increased likelihood of suffering an antibiotic-resistant infection. Others allege harm to recreational and aesthetic interests, like fishing less often to reduce exposure to bacteria-infested water. Still others allege economic injuries, like buying antibiotic-free meat to mitigate the risk of exposure to antibiotic-resistant bacteria or buying separate work clothes so that their care for infected patients does not jeopardize the health of their family members. But all of the injuries the plaintiffs' members identify come at the end of a causal chain at least as lengthy and uncertain as the one the *Alliance for Hippocratic Medicine* Court found too speculative and attenuated to establish standing. So they have not satisfied the causation requirement for standing.

Even if one of these causal links is less speculative than the causal links in *Alliance for Hippocratic Medicine*—the plaintiffs have introduced significant evidence that the use of antibiotics in agriculture is one cause of the development of antibiotic-resistant bacteria, *see* ECF 24-3—the other causal links are as speculative. Tellingly, none of the plaintiffs' members reports that they have ever contracted an antibiotic-resistant infection—let alone one traceable to FDA's actions. (The only member to report an infection—Haller—acknowledges that his infection was not antibiotic-resistant. ECF 24-4, ¶ 10.) And again, the complete causal chain connecting FDA's actions to the plaintiffs' alleged injuries is at least as attenuated as the chain in *Alliance for Hippocratic Medicine*. So the plaintiffs' theory of causation is "too speculative or otherwise too attenuated to establish standing." *See id.* at 393.

The declarant nurses also rely on the resource diversion theory the Court expressly rejected in *Alliance for Hippocratic Medicine*. *See id.* Buchheit, the travelling nurse, states that the prevalence of antibiotic-resistant bacteria has led hospitals where he has worked to adopt "time consuming" isolation protocols that "slow[] down the care [he is] able to provide to patients." ECF

24-1, ¶ 7. "Put simply, the more patients are in isolation, the less time there is for other aspects of patient care." *Id.* His claims about the use of "broad-spectrum antibiotics" have the same form. *See id.* ¶ 8. He insists it would be "best to save drugs like vancomycin for patients with severe medical conditions," but "[m]ore and more" Buchheit is "seeing in [his] practice that vancomycin is prescribed routinely, in part because bacteria are becoming resistant to other, more narrow-spectrum antibiotics." *Id.* And this increased use of vancomycin requires "complicated" dosing and careful monitoring. *Id.* Murphy, another nurse, also points to the increasing use of broad-spectrum antibiotics, the need for time-consuming diagnostic cultures to identify the bacteria afflicting a patient, and the use of isolation procedures. ECF 24-6, ¶¶ 4, 6. She warns that "[w]e are running out of effective antibiotics to treat infections, putting all our lives at risk." *Id.* ¶ 9. The *Alliance for Hippocratic Medicine* plaintiffs told similar stories. They, too, claimed that FDA's decision not to regulate access to a drug as tightly as it should compelled them to "divert[] resources and time from other patients." *All. for Hippocratic Med.*, 602 U.S. at 390. The Court squarely rejected that theory for "a lack of causation." *Id.* This Court must do the same here.

The declarant nurses suggest that they have come to court on behalf of their patients and other people especially susceptible to antibiotic-resistant infections as well. *See, e.g.*, ECF 24-1, ¶¶ 9, 11; ECF 24-6, ¶¶ 5–6, 8. *Alliance for Hippocratic Medicine* rejected that theory, too. *All. for Hippocratic Med.*, 602 U.S. at 393 n.5. Healthcare providers may not "shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries." *Id.*

To be clear, the Court recognizes that the plaintiffs' theory of injury differs significantly from the theory the plaintiffs advanced in *Alliance for Hippocratic Medicine*. The *Alliance for Hippocratic Medicine* Court reasoned that "[b]ecause the plaintiffs do not use mifepristone, they

obviously can suffer no physical injuries from FDA's actions relaxing regulation of mifepristone." *Id.* at 386. Here, that inference is unwarranted. Some of the plaintiffs' members claim that FDA's refusal to restrict access to antibiotics heightens their risks of contracting antibiotic-resistant infections. And they explain how: Antibiotic use may generate antibiotic-resistant bacteria, which in turn may cause antibiotic-resistant infections. So the fact that the plaintiffs do not sue as users of the drugs they want FDA to restrict does not mean they cannot be physically harmed by FDA's permissive regulatory posture. The problem remains causation. These alleged future physical injuries are as causally distant from FDA's denial of the plaintiffs' petition as the alleged injuries in *Alliance for Hippocratic Medicine* were from the regulations challenged there. *See All. for Hippocratic Med.*, 602 U.S. at 390–93. So the plaintiffs' claims meet the same end.

Even setting *Alliance for Hippocratic Medicine* aside, however, the plaintiffs would not have standing. The only other court to consider a standing theory like the plaintiffs' theory rejected it on multiple grounds, causation included. In *Natural Resources Defense Council, Inc. v. U.S. Food and Drug Administration* ("*NRDC*"), NRDC sued FDA for violating the APA by failing to finalize regulations restricting two drugs used in antimicrobial soap, triclosan and triclocarban. 710 F.3d 71, 74–76 (2d Cir. 2013). NRDC claimed that it had standing to challenge FDA's failure to regulate triclosan because the chemical is a potentially dangerous carcinogen and at least one of NRDC's members was frequently exposed to it. *Id.* at 74–75. By contrast, NRDC claimed that it had standing to challenge FDA's failure to regulate triclocarban because the chemical contributes to the development of antibiotic-resistant bacteria—putting its members' health at risk. *Id.* The Second Circuit accepted the first theory but rejected the second. *Id.* Although FDA acknowledged the risk that triclocarban would contribute to the development of antibiotic-resistant bacteria and the court did not doubt that claim, the court found that any resulting injury was insufficiently

particularized to the plaintiffs and "too causally remote" from FDA's failure to regulate triclocarban. *Id.* at 86.

> The claim that the proliferation of triclocarban may lead to the development of antibiotic-resistant bacteria, in contrast, involves unspecified bacteria or microbes that NRDC members may not ever come into contact with. And in order for those bacteria or microbes to harm plaintiffs, there must be an intermediate step in which triclocarban causes those bacteria to become resistant to antibiotics. This claim thus seems less like a present injury and more like a *threatened* injury that is contingent and far-off rather than imminent.

Id. Because NRDC thus failed to establish injury and causation, the Second Circuit held "that NRDC lacks standing as to the regulation of triclocarban." *Id.*

Here, the plaintiffs advance a similar theory of standing with similarly fatal flaws. They claim that the proliferation of antibiotics in the feed of food-producing animals will lead to the development of antibiotic-resistant bacteria. And some of their members claim that these antibiotic-resistant bacteria will then enter society by one path or another and cause them disease. So like the *NRDC* plaintiffs' theory of standing to challenge FDA's regulation of triclocarban, these plaintiffs' theory concerns an injury "too causally remote" from the regulations they challenge to establish standing. *See id. NRDC*—the closest case to this one—counsels that the plaintiffs lack standing.

Under *Alliance for Hippocratic Medicine* and *NRDC*, the plaintiffs have not established that FDA's denial of their petition caused the injuries they allege.[2] Accordingly, they lack standing to bring this case.

B. Counterarguments

Resisting these conclusions, the plaintiffs argue that FDA's denial of their petition caused them the sort of recreational, health, and economic harms that routinely secure standing. But the plaintiffs' authorities do not show they have established causation.

1. Recreational Injuries

First, the plaintiffs argue FDA's denial of their petition caused the recreational injuries Haller asserts in his declaration. For example, Haller reports that he uses nearby streams less often and fishes less frequently because he is "worried about exposing [himself] to drug-resistant bacteria in the water." ECF 24-4, ¶ 9. But the three recreational interest cases the plaintiffs cite do not support their position.

Consider *Friends of the Earth, Inc. v. Gaston Copper Recycling Corporation*, 204 F.3d 149 (4th Cir. 2000) (en banc). Two environmental organizations sued a smelting facility under the

[2] In *Alliance for Hippocratic Medicine*, the Supreme Court indicated that in cases like this one, the causation analysis and the injury analysis concern the same question:

> In cases of alleged future injuries to unregulated parties from government regulation, the causation requirement and the imminence element of the injury in fact requirement can overlap. Both target the same issue: Is it likely that the government's regulation or lack of regulation of someone else will cause a concrete and particularized injury in fact to the unregulated plaintiff?

602 U.S. at 385 n.2; *see also id.* at 385 ("[T]o establish causation, the plaintiff must show a predictable chain of events leading from the government action to the asserted injury—in other words, that the government action has caused or likely will cause injury in fact to the plaintiff."). Accordingly, in holding that the plaintiffs have not established causation, this Court also holds on the same grounds that the plaintiffs have not established an imminent injury.

citizen suit provision of the Clean Water Act for illegally discharging pollutants into a South Carolina waterway. *Id.* at 150–52. The smelter, Gaston Copper, had a permit to discharge a limited amount of contaminated wastewater into nearby waterways; the plaintiffs claimed the smelter was discharging even more. *Id.* at 150, 152. The Fourth Circuit, sitting en banc, held that one of the organizations had standing on behalf of one of its members, Wilson Shealy. *Id.* at 163–64. Shealy owned property four miles downstream from Gaston Copper. *Id.* at 152. That property included a 67-acre lake fed by the allegedly contaminated waterway. *Id.* Shealy and his family liked to fish, swim, and boat in the lake, but they significantly reduced how often they used it from fear of Gaston Copper's pollution. *Id.* at 152–53. To establish that his "fears [were] reasonable" rather than conjectural, Shealy submitted evidence that discharge monitoring reports showed Gaston Copper had violated the terms of its permit over 500 times; that the metals it had discharged into the local waterway were harmful to human health; that Gaston Copper's illegal discharge would travel more than 16 miles from its source—putting his property well within the "discharge zone"; and that Shealy's lake had tested positive for the discharged substances in the past. *Id.* at 157–58. The Fourth Circuit had no trouble concluding that this evidence established both injury and causation. *See id.* at 161–62.

Disanalogies abound. In *Gaston Copper*, the defendant was the polluter—the nearest agent in the causal chain. *Id.* at 150. That mattered. The Fourth Circuit underscored that "[w]here a plaintiff has pointed to a polluting source as the seed of his injury, and the owner of the polluting source has supplied no alternative culprit, the 'fairly traceable' requirement can be said to be fairly met." *Id.* at 162. In this case, the defendant is the federal regulator the plaintiffs think should crack down on the emitter's practices—an agent whose actions are separated from the plaintiffs' alleged injuries by the actions of at least two independent actors, the veterinarians who prescribe the

antibiotics to the animals and the farmers who manage those animals and their waste. In *Gaston Copper*, Shealy submitted evidence that his property was in the "discharge zone" that would be contaminated by the defendant's illegal pollution. *Id.* at 158. In this case, Haller has not even alleged facts indicating that the water he fears to use has or will have any antibiotic-resistant bacteria in it, let alone antibiotic-resistant bacteria caused by the use of antibiotics for disease-prevention in livestock herds. In fact, Haller does not even attest that any of the animals held in the nearby CAFOs are prescribed antibiotics for disease prevention. *See* ECF 24-4. He says only that they "are fed a lot of antibiotics because they tend to get sick." *Id.* ¶ 4. If the animals are fed those antibiotics only when and because they are sick already, then their treatment is not even the subject of the regulation the plaintiffs petitioned FDA to withdraw. In *Gaston Copper*, Shealy submitted evidence that the defendant's conduct had injured him before in the very way he alleged it would injure him again: Testing confirmed his lake had been contaminated in the past by the same metals he was suing the defendant for releasing. *Id.* at 161–62. That substantiated his claim "that his injuries are fairly traceable to" the defendant. *Id.* at 162. Here, Haller does not allege his land or the surrounding waterways have ever been contaminated with antibiotic-resistant bacteria before or even that he or anyone he knows has ever contracted an antibiotic-resistant infection—casting doubt on his claims about causation. *Gaston Copper* cannot sustain the plaintiffs' argument that they have pled causation.

In response, the plaintiffs fixate on the Fourth Circuit's holding that the district court in *Gaston Copper* erred in "requir[ing] that plaintiffs present further evidence concerning one or more of the following: (1) 'the chemical content of the waterways affected by the defendant's facility'; (2) 'any increase in the salinity of the waterways'; and (3) 'other negative change in the ecosystem of the waterway.'" *Id.* at 159 (quotation omitted). As the plaintiffs see it, that means Haller need

not attest that antibiotic-resistant bacteria attributable to the preventative use of antibiotics at the nearby CAFOs are present or likely will be present in the waterways Haller would like to use more often. ECF 24, at 25. But the key phrase in that passage from *Gaston Copper* is "*further* evidence." 204 F.3d at 159 (emphasis added). The Fourth Circuit did not hold that Shealy need not present any evidence linking his fear of using the lake to Gaston Copper's discharges. *See id.* at 159–60. Rather, the Fourth Circuit held that because he had submitted enough evidence to establish that "Gaston Copper's alleged permit violations threaten the waters within the acknowledged range of its discharge, including the lake on Shealy's property," he had established that he had a "reasonable fear and concern of pollution" and need not also supply "specific allegations or evidence about the actual level of pollution in the waterway." *See id.* Haller's declaration does not clear that bar. Even if it did, the presence of antibiotic-resistant bacteria in the water would be farther causally removed from FDA's actions by two independent actors: the CAFOs leaking contaminated waste and the veterinarians prescribing the antibiotics to prevent the animals held there from getting sick. For that reason alone, the causal chain is significantly more attenuated here.

The plaintiffs' citations to *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167 (2000), and *Congaree Riverkeeper, Inc. v. Carolina Water Service, Inc.*, 248 F. Supp. 3d 733 (D.S.C. 2017) are no more availing. *Laidlaw*, like *Gaston Copper*, held that an environmental organization had standing to sue a polluter under the Clean Water Act on behalf of its members, some of whom used the impacted waterway. 528 U.S. at 180–88. The plaintiffs here argue that it is enough that Haller, like one of the members of one of the plaintiff organizations in *Laidlaw*, attests that he avoids using nearby streams "because he [is] concerned that the water contain[s] harmful pollutants." ECF 24, at 25 (quoting *Laidlaw*, 528 U.S. at 183). But the plaintiff in *Laidlaw* had standing to sue *the alleged polluter* because that member was concerned that the

water he wanted to use contained harmful pollutants *the defendant allegedly discharged*. *See Laidlaw*, 528 U.S. at 183. Haller seeks standing to sue *a government regulator* because he is concerned that the water he wants to use contains harmful pollutants *someone else discharged* after *yet another person* did something the regulator permitted (prescribing antibiotics for disease-prevention in food-producing animals) causing *some further development* (the development of antibiotic-resistant bacteria). There is no comparison.

Meanwhile, in *Congaree Riverkeeper*, another environmental organization sued a defendant for illegally discharging wastewater into a river in violation of the Clean Water Act. 248 F. Supp. at 740–45. Several of the plaintiff's members attested that they enjoyed fishing, kayaking, and canoeing in the impacted river, but that they had to avoid doing so near the defendant's waste discharge pipe. *Id.* at 746–47. After all, the defendant had been found to have exceeded the discharge limits in its permit 23 times in the years prior. *Id.* at 745. The court held that these allegations sufficed to establish injury and causation. *Id.* at 746–48. Any analogy to this case fails for much the same reasons the analogy to *Gaston Copper* failed: The *Congaree Riverkeeper* plaintiff sued the polluter, not a causally distant regulator; the *Congaree Riverkeeper* plaintiff alleged in detail that the defendant's illegal conduct directly contaminated an area its members used, impairing their ability to enjoy it safely; and the *Congaree Riverkeeper* plaintiff alleged that the defendant had contaminated the waterway in this way before. None of that is the case here.

In addition, some of the recreational injuries Haller identifies are not traceable to antibiotic-resistant bacteria at all, let alone FDA's denial of the petition. For instance, Haller describes in harrowing detail how local streams and rivers are so contaminated by animal waste that the Iowa Department of Natural Resources often warns against swimming and tubing in them. ECF 24-4, ¶¶ 5–6, 8. But by Haller's own account, what keeps people out of the water is the "high bacteria

count" and the "contaminant levels." *See id.* ¶ 8. He does not even mention whether these bacteria are antibiotic resistant. *See id.*

The authorities the plaintiffs cite do not support their arguments that FDA's denial of their petition caused their members the recreational injuries they allege.

2. Health Injuries

The plaintiffs also contend that they have standing despite *Alliance for Hippocratic Medicine* because FDA's denial of their petition heightens the risk that their members will contract antibiotic-resistant infections and reduces the efficacy of antibiotics against bacteria. *See, e.g.*, ECF 24, at 21–22; ECF 24-1, ¶¶ 5, 10–11; ECF 24-2, ¶ 5; ECF 24-4, ¶ 10; ECF 24-6, ¶¶ 5–9; ECF 24-7, ¶ 3. For support, they rely on the Second Circuit's decision in *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003). However, the Second Circuit has held that *Baur* does not support standing to challenge FDA's failure to restrict a drug that may cause bacteria to develop antibiotic resistance. *See NRDC*, 710 F.3d at 85–86. Rightly so.

Baur began when the plaintiff, Michael Baur, petitioned FDA and the United States Department of Agriculture ("USDA") to ban the use of "downed livestock" as food for human consumption. *Baur*, 352 F.3d at 628. Downed livestock are "animals that collapse for unknown reasons and are too ill to walk or stand prior to slaughter." *Id.* Baur's petition to the agencies explained that "exposure to downed cattle posed a significant health risk" to human beings because the animals were more likely to have neurological diseases that can kill people, like bovine spongiform encephalopathy—"mad cow" disease. *Id.* at 627–28. By permitting the sale of potentially contaminated animals as food, he argued, the government was putting people's lives at risk. *Id.* USDA denied Baur's petition. *Id.* at 629. In response, Baur sued USDA under the APA. *Id.* at 630. The Second Circuit held that "exposure to an enhanced risk of disease transmission may

qualify as injury-in-fact in consumer food and drug safety suits" and found Baur had "alleged a sufficiently credible risk of harm to survive a motion to dismiss" for lack of subject matter jurisdiction. *Id.* at 628. But the court limited its holding to cases "where the plaintiff alleges exposure to potentially harmful products." *Id.* at 634. And the court disavowed any intent to "decide as a matter of law whether enhanced risk generally qualifies as sufficient injury to confer standing." *Id.*

In *NRDC*, the Second Circuit case about two substances in antimicrobial soap, the court held that *Baur* supported the plaintiffs' argument that they had standing to challenge FDA's failure to finalize its regulations of triclosan. *NRDC*, 710 F.3d at 83–84. *Baur*, the *NRDC* Court explained, held that exposure to a potentially harmful substance constituted an injury sufficient for standing in a challenge to a food or drug regulation. *Id.* NRDC alleged that one of its members was routinely exposed to triclosan, a potentially carcinogenic substance. *Id.* at 83. So NRDC pled an injury sufficient for standing. *Id.* at 84. The Second Circuit then held that NRDC had pled causation as well. *Id.* at 84–85. "NRDC's evidence shows that FDA's conduct contributes to [the NRDC member's] triclosan exposure because triclosan would not be available on the market but for FDA's failure to finalize its regulation." *Id.* at 85. "Neither [the member's] failure to purchase triclosan-free soap nor her failure to advocate more forcefully with her employer [to use triclosan-free soap] is sufficient to break the causal chain." *Id.*

However, the Second Circuit held that *Baur* did not support NRDC's argument that it had standing to challenge FDA's failure to finalize the regulation of the other substance, triclocarban. *Id.* at 85–86. For one thing, because "NRDC provided no evidence that its members were directly exposed to triclocarban," its "theory of standing as to triclocarban thus cannot be that, under *Baur*, its members are exposed to a potentially dangerous substance." *Id.* at 85. For another, NRDC did

not allege that triclocarban was a potentially dangerous substance in itself. *See id.* at 85–86. Rather, NRDC alleged that the use of triclocarban in antimicrobial soap increased the likelihood of a distinct danger: the development of antibiotic-resistant bacteria. *Id.* at 85. NRDC's allegation was that "the proliferation of triclocarban, together with other antimicrobial antiseptic chemicals, may lead to the development of antibiotic-resistant bacteria." *Id.* That claim, the Second Circuit held, was "too causally remote to fit comfortably within the *Baur* standard." *Id.* at 86.

Baur cannot help the plaintiffs here establish causation for the same reason *Baur* could not help the plaintiff in *NRDC* establish causation. The antibiotics the plaintiffs petitioned FDA to restrict are not the dangerous substance to which they allege they are exposed—the analog of triclosan. Rather, these antibiotics are a potential cause of antibiotic-resistant bacteria, the substance to which they fear being exposed—the analog of triclocarban. For that reason, the plaintiffs' theory of standing is outside *Baur*'s ambit. Even if the Fourth Circuit had adopted *Baur* or a similar rule—which it has not—it would not support the plaintiffs' claim that FDA's denial of their petition to withdraw approval of the use of certain antibiotics for disease-prevention in food-producing animals caused the health risks they allege. The connection is "too causally remote." *Id.* at 86. Or on the terms of *Alliance for Hippocratic Medicine*, too speculative or attenuated.

The other authorities the plaintiffs cite to support their health-based claims fall short for the same reasons. In each case, the plaintiffs had standing to challenge a regulator's failure to adequately restrict a potentially dangerous substance or product, increasing the risk the plaintiffs would be exposed to that substance and the dangers of contact. *See NRDC v. EPA*, 735 F.3d 873, 878 (9th Cir. 2013); *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 572, 575 (6th Cir. 2005). The plaintiffs here seek to challenge a regulator's failure to adequately restrict a generally safe

substance, certain uses of which by third parties increase the odds that bacteria will develop antibiotic resistance. In other words, the plaintiffs are citing triclosan cases. What they need is a triclocarban case. And the only one they have—*NRDC*—implies that they do not have standing.

The plaintiffs' authorities do not show that the health risks they allege are caused by FDA's denial of their petition.

3. Economic Injuries

Last, the plaintiffs contend the expenses their members have incurred to reduce their risks of antibiotic-resistant infection—injuries without analogs in *Alliance for Hippocratic Medicine* or *NRDC*—secure their standing to sue FDA for denying their petition. They do not.

Sometimes, plaintiffs have "standing to sue on the basis of costs incurred to mitigate or avoid harm." *Hutton v. Nat'l Bd. of Examiners in Optometry, Inc.*, 892 F.3d 613, 622 (4th Cir. 2018). But only "when a substantial risk of harm actually exists." *Id.* "[I]ncurring costs for mitigating measures to safeguard against" some injury does not "constitute an injury-in-fact when that injury is speculative." *Id.* (citing *Beck v. McDonald*, 848 F.3d 262, 276 (4th Cir. 2017)).

This Court has concluded already that pursuant to *Alliance for Hippocratic Medicine*, which transposed the analysis of whether a future injury is imminent or speculative from the injury inquiry to the causation inquiry, *see All. for Hippocratic Med.*, 602 U.S. at 385 & n.2, the future injuries the plaintiffs allege here are speculative. And the Court also has noted that *NRDC*, a pre-*Alliance for Hippocratic Medicine* case, supports the same result. Because the plaintiffs have not established that it is "likely that the government's . . . lack of regulation of someone else will cause a concrete and particularized injury in fact to [their] unregulated" members, they have not established that the costs they have incurred to prevent that potential future injury are an injury fairly traceable to FDA's denial of their petition either. *See id.* at 385 n.2.

The United States Court of Appeals for the District of Columbia Circuit persuasively rejected a theory like the plaintiffs' in *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 918–19 (D.C. Cir. 2015). There, two individuals and an environmental organization sued USDA for adopting regulations the plaintiffs alleged "may result in an increase in foodborne illness from contaminated poultry." *Id.* at 909. The individual plaintiffs identified their primary injury as "an increased risk of foodborne illness from unwholesome, adulterated poultry resulting from the Defendants' regulation." *Id.* at 914. They further alleged that they were injured by the burdens they incurred trying to avoid poultry produced under the new regulatory regime, like the higher price they had to pay to buy poultry from local farmers instead. *Id.* at 918. The D.C. Circuit held that the economic costs the plaintiffs incurred to avoid their primary alleged injury were not caused by the regulations they challenged. *Id.* at 918–19. Because the plaintiffs had not plausibly alleged the regulations substantially increased their risk of contracting a foodborne illness, they could not "establish standing by incurring costs that 'are simply the product of their fear.'" *Id.* at 919. So the court held that the "Plaintiffs' 'self-inflicted injuries are not fairly traceable' to the [regulations], 'and their subjective fear . . . does not give rise to standing.'" *Id.* (quoting *Clapper*, 568 U.S. at 418).

By the logic of *Food & Water Watch*, the plaintiffs in this case cannot trace the expenses their members have incurred trying to avoid antibiotic-resistant infections to FDA's denial of their petition. As the Court explained in the prior section, the plaintiffs have not established that the health risks they allege are caused by the FDA action they claim is illegal. Because they have not established that the threat to their members' health is traceable to the action they challenge, they have not established that the costs their members have incurred to mitigate that threat are traceable to the action they challenge either. *See id.* at 919.

Making matters worse, some of the economic injuries the plaintiffs' members identify are not caused by antibiotic-resistant bacteria at all. Haller, for example, explains that in 1998 he went to great expense to have a water well dug far deeper than he otherwise would have because water closer to the surface is so "contaminated by bacteria from animal waste runoff" that it is unfit for human consumption. ECF 24-4, ¶ 7. And he "worr[ies] that it is only a matter of time before [his current water] source is also contaminated." *Id.* By Haller's own account, he had to go to this expense—and may have to again—because surface water is so thoroughly contaminated by animal waste that human beings cannot safely use it. *See id.* The presence or absence of antibiotic-resistant bacteria is beside the point.

The plaintiffs have not shown that FDA's denial of their petition caused their economic injuries.

* * *

In sum, the plaintiffs have not shown that FDA's denial of their petition caused or likely will cause the alleged injuries to their members. For that reason, they have not established that they have standing.

IV. Conclusion

The defendants' motion to dismiss for lack of subject matter jurisdiction is granted. A separate order follows.

Date: July 15, 2024

Deborah L. Boardman
United States District Judge