

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION**

ALLIANCE OF NURSES FOR HEALTHY
ENVIRONMENTS, et al.,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

No. 8:23-cv-176-DLB

**PLAINTIFFS' SUPPLEMENTAL BRIEF
IN OPPOSITION TO MOTION TO DISMISS**

Plaintiffs submit this supplemental brief in accordance with the Court's order, ECF No. 28, to explain how the Supreme Court's recent decision in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. ___, 2024 WL 2964140 (2024), affects the pending motion to dismiss. The Supreme Court's analysis supports Plaintiffs' standing in this case.

DISCUSSION

In *Alliance for Hippocratic Medicine*, the Supreme Court found that the plaintiff organizations lacked standing to challenge the U.S. Food and Drug Administration's (FDA) regulation of the drug mifepristone. *Id.* at *12, *14. The members of the organizations were physicians who did not use mifepristone and who did not allege risks to their own health from FDA's actions. *Id.* at *9. The members instead asserted a conscience injury, based on an allegedly increased chance that they would be forced to treat patients experiencing medical complications from using mifepristone. *Id.* They also alleged monetary and related injuries, based on claims that they would be diverted from seeing other patients and would face an

increased risk of medical malpractice lawsuits and, therefore, an increase in insurance costs. *Id.* at *11.

The Court found no facts supporting a chain of causation between the alleged injuries and FDA’s decisions about how to regulate the drug. First, the Court concluded that FDA’s actions did not cause a conscience injury because “federal conscience laws definitively protect doctors from being required to . . . provide [medical] treatment that violates” their moral beliefs. *Id.* at *10. Second, the Court found that the plaintiffs had presented no evidence that FDA’s actions increased the number of pregnant patients seeking treatment so as to divert the doctors’ time from other patients, and no evidence that doctors had been sued because they treated patients with mifepristone complications. *Id.* at *11. For these reasons, the Court concluded that the physicians lacked standing.

Unlike in *Alliance for Hippocratic Medicine*, Plaintiffs in this case have adequately alleged standing. Plaintiffs Alliance of Nurses for Healthy Environments (“Alliance of Nurses”), Natural Resources Defense Council (NRDC), and Public Citizen allege that their members suffer recreational, health, and economic harms that are caused by FDA’s denial of the citizen petition concerning use of antibiotics in animal feed and that would be redressed by FDA’s granting of the petition.¹ Their standing is supported by declarations from individual members and an environmental microbiologist. *See* ECF Nos. 24-1 to 24-4, 24-6 to 24-7. We address each element of standing in turn.

¹ Plaintiff Food Animal Concerns Trust (FACT) has filed an unopposed motion to voluntarily dismiss FACT’s claims in this matter. ECF No. 31.

I. Plaintiffs' Members Suffer Cognizable Harms

Plaintiffs' members face three types of cognizable injuries. First, as the declarations show, FDA's refusal to halt the misuse and overuse of antibiotics in factory farms harms the recreational and aesthetic interests of Plaintiffs' members. *See* Compl. ¶ 54, ECF No. 1; Decl. of Dennis Haller ¶¶ 6, 8-9, ECF No. 24-4 ("Haller Decl."). As *Alliance for Hippocratic Medicine* confirms, this injury provides standing. There, the Court reiterated that government action may cause harm to an unregulated plaintiff sufficient to create standing when that action impairs the plaintiff's interest in using a park, national forest, or body of water. 2024 WL 2964140, at *8; *see* Pls.' Opp'n to Defs.' Mot. Dismiss 15-16, ECF No. 24 ("Pls. Opp'n") (citing *Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 158-60 (4th Cir. 2000) (en banc)).

Plaintiffs' members suffer such injury here. Members who live in areas with industrial livestock operations avoid fishing, swimming, and other activities because they have well-founded apprehensions of exposure to drug-resistant bacteria from animal waste that contaminates the water and air. *See* Compl. ¶¶ 36, 54 (listing vectors of exposure). For instance, Mr. Haller—an NRDC member who lives near swine facilities—states that he would go fishing more often, and worry less about exposure to harmful pathogens, if FDA withdrew its approval of disease-prevention uses of antibiotics in animal feed. Haller Decl. ¶¶ 9, 13. The impairment of an individual's enjoyment of natural resources is a well-recognized injury for purposes of establishing standing. *See* Pls. Opp'n 12.

Second, Plaintiffs' members assert a credible risk of health harm: contracting an antibiotic-resistant infection as a direct result of the challenged action. Because the members in *Alliance for Hippocratic Medicine* did not use mifepristone, they "obviously can suffer no physical injuries from FDA's actions." 2024 WL 2964140, at *9. By contrast, Plaintiffs'

members are directly exposed to dangerous pathogens in their workplace. *See* Decl. of David Buchheit ¶¶ 5, 10-11, ECF No. 24-1 (“Buchheit Decl.”) (triage nurse who worries about contracting a drug-resistant infection from patient contact). Some members have chronic health conditions that require frequent hospital visits, which increases their vulnerability to hard-to-treat bacterial infections. *See* Decl. of Scott L. Nelson ¶ 3, ECF No. 24-7 (“Nelson Decl.”); *see also* Haller Decl. ¶ 10. Others face heightened risk in their everyday activities, *see* Decl. of Dr. Kathryn Murphy ¶ 7, ECF No. 24-6 (“Murphy Decl.”) (exposure from physical therapy and grocery shopping), and through eating meat products, Decl. of Stephanie Donne ¶ 5, ECF No. 24-2 (“Donne Decl.”); Nelson Decl. ¶ 5. Still others are exposed to antibiotic-resistant bacteria through environmental pathways. *See* Haller Decl. ¶¶ 5-6 (describing manure sprayed as fertilizer and waste runoff contaminating groundwater and nearby streams). Plaintiffs cannot avoid this health risk. *Cf. Coal. for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275, 1280 (D.C. Cir. 2012) (holding that the plaintiffs lacked standing where they could not show a risk of injury from a preservative in vaccines because of their “avowed intention to refuse” the vaccines), *cited in Alliance for Hippocratic Medicine*, 2024 WL 2964140, at *12.

Third, to the extent that Plaintiffs’ members try to limit their exposure to drug-resistant pathogens, they incur a cost in doing so. That economic injury is cognizable. *See* Pls. Opp’n 21 (collecting cases). Unlike in *Alliance for Hippocratic Medicine*, where the member declarants evidenced no monetary harms, in this case, Plaintiffs’ members have paid to dig a deeper (and thus more expensive) well to reach uncontaminated drinking water, Haller Decl. ¶ 7, purchased shoes worn only at work to avoid bringing pathogens home, Buchheit Decl. ¶ 10, and spent extra money on antibiotic-free meat, Donne Decl. ¶ 5; Nelson Decl. ¶ 5.

For these reasons, Plaintiffs’ members’ harms are legally cognizable.

II. FDA's Denial of the Citizen Petition Causes Plaintiffs' Members' Injuries

The “chain of causation” between FDA’s decision to deny the citizen petition and the members’ injuries is not “speculative” or “attenuated.” *Alliance for Hippocratic Medicine*, 2024 WL 2964140, at *7. FDA’s denial allows the continued use of vast quantities of medically important antibiotics in factory farms, which directly increases the quantity of antibiotic-resistant bacteria in the environment and in food and contributes significantly to increased prevalence of antibiotic-resistant infections in humans. *See* Compl. ¶¶ 46, 52; Decl. of Dr. Jay Graham ¶¶ 19-24, 31-37, ECF No. 24-3 (“Graham Decl.”) (detailing how antibiotic use in livestock leads to antibiotic resistance in humans, using tetracyclines as an example). This causal chain is backed by empirical data and microbiology principles, none of which FDA rebuts. *See, e.g.*, Graham Decl. ¶¶ 23-24, 36-37 (reviewing studies showing that antibiotic use in livestock and poultry increases the spread of resistant bacteria in humans, and that reducing antibiotic use has led to significant declines in resistant bacteria); *cf. Alliance for Hippocratic Medicine*, 2024 WL 2964140, at *11 (noting that plaintiffs “have not offered evidence tending to suggest that FDA’s deregulatory actions . . . caused an increase in the number of pregnant women seeking treatment from the plaintiff doctors”).

III. The Injuries Are Redressable

Finally, the requested relief would redress the injuries described by the member declarants. If FDA were to withdraw approval of the antibiotic uses at issue, manufacturers of medically important antibiotics would not be permitted to market the drugs to industrial livestock facilities for disease-prevention purposes. The resulting reduction in the routine use of antibiotics in livestock would directly benefit Plaintiffs by eliminating a major driver of antibiotic resistance that threatens Plaintiffs’ members’ health and hampers their recreational and fiscal interests. *See*

Compl. ¶¶ 3, 34-37; *e.g.*, Graham Decl. ¶ 23 (providing example of decreased antibiotic use in livestock resulting in steep decline in drug-resistant bacteria in meat products and humans); Buchheit Decl. ¶ 13; Haller Decl. ¶ 13; Murphy Decl. ¶ 10.

CONCLUSION

For the foregoing reasons and those set forth in Plaintiffs' Opposition to Defendants' Motion to Dismiss, Alliance of Nurses, NRDC, and Public Citizen have standing to challenge FDA's denial of the citizen petition.

Respectfully submitted,

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