UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION

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

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS

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INTRODUCTION

Plaintiffs and Defendants agree that antimicrobial resistance is a serious public health problem.[1] To address it, FDA has sought the voluntary cooperation of drug manufacturers, livestock and poultry producers, and veterinarians in the judicious preventive use of veterinary antibiotics. Plaintiffs disagree with that approach and seek to force FDA to adopt a different one: initiate proceedings to withdraw approval for those preventive uses altogether. But Plaintiffs' policy disagreement and speculation about possible future harm are insufficient to demonstrate standing. Moreover, FDA's choice to encourage voluntary cooperation rather than initiate withdrawal proceedings is committed to agency discretion by law. Thus, as Defendants explained in their opening brief, this Court lacks subject matter jurisdiction. Plaintiffs' Opposition (and newly filed declarations) fail to show otherwise.

First, Plaintiffs still have not shown their standing to sue. Food Animal Concerns Trust ("FACT")[2] argues that FDA's approach has harmed its mission to reduce the incidence of antibiotic resistance and caused it to spend money in response. But it has

[1] In particular, FDA broadly shares the concern of Plaintiffs' declarant Dr. Jay Graham that antimicrobials should be used "prudent[ly]" and with the goal of "avoiding . . . excessive and inappropriate use." ECF No. 24-3 at ¶ 38; *see* FDA, *Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* at 17-18 (Apr. 3, 2012) ("The scientific community generally agrees that antimicrobial drug use is a key driver for the emergence of antimicrobial-resistant bacteria. It is imperative that strategies for controlling antimicrobial resistance include a consideration of how antimicrobial drugs are being used and measures to address those uses that are injudicious in nature."), https://perma.cc/24AY-VJLQ.

[2] Other capitalized terms have the same meanings defined in Defendants' opening brief.

not shown any interference with its ability to function as an organization and cannot establish an injury-in-fact simply by alleging that it has spent resources advocating against FDA's actions. The Membership Organizations have also failed to demonstrate standing, because none of their members has identified an imminent threat of harm that is fairly traceable to FDA's actions. Neither speculation about possible exposure to an unknown drug-resistant bacteria nor any self-inflicted costs incurred based on that speculation suffice to satisfy Article III.

Second, even if Plaintiffs had standing, this Court would still lack subject matter jurisdiction because this suit challenges FDA's discretionary decision not to initiate adversarial proceedings, under FDA's rules for formal evidentiary hearings, to withdraw certain new animal drug approvals. Since the FDCA provides no judicially manageable standards for review of that decision, the decision cannot be the subject of an APA claim.

Plaintiffs cannot escape this result merely because FDA's underlying discretionary choice—not to commence proceedings to withdraw approved uses for specific classes of antibiotics—came in response to a citizen petition. Contrary to Plaintiffs' argument, the APA itself does not provide judicially manageable standards to apply in cases arising out of citizen petitions. Rather, such standards must be found in the statute that empowers the agency to take the action the petition requests. Whether a court has jurisdiction to review the denial of a citizen petition depends on whether that underlying statute provides the court with law to apply, and this Court lacks jurisdiction because the FDCA provides none here.

ARGUMENT

I. Plaintiffs Have Not Established Article III Standing.

Defendants' opening brief explained at length why the Complaint fails to demonstrate Plaintiffs' standing to sue. *See* ECF No. 16-1 at 13-23 ("Mot."). Plaintiffs' Opposition, in turn, offers only a few cursory paragraphs in support of their original pleading. *See* ECF No. 24 at 13-14 ("Opp."). Instead of seriously defending their initial allegations, Plaintiffs submit ten declarations' worth of new ones. *See generally* ECF Nos. 24-1 to 24-10. These new allegations likewise fail to meet Plaintiffs' burden to show Article III standing as to either FACT or the Membership Organizations.

A. FACT's Voluntary Response to Policies That Do Not Directly Affect Its Operations Is Not a Cognizable Injury-In-Fact.

Defendants explained that FACT does not have standing because it alleged a setback to its mission rather than an injury to its ability to operate as an organization. *See* Mot. 15-17. Plaintiffs respond by citing several nonprecedential cases that found standing where an organization voluntarily diverted its resources in response to conditions that were contrary to its *overall goals* but did not affect the functioning of *the organization itself*. Opp. 25-26; *see People for the Ethical Treatment of Animals, Inc. v. Tri-State Zoological Park of W. Md.*, 843 F. App'x 493, 496 (4th Cir. 2021) (per curiam) (finding animal welfare organization's mission impeded by alleged "increase[] [in] animals subject to abuse"); *People for the Ethical Treatment of Animals, Inc. v. Tabak*, 2023 WL 2599573, at *3 (D. Md. Mar. 21, 2023) (same); *Defenders of Wildlife v. Boyles*, 608 F. Supp. 3d 336 (D.S.C. 2022) (finding conservation organization's mission impeded by alleged harm to endangered species).

These nonprecedential decisions cannot be reconciled with the Fourth Circuit's binding decision in *Lane v. Holder*, 703 F.3d 668 (4th Cir. 2012), which allows standing based on a specific, narrow type of organizational injury: direct impediments to an organization's "*efforts to carry out* its mission." *Id.* at 674 (emphasis added) (citing *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). Later in *CASA de Maryland, Inc. v. Trump*, 971 F.3d 220 (4th Cir. 2020), *vacated on grant of reh'g en banc*, 981 F.3d 311 (4th Cir. 2020),[3] the Fourth Circuit elaborated on why organizational plaintiffs must show "operational harm—that is, [harm to] the ability of an organization to function." *Id.* at 240. Holding otherwise would permit "virtually limitless" organizational standing by allowing an organization to sue "any time [it] (1) alleges that a governmental action undermines its policy, and (2) spends some money in response to that action." *Id.* at 239-240. That would "essentially waive" the requirement of a concrete injury-in-fact "for any entity with a policy position and a dollar." *Id.* at 240.

Comparing this case with *Lane* is instructive. In *Lane*, a firearms advocacy group sued to enjoin laws restricting the interstate transfer of handguns. 703 F.3d at 670. Like the organization in *Lane*, FACT has "decide[d] to spend its money" on education and advocacy that responds to the government policy with which it disagrees. *See id.* at 675; Opp. 27 (alleging commitment of "considerable resources . . . to ameliorating the effects of FDA's decision"). And like the organization in *Lane*, FACT claims that because its

[3] Plaintiffs do not dispute that the vacated *CASA* panel opinion may still be considered as persuasive authority. *See* Opp. 26-27; *see also* Mot. 15 n.14 (explaining why *CASA* may be cited for its persuasive value).

"resources are taxed" by those activities, there are "reduce[d] . . . funds available for [its] other purposes." *See Lane*, 703 F.3d at 675; Opp. 25 (arguing that FACT's "expend[iture] of limited resources" on advocacy relating to veterinary antibiotics "thwarts [its] ability to allocate funds and staff time to other programs").

Lane held that those facts are inadequate to show organizational standing. The Fourth Circuit unequivocally rejected the same theory that FACT advances here—that "any sincere" organization can "bootstrap standing by expending its resources" in response to government action that clashes with its policy preferences but does not otherwise "impede its efforts" to pursue them. *Lane*, 703 F.3d at 674-75.[4]

One of Plaintiffs' own authorities makes the distinction clear. The court in *National Federation of the Blind v. U.S. Department of Education* ("*NFB*"), 407 F. Supp. 3d 524, 532–33 (D. Md. 2019), held that an organization that pursued administrative civil rights complaints had standing to challenge the adoption of new procedures that made such complaints more burdensome to prosecute and less likely to prevail. *NFB* made clear that standing existed because, among other things, the plaintiff organization was "*not* merely in the business of advising the public about potential changes in the law."

[4] D.C. Circuit precedent is in accord. *See Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919-21 (D.C. Cir. 2015); *Ams. for Safe Access v. DEA*, 706 F.3d 438, 458 (D.C. Cir. 2013); *see also Int'l Acad. of Oral Med. & Toxicology v. FDA*, 195 F. Supp. 3d 243, 257 (D.D.C. 2016). Plaintiffs have failed to distinguish FACT's circumstances from those found insufficient to support standing in those cases. Like FACT, the plaintiffs in both *Food & Water Watch* and *International Academy of Oral Medicine* "detail[ed] the considerable resources" that they spent responding to the government policies they challenged. *See* Opp. 26; *Food & Water Watch*, 808 F.3d at 920; *Int'l Acad. of Oral Med.*, 195 F. Supp. 3d at 257-59. Those organizations, like FACT, lacked standing not because they failed to describe the money they spent, but because the fact of spending it was not enough to satisfy Article III.

Id. (emphasis added). Rather, it was a participant in the administrative process at issue; making that process more burdensome directly affected its operations. *Id.* ("[A]dditional resources had to be expended . . . [on] adjustments to their own complaint-filing processes . . . ."). FACT, by contrast, does not assert any direct impact on its operations, and its "mere expense . . . does not constitute an injury in fact." *Lane*, 703 F.3d at 675 (quotations omitted).

Plaintiffs ignore the relevant portion of *Lane*'s analysis. They rely on the Fourth Circuit's discussion of *individual* standing, *see* Opp. 25 (quoting *Lane*, 703 F.3d at 672-74), but neglect its analysis of an *organization's* standing based on policies that impede the organization's "efforts to carry out its mission," *Lane*, 703 F.3d at 675. Moreover, it is not enough to state that any hypothetical increase in the risk of antibiotic resistance "impedes [FACT]'s ability to operate" because its mission is "protecting human and animal health." *See* Opp. 27. The question under *Lane* is whether FACT has been harmed in its "ability . . . to *function*" as an organization, not whether Defendants' actions make it less likely in the abstract that those functions will ultimately "effectuate [their] *objectives*." *CASA*, 971 F.3d at 239-240 (emphasis added); *see also Lane*, 703 F.3d at 674-75. FACT lacks standing under *Lane* because it fails to show any direct impairment to its own organizational functions.

B. Alliance of Nurses, NRDC, and Public Citizen Have Not Met the Requirements of Associational Standing.

With respect to the Membership Organizations, their newly submitted declarations do not show a concrete harm to their members' alleged recreational, health, or economic interests, much less harm fairly traceable to FDA's actions.

Recreational Harms. Plaintiffs' sole declarant as to recreational injury is NRDC member Dennis Haller. *See* ECF No. 24-4 at ¶ 1 ("Haller Decl."). Haller states that he lives near large animal feeding operations that treat their animals with antibiotics, *id.* ¶ 4, that the rivers and streams near his home are contaminated with waste from those animals, *id.* ¶¶ 5-6, 8, and that because he is concerned that this waste contains antibiotic-resistant bacteria, he chooses to fish in and otherwise enjoy those waterways less frequently than he otherwise would, *id.* ¶ 9.

Haller's assertions of self-inflicted injury, in response to a highly speculative fear of future exposure to unknown antibiotic-resistant bacteria, do not show injury-in-fact. The Second Circuit has rejected standing based on a similar epidemiological theory—that FDA's regulation of the antibiotic triclocarban injured plaintiffs by contributing to the development of bacterial resistance writ large. *See Nat. Res. Def. Council v. FDA* (*NRDC I*), 710 F.3d 71, 86 (2d Cir. 2013). Applying that court's analysis here, the claim that FDA's approach to regulating an antimicrobial drug "may lead to the development of antibiotic-resistant bacteria . . . involves unspecified bacteria that [Haller] may not ever come into contact with," and that may never take the "intermediate step" of becoming resistant to antibiotics. *Id.* That is not a "present injury" that supports

standing, but a "*threatened injury* that is contingent and far-off rather than imminent." *Id.*; *see also Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416-17 (2013). Self-inflicted injury "based on fears of hypothetical future harm that is not certainly impending" is not an Article III injury-in-fact. *Clapper*, 568 U.S. at 416. Likewise, because Haller's injury is self-inflicted based on his own speculation about possible future harm, and because any such harm would result from environmental degradation caused by third-party agricultural operators, Haller's injuries are not fairly traceable to the challenged agency action. *Id.* at 417.

Plaintiffs' discussion of *NRDC I*, Opp. 19, misses the mark. Plaintiffs rely on the Second Circuit's separate discussion of *triclosan* (not triclocarban), a different antimicrobial at issue in the same case. *Id.* (discussing *NRDC I*, 710 F.3d at 82). *NRDC I* held that the plaintiffs had standing to challenge FDA's triclosan regulation because they had shown that exposure to the drug itself was dangerous to humans and an NRDC member was exposed to the drug at her workplace. *NRDC I*, 710 F.3d at 81-84. That is not Plaintiffs' theory of standing here. In this case, Plaintiffs make the same standing argument (based on an increased risk of drug resistance rather than any inherently dangerous property of the antimicrobial drug itself) as did the *NRDC I* plaintiffs with respect to *triclocarban*. *See id.* at 85-86. The Second Circuit's analysis *rejecting* that argument is what is relevant here.

Haller's declaration also does not bring this case in line with the decisions cited in Plaintiffs' brief. *See* Opp. 16 (citing *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167 (2000); *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*,

204 F.3d 149 (4th Cir. 2000) (en banc); and *Congaree Riverkeeper, Inc. v. Carolina Water Serv., Inc.*, 248 F. Supp. 3d 733 (D.S.C. 2017)). In each of those cases arising under the Clean Water Act ("CWA"), the plaintiff showed—rather than merely speculated—that specific pollutants were *actually present* in the recreational environment.

In *Gaston Copper*, for example, the Fourth Circuit found standing to sue the operator of an industrial facility for violations of the CWA. The facility in question had "unlawful[ly] release[d] . . . [toxic] cadmium, copper, iron, lead, and zinc" into a stream. 204 F.3d at 157. That stream fed a lake on property owned by one of the plaintiff's members, which was well within "the acknowledged outer perimeter of the discharge zone," and in which "the types of chemicals released into the water . . . had been previously found." *Id.* at 158. Based on that "ample evidence," the Fourth Circuit concluded that the member's "fears [were] reasonable and not based on mere conjecture." *Id.* at 157.[5] In *Laidlaw*, there was no question that the relevant facility had unlawfully discharged "extremely toxic" mercury on hundreds of occasions over almost a decade. 528 U.S. at 176. And in *Congaree Riverkeeper*, standing was based on plaintiffs' members' desire to use a river in the immediate vicinity of a pipe from which

[5] Plaintiffs assert that *Gaston Copper* excuses them from showing that resistant bacteria are actually present. Opp. 16. That is incorrect. Where the *Gaston Copper* plaintiffs had presented the evidence of actual contamination discussed above, the Fourth Circuit held that they were not required to submit "*further* evidence" concerning specific measures of environmental degradation. *Gaston Copper*, 204 F.3d at 159 (emphasis added). Nothing in that opinion holds (or even suggests) that Plaintiffs may support standing with claims of purely hypothetical bacteria.

the defendant's facility was discharging municipal wastewater. 248 F. Supp. 3d at 746-47.

Here, by contrast, Haller only speculates that antibiotic-resistant bacteria are present, or will imminently be present, in the streams near his home. *See* Haller Decl. ¶ 8 ("I *worry that* these bacteria are resistant to antibiotics . . . .") (emphasis added). Notably, he offers no evidence that *anyone* in the vicinity of his home has *ever* contracted an antibiotic-resistant infection attributable to recreation on those waterways. *See Animal Welfare Inst. v. Vilsack*, 2022 WL 16553395, at *8 (W.D.N.Y. Oct. 31, 2022) (fact that plaintiffs had not *previously* encountered alleged pathogens weighed against standing based on risk of *future* exposure); *cf. Gaston Copper*, 204 F.3d at 158 ("[E]vidence of past pollution is . . . directly relevant to the question of whether Gaston Copper subsequently affected or could affect [the waters at issue]."). Simply put, Haller cannot establish standing based on a self-inflicted injury: the choice to fish less frequently based on a fear of hypothetical future harm from drug-resistant bacteria in the streams near his home, where such bacteria may not exist, either now or in the imminent future, and where Haller may never be exposed to them. *See Clapper*, 568 U.S. at 416; *Food & Water Watch*, 808 F.3d at 918-19.

Health Risks. Several declarants claim that FDA's decision not to initiate the withdrawal proceedings that Plaintiffs seek puts them at increased risk of antibiotic-resistant infection from food products or healthcare facilities. *See* ECF No. 24-1 at ¶¶ 5, 10-12 ("Buchheit Decl."); ECF No. 24-2 at ¶ 5 ("Donne Decl."); Haller Decl. ¶¶ 10-11; ECF No. 24-6 at ¶¶ 7-8 ("Murphy Decl."); ECF No. 24-7 at ¶¶ 3, 5 ("Nelson Decl.").

That fear is based on the same chain of speculation about *potential* exposure to *hypothetical* drug-resistant bacteria that the Second Circuit rejected in *NRDC I*. *See NRDC I*, 710 F.3d at 86. Before the future harm that Plaintiffs fear could manifest, (1) veterinarians would have to independently decide to injudiciously prescribe preventive antibiotics; (2) those injudicious uses would have to create populations of resistant bacteria; (3) bacteria with those resistant traits would have to enter the food supply (or, even more speculatively, those traits would have to be transferred to bacteria outside of the meat and poultry production process altogether); and (4) Plaintiffs' members would have to be actually exposed to those resistant bacteria. *See* Mot. 21-22. The Second Circuit has held that this exact theory is too speculative to satisfy Article III because plaintiffs' "members may not ever come into contact with" the hypothetical bacteria at issue. *NRDC I*, 710 F.3d at 86; *see also Food & Water Watch*, 808 F.3d at 915-18. This Court should do the same.

Plaintiffs try to reframe their speculative injury as a "credible threat" or "serious risk" of medical harm rather than the "harm itself." Opp. 16-17 (quotations omitted); *see also id.* at 16-20. But their supporting cases are inapposite. In those cases, exposure to a harmful chemical or other agent was close to a functional certainty (or simply undisputed), and the courts applied a "credible risk" standard to the *consequences* of that exposure.[6] *See Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 878-79 (9th Cir. 2013)

[6] The one exception is *Baur v. Veneman*, 352 F.3d 625 (2d Cir. 2003), in which a split panel of the Second Circuit found standing despite substantial uncertainty as to whether the plaintiff in particular would ever be exposed to meat from cattle that

("[T]he ubiquity of textiles and the lack of public information concerning the chemical treatments applied to them . . . make it nearly impossible for NRDC members to eliminate AGS-20-treated textiles from their children's lives . . . ."); *NRDC I*, 710 F.3d at 81 ("Owens's declaration establishes that she washes her hands with triclosan-containing soap more than fifty times in a typical workday"); *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 569 (6th Cir. 2005) ("Sutton was implanted with the [allegedly defective medical] device during treatment for his heart condition."); *Nat. Res. Def. Council v. U.S. Consumer Prod. Safety Comm'n*, 2017 WL 3738464, at *4 (S.D.N.Y. Aug. 18, 2017) ("[A] government study sampled 1,125 children's toys and child care articles, and found that [64.4%] contained one of three types of phthalate . . . ."); *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153-54 & n.3 (2010) (no dispute that pollinating animals would carry genetically modified alfalfa pollen throughout growing region, without regard for borders of farms that intended to grow only unmodified crop); *Clean Wisc. v. EPA*, 964 F.3d 1145, 1157-58 (D.C. Cir. 2020) (no dispute that plaintiffs' members would be "expose[d] . . . to higher ozone levels" in the air they breathed); *Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751, 756 (S.D. W. Va. 2009) (no dispute that users of allegedly contaminated drinking water would be exposed to any contamination

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suffered from mad cow disease. This Court should not follow *Baur*, which would "allow[] the requirement of an imminent threat of injury to be satisfied by the merely conceivable," *Baur*, 352 F.3d at 647-48 (Pooler, J., dissenting), and which the Second Circuit subsequently refused to apply to the standing theory advanced by Plaintiffs here, *see NRDC I*, 710 F.3d at 85 (distinguishing *Baur* because it involved direct "expos[ure] to a potentially dangerous substance" and was inapplicable to claims that a product's use "may lead to the development of antibiotic-resistant bacteria").

present therein). Here though, Plaintiffs have not demonstrated certainly impending exposure to resistant bacteria attributable to preventive use of veterinary antibiotics.

Economic Injuries. Plaintiffs' members' self-inflicted economic costs, *see* Buchheit Decl. ¶ 10; Donne Decl. ¶ 5; Haller Decl. ¶ 11; Murphy Decl. ¶ 8; Nelson Decl. ¶ 5, cannot support standing for the same reasons. As discussed above, the underlying risks those self-inflicted harms seek to mitigate are not "certainly impending" injuries-in-fact, and the harms themselves are not fairly traceable to the challenged FDA action. *See supra* at 7-12; *Clapper*, 568 U.S. at 416; *Food & Water Watch*, 808 F.3d at 918-19.

II. FDA's Discretionary Decision Not to Initiate Drug Withdrawal Proceedings Is Not Reviewable Under the Administrative Procedure Act.

As Defendants showed in their opening brief, FDA has unreviewable discretion regarding whether to initiate withdrawal proceedings for a New Animal Drug Application. Mot. 26-32. Applying the Fourth Circuit's test for whether an action is "committed to agency discretion by law," *see* 5 U.S.C. § 701(a)(2), both (1) the "language and . . . structure" of the FDCA and (2) the "nature of the administrative action" at issue demonstrate that FDA's decision not to initiate withdrawal proceedings is unreviewable. *Speed Mining, Inc. v. Fed. Mine Safety & Health Rev. Comm'n*, 528 F.3d 310, 317 (4th Cir. 2008). Plaintiffs largely seek to avoid that binding test.

Instead of analyzing whether the underlying provisions of the *FDCA* offer any "law to apply" to the decision not to initiate withdrawal proceedings, *id.* (quotations omitted), Plaintiffs assert that the *APA* provides standards to review *every* denial of a citizen petition. *See* Opp. 28-29 (arguing that "the APA provides 'judicially manageable

standards'" for reviewing "a final decision on a citizen petition").[7] But that position would vitiate the "committed to agency discretion" exception because the APA will by definition *always* apply in an APA challenge. *See generally Nielsen v. Preap*, 139 S. Ct. 954, 969 (2019) (explaining that statutes should not be "given an interpretation that causes" a provision "to have no consequence").

When asking whether there is "law to apply" to review an agency decision, courts look to the underlying statute that empowered the agency to act, not the APA. *See Heckler v. Chaney*, 470 U.S. 821 (1985), 834-35 ("[W]e therefore turn to the FDCA to determine whether in this case Congress has provided us with 'law to apply.'"); *Speed Mining*, 528 F.3d at 317 (finding no law to apply where "the relevant provisions of the Mine Act provide no meaningful standard for review"). And specifically for the denial of a citizen petition, whether there is "law to apply" depends on the *underlying agency action that the petition requests*. *Heckler* itself demonstrates the point.

In *Heckler*, death-row inmates filed a citizen petition asking FDA to take enforcement action against lethal-injection drugs, which they argued ran afoul of the FDCA's prohibitions against misbranded and unapproved new drugs. 470 U.S. at 823-24. FDA denied the petition and refused to take the requested actions. *See id.* Such "refusals to institute investigative or enforcement proceedings," the Supreme Court held, were encompassed by the "exception to reviewability provided by [5 U.S.C.] § 701(a)(2)." *Id.* at 838. Specifically as to the denial of the inmates' petition, the Court

[7] Plaintiffs also emphasize that the denial of the Citizen Petition was "*final* agency action," *see* Opp. 27 (emphasis added), a point Defendants have never contested.

relied on how the FDCA's "enforcement provisions . . . commit complete discretion to [FDA] to decide how and when they should be exercised." *Id.* at 835; *see also Ctr. for Auto Safety v. Dole*, 846 F.2d 1532, 1535 (D.C. Cir. 1988) (holding unreviewable denial of a citizen petition by the National Highway Traffic Safety Administration).

Plaintiffs rely on the very approach rejected in *Heckler*, under which the denial of a citizen petition would be subject to APA review regardless of whether the underlying statute provided any substantive law to apply. *See* Opp. 28 (arguing that the APA always permits review of whether "FDA failed to address [a citizen petition's] argument and evidence"). Before *Heckler* reached the Supreme Court, the D.C. Circuit had vacated FDA's decision for failure to provide "an acceptable explanation" of its refusal to institute proceedings. *Chaney v. Heckler*, 718 F.2d 1174, 1191 (D.C. Cir. 1983); *see also Heckler*, 470 U.S. at 827 (recounting the D.C. Circuit's holding that the petition's "evidence . . . was entitled to more searching consideration"). The Supreme Court reversed the D.C. Circuit's decision that more explanation was required in response to the citizen petition's contents. It held instead that because the underlying enforcement provisions of the FDCA did not provide any law to apply, FDA's decision not to invoke them (even if made in response to a citizen petition) was simply "not subject to judicial review" under the APA. *Heckler*, 470 U.S. at 837-38. If Plaintiffs' theory were correct, then any party could circumvent that crucial constraint on APA review simply by filing a citizen petition first. And *Heckler* forecloses such end runs around 5 U.S.C. § 701(a)(2).

Additionally, to the limited extent Plaintiffs *do* engage with Defendants' analysis of whether the FDCA provides a basis for review of FDA's decision not to initiate

withdrawal hearings, their arguments on both (1) the language and structure of the statute and (2) the nature of the administrative action are unavailing. *See Speed Mining*, 528 F.3d at 317.

Statutory Language and Structure. At the threshold, Plaintiffs other than Alliance of Nurses are barred by the Second Circuit's decision in *Natural Resources Defense Council v. FDA* (*NRDC II*), 760 F.3d 151 (2d Cir. 2014), from re-litigating the first prong of the *Speed Mining* inquiry: whether the language and structure of the FDCA constrains FDA's discretion whether to initiate new animal drug withdrawal proceedings. Mot. 28-29. Plaintiffs attempt to distinguish *NRDC II* by pointing to a handful of issues in that case that are not presented here. *See* Opp. 31. But Plaintiffs ignore the Second Circuit's holding on an issue that *is* presented here: whether the text and structure of the FDCA show that "the decision whether to institute or terminate a hearing process that may lead to a finding requiring withdrawal of approval for an animal drug is a discretionary determination left to the prudent choice of the FDA." *NRDC II*, 760 F.3d at 175. *NRDC II* concluded that it is, based on the same statutory analysis called for under *Speed Mining*.

As the Second Circuit explained, nothing in the text of the FDCA "require[s] that the agency investigate the need for withdrawing approval of [new] animal drugs under any particular circumstance," "limits the considerations that FDA may take into account in deciding whether to initiate the hearing process," or "mandate[s] that . . . FDA take any action until and unless [a hearing results in] certain findings." *NRDC II*, 760 F.3d at 174 (analyzing 21 U.S.C. § 360b(e)(1)). In other words, the FDCA provides no judicially

manageable standard against which the agency's exercise of discretion could possibly be reviewed. Thus, Plaintiffs (other than Alliance of Nurses) are precluded from disputing the Second Circuit's resolution of that issue.

Beyond the application of issue preclusion, the Second Circuit's analysis of the FDCA—which Plaintiffs make no effort to dispute—is persuasive in its own right. *See* Mot. 28, 30 (discussing *NRDC II*, 760 F.3d at 170-72, 174-75). Plaintiffs accuse Defendants of taking *NRDC II*'s "analysis out of context," Opp. 30-31, but it is they who misunderstand its significance here.

Defendants do not argue that *NRDC II* ultimately held that the decision to initiate withdrawal proceedings falls within the APA's exception for actions committed to agency discretion by law. Rather, the point is that the Second Circuit's analysis, and the specific issue it decided, are dispositive of the first prong of the Fourth Circuit's test for unreviewability—whether the "particular language and overall structure" of the underlying statute provide a court with law to apply. *See Speed Mining*, 528 F.3d at 317; Mot. 30. The FDCA simply provides no law to apply here.

Nature of the Administrative Action. FDA's challenged decision not to initiate an adversarial adjudicatory process to withdraw approval of a New Animal Drug Application[8] is analogous to other "refusals to institute investigative or enforcement

[8] Withdrawal proceedings under Section 512(e) of the FDCA, 21 U.S.C. § 360b(e), are adversarial: the statute provides for notice of opportunity for a hearing on a proposal to withdraw a new animal drug approval, 21 C.F.R. § 12.21, and those proceedings are conducted under FDA's regulations for "Formal Evidentiary Public Hearing[s]," *see generally* 21 C.F.R. Part 12.

proceedings" that courts have consistently deemed unreviewable under the APA. *See Heckler*, 470 U.S. at 838; *Speed Mining*, 528 F.3d at 318 ("[E]nforcement discretion is an area in which the courts have traditionally been most reluctant to interfere"); *NRDC II*, 760 F.3d at 171 ("Ordinarily, administrative discretion is at its zenith when an agency decides whether to initiate enforcement proceedings."); *see also* Mot. 30-31. Defendants' characterization of the Second Circuit's analysis as relating to FDA's "enforcement" discretion, *see* Mot. 28, is not a misreading of that case—much less a "surprising" one as Plaintiffs suggest, *see* Opp. 30. That court's analysis rested in part on what it described as a "helpful analogy," *NRDC II*, 760 F.3d at 175 n.28, to "the traditional model of enforcement action," *id.* at 170-71.

Plaintiffs do not appear to dispute that FDA's underlying decision not to initiate withdrawal proceedings was akin to an "enforcement choice[]." *See* Opp. 29-30. Instead, they argue (wrongly, as discussed *supra* 13-15) that the Court should apply a different standard in its reviewability analysis because FDA made that decision in response to a citizen petition. *See id.* ("Plaintiffs challenge FDA's final decision denying a citizen petition . . . , which is not an enforcement decision."). But regardless of the precipitating event, the decision not to initiate withdrawal proceedings is substantively a "refusal[] to institute investigative or enforcement proceedings." *See Heckler*, 470 U.S. at 837. Indeed, analogous agency nonenforcement decisions have been held unreviewable. *See, e.g.*, *Trout Unltd. v. Pirzadeh*, 1 F.4th 738, 752-53 (9th Cir. 2021) (decision not to initiate fact-gathering proceedings that could lead to decision to restrict pollutant discharge into certain waters); *Drake v. FAA*, 291 F.3d 59, 70-71 (D.C. Cir. 2002) (decision not to hold

hearing on citizen complaint that airline violated federal regulations); *Center for Auto Safety*, 846 F.2d at 1535 (decision not to initiate investigative hearing into automobile safety under statute that would have required agency to order a recall if hearing found vehicle unsafe); *Env't. Prot. Info. Ctr. v. U.S. Fish & Wildlife Serv.*, 2005 WL 3021939, at *9-10 (N.D. Cal. Nov. 10, 2005) (decision not to make finding as to compliance with terms of federal permit, even where the underlying statute would have required agency to revoke permit upon a finding of non-compliance).

Like those decisions, FDA's decision not to initiate withdrawal proceedings "involves a complicated balancing of a number of factors which are peculiarly within [FDA's] expertise." *See Heckler*, 470 U.S. at 831. These include scientific determinations regarding the impact of the preventive antibiotic uses on human safety, "whether the agency has enough resources" to hold adversarial withdrawal proceedings and "is likely to succeed" in them, "whether agency resources are best spent" on such proceedings instead of on other agency priorities, and whether holding such proceedings would "best fit[] the agency's overall policies." *See id.*[9] "Deciding whether and when to deploy [limited agency resources] in an arduous, contested adversarial

[9] These concerns are not hypothetical. Withdrawal proceedings can be lengthy and resource-intensive. For example, in October 2000 FDA proposed to withdraw approval of a *single antibiotic drug* for use in chickens and turkeys. The proceedings that followed lasted the better part of five years (including eight days of oral hearings), and the agency's final decision was 121 pages long. *See Withdrawal of Approval of the New Animal Drug Application for Enrofloxacin in Poultry*, FDA Docket No. 2000N-1571 (July 27, 2005), https://perma.cc/LB6P-VRG4 (Part 1), https://perma.cc/7WAV-W4ZR (Part 2). And Plaintiffs demand a far larger withdrawal proceeding, covering *seven classes of antibiotics*, Compl. ¶ 43, each containing multiple drugs.

process is an important and difficult responsibility" as to which "[i]t is rare that agencies lack discretion." *NRDC II*, 760 F.3d at 170-71.

The language and structure of the FDCA and the nature of the administrative action at issue here demonstrate that FDA's decision not to initiate the withdrawal process sought by the Citizen Petition was committed to the agency's discretion by law. Since the APA bars judicial review of such decisions, 5 U.S.C. § 701(a)(2), Plaintiffs' suit should be dismissed for lack of subject matter jurisdiction, *see Angelex Ltd. v. United States*, 723 F.3d 500, 505-06 (4th Cir. 2013).

CONCLUSION

The Court should dismiss the Complaint for lack of subject matter jurisdiction.

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Respectfully submitted,

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