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' SUPPLEMENTAL BRIEF REGARDING
FDA v. ALLIANCE FOR HIPPOCRATIC MEDICINE

OF COUNSEL:

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

MARK RAZA
Chief Counsel
Food and Drug Administration

WENDY S. VICENTE
Deputy Chief Counsel, Litigation

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

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

LISA K. HSIAO
Senior Deputy Director

HILARY K. PERKINS
Assistant Director

GABRIEL I. SCHONFELD
ISAAC C. BELFER
Trial Attorneys
Consumer Protection Branch
Civil Division
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 353-1531 (Schonfeld)
(202) 305-7134 (Belfer)

(202) 514-8742 (fax)
Gabriel.I.Schonfeld@usdoj.gov
Isaac.C.Belfer@usdoj.gov

INTRODUCTION

The Supreme Court's decision in *FDA v. Alliance for Hippocratic Medicine*, No. 23-235, 2024 WL 2964140 (U.S. June 13, 2024), confirms that Plaintiffs lack standing.

First, *Alliance* confirms that FACT lacks organizational standing to sue on its own behalf.[1] The Supreme Court held that such an organization must show direct interference with its business activities to establish standing, but FACT has not done so. Instead, like the plaintiffs in *Alliance*, FACT alleges only that it has responded to FDA's challenged action by expending resources on education and advocacy. As the Supreme Court clearly explained, an organization cannot manufacture standing simply by spending money in response to a policy it dislikes.

Second, *Alliance* confirms that the Membership Organizations lack associational standing to sue on behalf of their members. Because those members are not directly regulated by FDA, Plaintiffs have resorted to complicated, speculative, and highly attenuated causation theories. *Alliance* holds that such theories are not enough to establish that FDA's actions caused Article III injury—especially where the Membership Organizations provide no evidence that the harms they fear have actually materialized.

In sum, *Alliance* reinforces what Defendants have already shown: that Plaintiffs lack Article III standing and that this Court should grant Defendants' motion to dismiss for lack of subject-matter jurisdiction.

[1] All capitalized terms and other abbreviations have the same meaning as in Defendants' prior briefing in support of their motion to dismiss.

ARGUMENT

In *Alliance*, doctors and associations of doctors challenged FDA's decisions to modify certain conditions of use for mifepristone, a drug product approved (in a regimen with a second drug) for medical termination of early pregnancy. *Alliance*, 2024 WL 2964140, at *4. The Court held that the plaintiffs lacked organizational standing because "expending money to gather information and advocate against" FDA's actions was not a cognizable injury in fact, *id.* at *13-14, and that they lacked associational standing because the "causal link" between FDA's actions and their members' alleged injuries was "too speculative or . . . attenuated," *id.* at *11-12. Plaintiffs here lack standing for the same reasons.

I. *Alliance* Confirms that FACT Lacks Organizational Standing.

FACT alleges that FDA's refusal to withdraw approval of certain antibiotics for disease prevention in food animals has caused it to spend resources working against that practice by "raising awareness," "monitoring government . . . activity," and "pressuring companies" to adopt more restrictive limits than FDA has imposed. Compl. ¶ 59. *Alliance* confirms what Defendants previously demonstrated: that an organization must show a concrete injury to itself (such as interference with its "core business activities"), not just a setback to its "abstract social interests." *Alliance*, 2024 WL 2964140, at *13 (quotations omitted).

FACT has not made the requisite showing because FDA's decision not to adopt FACT's preferred policy "has no impact whatsoever on [FACT's] *ability* to gather information, collect and present data, communicate its belief[s] . . . or otherwise

convince pertinent actors [that its views should be adopted]." ECF No. 16-1 at 16 ("Mot.") (quoting *Int'l Acad. of Oral Med. & Toxicology v. FDA*, 195 F. Supp. 3d 243, 258 (D.D.C. 2016)). FACT likewise "cannot manufacture its own standing" simply "by expending money to gather information and advocate against [FDA's] action." *Alliance*, 2024 WL 2964140, at *13. FACT's allegations to that effect are indistinguishable from those rejected in *Alliance* and should be rejected here for the same reason—finding standing on that basis would allow organizations to "challenge almost every federal policy that they dislike, provided they spend a single dollar opposing those policies." *Id.* at *13.

II. *Alliance* Confirms that the Membership Organizations Lack Associational Standing.

The Membership Organizations assert associational standing to sue on behalf of their members, which requires, among other things, that at least one identified member would have standing in his or her own right. Mot. 17 (citing *Lane*, 703 F.3d at 674 n.6). The Membership Organizations contend that their members have suffered or will suffer increased health risk from antibiotic-resistant disease, and economic and recreational harms based on steps taken to limit possible exposure to antibiotic-resistant bacteria, but they have failed to link these alleged injuries to identified members. Mot. 18–20.

Even absent that defect, Plaintiffs' reliance on a speculative causal chain between the challenged action and the members' alleged risk of exposure to antibiotic-resistant bacteria is the very type of causal connection *Alliance* rejected as insufficient. Like the plaintiffs in *Alliance*, the Membership Organizations' members "are unregulated parties

who seek to challenge FDA's regulation *of others*." *Alliance*, 2024 WL 2964140, at *9. And like the *Alliance* plaintiffs, "FDA has not required [Plaintiffs' members] to do anything or to refrain from doing anything," or caused them direct monetary, property, or physical injuries. *Id.* As in *Alliance*, Plaintiffs here assert a "complicated causation theor[y]" that purports to fill that gap. *Id.* The Court should reject it as equally, if not more, speculative and attenuated as the ones held insufficient in *Alliance*.

Plaintiffs rely on the following speculative causal chain: (1) veterinarians making independent decisions regarding the preventive use of antibiotics; (2) those independent treatment decisions creating populations of resistant bacteria; (3) bacteria with those resistant traits entering the food supply (or, even more speculatively, transferring resistance to bacteria outside of meat and poultry production); and (4) Plaintiffs' members being actually exposed to those resistant bacteria. ECF No. 25 at 121 ("Reply"). Each link in this causal chain is speculative, and the causal chain is *at least* as attenuated as that rejected in *Alliance*, in which the plaintiffs alleged that changed conditions for the use of mifepristone would lead to their being required against their conscience to provide abortion-related treatment to patients who had taken the drug, which would then also lead to economic and other injuries. *Alliance*, 2024 WL 2964140, at *11. And because the fears of Plaintiffs' members are speculative, they cannot claim standing based on those members' self-inflicted injuries in response to that speculation. Mot. 22–23 (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 415–18 (2013)); Reply 7–13.

The speculative nature of Plaintiffs' causal theory is also—as in *Alliance*—confirmed by the lack of evidence that their feared injuries have ever materialized. *See Alliance*, 2024 WL 2964140, at *10-11 (noting that plaintiffs had not identified any instance where a doctor was actually required to provide treatment that violated their conscience, to divert time and resources from other patients, or to pay higher insurance costs attributable to mifepristone). Despite the longstanding use of antibiotics for disease prevention by American farmers over many decades, *see* Compl. ¶ 29, Plaintiffs do not show that *any* of their members have *ever* contracted a resistant infection of the kind they allegedly fear. Mot. 22; Reply 10. Thus, like the plaintiff medical associations in *Alliance*, the Membership Organizations here have failed to establish associational standing.[2] Causation here is as speculative and attenuated as it was in *Alliance*, so the Membership Organizations have likewise failed to establish standing.

As the Supreme Court cautioned, courts should not venture down the "uncharted path" of accepting such speculative and attenuated standing theories, which "would seemingly not end until virtually every citizen had standing to challenge virtually every government action that they do not like—an approach to standing that

[2] To the extent the Membership Organizations seek to sue on behalf of their medical provider members' *patients*, *see* Compl. ¶ 55, they lack standing to do so. In addition to the reasons Defendants previously identified, Mot. 21 n.15, Plaintiffs have failed to show that the Membership Organizations themselves "have suffered an injury in fact, thus giving them a sufficiently concrete interest in the outcome of the issue in dispute." *Alliance*, 2024 WL 2964140, at *12 n.5 (quotations omitted). "The third-party standing doctrine does not allow doctors to shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries." *Id.*

[the Supreme] Court has consistently rejected as flatly inconsistent with Article III." *Alliance*, 2024 WL 2964140, at *12.

CONCLUSION

Alliance confirms that this Court should dismiss the Complaint for lack of subject-matter jurisdiction.

June 27, 2024

Respectfully submitted,

/s/ Gabriel I. Schonfeld

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