

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,
et al.,

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., *et al.*,

Defendants.

Case No. 1:25-cv-11916-BEM

**Reply in Support of Defendants' Motion to Dismiss the Third Amended Complaint for
Lack of Subject-Matter Jurisdiction and Failure to State a Claim for Relief**

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INTRODUCTION

Defendants’ opening brief showed that any challenge to the Secretarial Directive is moot, Plaintiffs lack standing, and Count II fails to state a claim. Tacitly conceding the inadequacy of the Third Amended Complaint, Plaintiffs supplement their opposition brief with 39 declarations, but to no avail. The declarations—some of which are months out of date—confirm what was clear from the complaint: although Plaintiffs disagree with the challenged actions, they do not face any concrete, actual or imminent injury that is traceable to the challenged actions and redressable by the requested relief. Because federal courts are not “a vehicle for the vindication of the value interests of concerned bystanders,” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024) (quotation omitted), this case should be dismissed.

ARGUMENT

I. Any Challenge to the May 2025 Secretarial Directive Is Moot

Defendants explained that any challenge to the Secretarial Directive is moot because the “October 6 immunization schedules reflect the September ACIP recommendations—not the earlier Secretarial Directive.” ECF No. 145 (“Defs.’ Mem.”) 8–9.¹ Plaintiffs erroneously claim the September ACIP recommendations impacted only the adult schedule but not the pediatric schedule. ECF No. 146 (“Pls.’ Opp.”) 10. Actually, “ACIP’s recommendation applies to all individuals six months and older.” HHS, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making*, <https://perma.cc/BP2T-97ZS> (September 19, 2025) (“ACIP Statement”); see Defs.’ Mem. 5. Adopting those recommendations, CDC “updated” both the “adult and child immunization schedules” on October 6. CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for*

¹ Defendants also explained why, for the same reasons, Plaintiffs lack standing to challenge the Directive. Defs.’ Mem. 9 n.6.

Chickenpox in Toddlers, <https://perma.cc/SD3P-G2V7> (Oct. 6, 2025) (“CDC Announcement”); *see* Defs.’ Mem. 5. ACIP’s recommendations were wholly independent of the Directive; indeed, the Directive does not mention ACIP. Nor do the ACIP Statement or CDC Announcement mention the Directive. Because the Directive has no effect on CDC’s current COVID-19 vaccine recommendations, Plaintiffs “lack a legally cognizable interest” in challenging this obsolete policy. *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotation omitted).

The “voluntary cessation” exception to mootness, Pls.’ Opp. 10, is inapposite. It “does not apply if the change in conduct is *unrelated* to the litigation.” *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 10 (1st Cir. 2021) (cleaned up). That’s the case here. CDC updated the immunization schedules because ACIP met in September and issued new recommendations for all individuals ages 6 months and older, which CDC’s Acting Director adopted. Plaintiffs do not—and cannot—suggest all this occurred just “to avoid a court judgment.” *Id.* Rather, events simply “transpired to render a court opinion” about the Directive “merely advisory” and thus impermissible under Article III. *ACLU of Mass. v. U.S. Conf. of Cath. Bishops*, 705 F.3d 44, 52–53 (1st Cir. 2013).

Finally, Plaintiffs argue ACIP’s September recommendations, as adopted by CDC, did not “eradicat[e]” the Directive’s effects. Pls.’ Opp. 11. That misses the point. “The significance of” ACIP’s and CDC’s actions “does not lie in whether they ‘cured’ any earlier-occurring” problem with the Directive. *Seafreeze Shoreside, Inc. v. U.S. Dep’t of the Int.*, 123 F.4th 1, 20 (1st Cir. 2024). “Rather, these later agency actions, taken as part of an ongoing and legally authorized” process to update immunization recommendations, “preclude[] any basis for finding that” any alleged infirmity in the Directive “ha[s] any ongoing effect.” *Id.* Because the Directive cannot cause current or future harm to Plaintiffs, judicial relief from the Directive could not remedy any harm to Plaintiffs, and therefore the challenge is moot. *See Already*, 568 U.S. at 91.

II. Plaintiffs Still Fail to Establish Standing

A. The Individual Plaintiffs Do Not Have Standing

Reiterating Jane Does’ theories of harm, Pls.’ Opp. 17, Plaintiffs do not respond to Defendants’ dispositive point that *past* harms do not show the “sufficient likelihood of *future* injury” necessary for “prospective relief.” *All. for Hippocratic Med.*, 602 U.S. at 381 (emphasis added); *see* Defs.’ Mem. 10-12. Plaintiffs also ignore how the individual plaintiffs’ alleged harms *predate* October 2025 and thus are neither “traceable to the current immunization schedules” nor redressable. Defs.’ Mem. 11 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016)). Because Plaintiffs “did not address” these arguments, they “waived” any “objections to the[m].” *Liberty Mut. Ins. Co. v. Aftermath Servs. LLC*, No. 22-CV-11052-ADB, 2023 WL 5435878, at *4 (D. Mass. Aug. 23, 2023); *see Mullane v. U.S. Dep’t of Just.*, 113 F.4th 123, 137 (1st Cir. 2024).

Jane Doe 1 claims she is “likely to become pregnant in the future” and that “[t]he prospect of needing to navigate the hurdle of” getting vaccinated during “a future pregnancy” contributes to “fatigue, headaches, and sleep loss.” ECF No. 146-2, ¶ 21. “Such ‘some day’ intentions” about a future pregnancy—“without any description of concrete plans, or indeed even any specification of *when* the some day will be—do not support a finding of the [required] ‘actual or imminent’ injury.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992). Nor can Jane Doe 1 “manufacture standing merely by inflicting harm on [herself] based on [her] fears of hypothetical future harm.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416 (2013).² Likewise, any “anxiety, depression, and . . . sleep disturbances” Jane Doe 2 still feels from her experiences in June and July 2025, ECF No. 146-3, ¶ 26, are not “fairly traceable to” the challenged actions,

² It is also baseless speculation that Jane Does 1 and 2 will need to spend time overcoming “obstacles” to their children getting vaccinated “when [they] become[] eligible in five months.” ECF No. 146-2, ¶ 19; ECF No. 146-3, ¶ 32.

Clapper, 568 U.S. at 416,³ or redressable by the requested relief, Defs.’ Mem. 11.

Plaintiffs invoke *Tignor v. Dollar Energy Fund, Inc.*, 745 F. Supp. 3d 189 (W.D. Pa. 2024), Pls.’ Opp. 17, which is readily distinguishable. *Tignor* applied Third Circuit precedent holding, “[i]n the data breach context, where the asserted theory of injury is a substantial risk of identity theft or fraud, a plaintiff suing for damages can satisfy concreteness as long as he alleges that the exposure to that substantial risk caused additional” harms such as “emotional distress.” 745 F. Supp. 3d at 199 (quoting *Clemens v. ExecuPharm Inc.*, 48 F.4th 146, 155–56 (3d Cir. 2022)). Here, Third Circuit precedent does not govern, there was no “data breach,” and the Jane Does do not allege a “substantial risk of identity theft or fraud” or request “damages.” *Id.*

B. The Plaintiff Organizations Cannot Manufacture Standing

Defendants showed the Plaintiff Organizations do not have standing in their own right. Defs.’ Mem. 12–13. Plaintiffs cite *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), Pls.’ Opp. 12–13, but that case was far different. The *Havens* defendants’ racial steering practices “perceptibly impaired” the plaintiff organization’s “ability to provide counseling and referral services” for certain homeseekers. 455 U.S. at 379. This showed a “concrete and demonstrable injury to the organization’s activities—with the consequent drain on the organization’s resources—[which] constitutes far more than simply a setback to the organization’s abstract social interests.” *Id.* “*Havens* was an unusual case” that should not be extended “beyond its context” and does not allow organizations to challenge any policy “they dislike” by “spend[ing] a single dollar opposing” it. *All. for Hippocratic Med.*, 602 U.S. at 395–96.

Here, the Plaintiff Organizations do not allege the challenged actions have “directly

³ Establishing traceability along these lines is especially difficult given Jane Doe 2’s admitted “underlying anxiety disorder and prenatal depression,” as well as the “sleep disturbances” that naturally accompany a new baby. ECF No. 146-3, ¶ 26.

affected and interfered with [their] core business activities.” *Id.* Take AAP, whose regular activities include publishing “immunization recommendations,” “clinical practice guidelines,” and “policies on a broad range of topics” impacting children’s health. ECF No. 146-5, ¶¶ 8, 12; *see* ECF No. 146-38, ¶ 6. It is proceeding full steam ahead, publishing immunization guidance, “[d]eveloping a new policy statement” about COVID-19 vaccines, and holding “meetings to align advocacy, clinical, and communications efforts.” ECF No. 146-15, ¶ 4; *see* ECF No. 139 (“TAC”) ¶ 86; ECF No. 146-5, ¶ 16. So too for the other Plaintiff Organizations.⁴

The Plaintiff Organizations argue that the challenged actions “interfere with th[eir] mission” to “enhance the quality and effectiveness of health care services in this country and to assist and support their members’ delivery of health care services consistent with the applicable standard of care.” Pls.’ Opp. 12–13. That kind of mission-impairment argument—asserting harm to an organization’s general policy goals rather than its specific operations—is exactly what “does not work to demonstrate standing.” *All. for Hippocratic Med.*, 602 U.S. at 394. Moreover, the alleged harm to “members’ ability to provide the optimal standard of care” or “members’ ability to protect their communities,” Pls.’ Opp. 13, does not describe an injury to the *Plaintiff Organizations themselves* (and is meritless in any event, *see infra* pp.6–9).

Finally, the Plaintiff Organizations cannot show standing by claiming they “would not be undertaking these” activities regarding COVID-19 vaccines “but for the Secretary’s actions challenged here.” Pls.’ Opp. 13. Their voluntary responses to the challenged actions are a continuation of their “ongoing” education and advocacy activities discussed above. *Friends of*

⁴ *See* ECF No. 146-17, ¶ 5 (ACP); ECF No. 146-19, ¶¶ 9, 11–13, 15, 27–30 (APHA); ECF No. 146-24, ¶¶ 12, 14–15, 24 (IDSA); ECF No. 146-30, ¶¶ 6, 23–24 (MCAAP); ECF No. 146-32, ¶¶ 1, 4, 7, 17, 21–23 (MPHA); ECF No. 146-34 ¶¶ 1, 4–6, 10, 17–18, 22–23 (SMFM); ECF No. 146-37, ¶¶ 6–11 (ACP).

the Earth v. Sanderson Farms, Inc., 992 F.3d 939, 942 (9th Cir. 2021) (citing cases). And it is beyond cavil that an organization “cannot manufacture its own standing” merely “by generating educational materials” and “expending money to gather information and advocate against the defendant’s action.” *All. for Hippocratic Med.*, 602 U.S. at 394; *Equal Means Equal v. Ferriero*, 3 F.4th 24, 29–30 (1st Cir. 2021) (quotation omitted).

C. The Plaintiff Organizations’ Members Lack Standing

As for associational standing, Plaintiffs assert three theories, but Defendants already debunked each of them. Defs.’ Mem. 13–18. **First**, Plaintiffs allege “the doctor-declarants have suffered financial injury” by “engaging in [shared clinical decision-making] conversations without compensation.” Pls.’ Opp. 14. But their own evidence is inconsistent on this point. *See, e.g.*, ECF No. 146-31, ¶¶ 15–16 (admitting providers are sometimes reimbursed for vaccine counseling). In any event, Defendants explained that any financial harm is not fairly traceable to the challenged CDC immunization recommendations or ACIP membership. Defs.’ Mem. 15. Third-party patients choose whether to discuss the vaccine with their healthcare provider; many decline to do so. ECF No. 146-12, ¶¶ 11–12. Moreover, Plaintiffs concede that healthcare providers are reimbursed for counseling patients about the vaccine “if the vaccine is actually administered to the patient” but not if the patient declines the vaccine. ECF No. 146-11, ¶¶ 13, 18; *see* ECF No. 146-18, ¶¶ 25, 36. Thus, any financial injury rests on “speculation” about how “independent” patients will exercise their “unfettered choices” whether to discuss the vaccine and get vaccinated. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted).

Plaintiffs also complain that some “counseling” time is “unbillable” under the “Current Procedural Terminology (‘CPT’) codes.” ECF No. 146-5, ¶ 27. Critically, Plaintiffs do not contend that Defendants are responsible for those CPT codes or determining what is “unbillable time.” *Id.* For good reason: billing and reimbursement rates are determined by insurers (or other

payors).⁵ ECF No. 146-33, ¶ 9. Therefore, any grievance by Plaintiffs’ members about unbillable time is traceable to “reimbursement decisions” by insurers, Defs.’ Mem. 15, who are paradigmatic independent actors, *All. for Hippocratic Med.*, 602 U.S. at 383.⁶ And if a healthcare provider chooses to perform work without attempting to get compensated, ECF No. 146-29, ¶¶ 16–17, that harm “is ‘self-inflicted’ and not fairly traceable to the challenged actions” either, Defs.’ Mem. 15 (quoting *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam)).

Plaintiffs further speculate that some members will “absorb[] the full cost of purchasing vaccine doses that go unused.” Pls.’ Opp. 14; *see* TAC ¶ 104. Yet their own declarant concedes “[i]t is unclear whether we will be able to return any or all of the unused” vaccine doses. ECF No. 146-11, ¶¶ 15–16. That will not suffice to show imminent injury. *See Clapper*, 568 U.S. at 414 n.5. Moreover, the “chain of causation” for this theory of injury “is simply too attenuated,” involving the decisions of numerous “independent actors,” from providers (how many doses to order) to patients (whether to get vaccinated) and vaccine manufacturers (what return policy to adopt). *All. for Hippocratic Med.*, 602 U.S. at 383, 391 (quotation omitted).⁷

Second, the Plaintiff Organizations assert interference with members’ “ability to do their jobs.” Pls.’ Opp. 14. Yet the challenged actions, on their face, do not erect any barriers to counseling patients according to members’ professional judgment, nor do they recommend

⁵ Defendants noted that insurers generally must cover COVID-19 vaccines administered through shared clinical decision-making. Defs.’ Mem. 15–16. Dr. Goldman claims some insurers do not, ECF No. 146-17, ¶ 11, but that only proves how insurers’ independent actions defeat traceability.

⁶ Similarly, if Dr. O’Shea is not compensated for “time and resources [on] developing a plan” for shared clinical decision-making about the COVID-19 vaccine, ECF No. 146-6, ¶ 8, and Dr. Andrae for the “time after office hours to complete documentation or other tasks not completed during or between wellness visits,” ECF No. 146-14, ¶ 18, that reflects insurers’ reimbursement policies or the providers’ own decisions not to seek payment from their patients.

⁷ If providers choose to “stock the vaccine” despite knowing they may “eat[] some of the cost,” ECF No. 146-11, ¶ 19, any harm is “self-inflicted.” *Pennsylvania*, 426 U.S. at 664.

against the vaccine or “discourag[e]” vaccination.⁸ ECF No. 146-11, ¶¶ 9–10; *see* TAC ¶¶ 90, 104; Defs.’ Mem. 13–14.⁹ Indeed, Plaintiffs’ members continue to recommend the vaccine to their patients and counsel them that “based on the evidence, [it] is safe and beneficial.” *E.g.*, TAC ¶ 88; ECF No. 146-8, ¶¶ 7–8; ECF No. 146-18, ¶¶ 24, 27. For example, Dr. Shah tells patients that “your neonatologist recommends these vaccines,” using “parent-centered communication strategies developed by” AAP. ECF No. 146-9, ¶ 13. Moreover, the assertion that Plaintiffs’ members lack the information necessary to provide shared clinical decision-making, *e.g.*, ECF No. 146-5, ¶ 18; ECF No. 146-27, ¶ 16, is belied by the resources Plaintiffs themselves provide, such as immunization schedules and guidance documents, TAC ¶ 86; ECF No. 146-5, ¶ 16; ECF No. 146-15, ¶ 4; ECF No. 146-24, ¶¶ 14–15; ECF No. 146-37, ¶¶ 9–11—and publicly available data, *see, e.g.*, ECF No. 146-5, ¶ 19; ECF No. 146-24, ¶¶ 26, 29.¹⁰

Likewise, any abstract harm to members’ relationships with patients, *e.g.*, Pls.’ Opp. 8, is not a concrete injury-in-fact, *see All. for Hippocratic Med.*, 602 U.S. at 381. And if patients choose to “drop[] out of [a doctor’s] practice,” Pls.’ Opp. 6, that is traceable to the patient’s “independent action,” *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976).¹¹

⁸ Plaintiffs concede it is “mistaken” to believe that CDC’s shared clinical decision-making recommendation means “the vaccine is no longer important.” ECF No. 146-33, ¶ 8.

⁹ Nor do the challenged actions limit providers to spending 20 minutes with patients, *e.g.*, ECF No. 146-26, ¶¶ 11, 14–15, a constraint that may reflect employers’ or insurers’ policies.

¹⁰ For example, Dr. Pring explained that “[t]he AAP guidance works well for children under 2” and that “because [she] also care[s] for older patients, [she] rel[ies] on the Massachusetts [Department of Public Health] recommendations that advise vaccination for everyone over 6 months of age.” ECF No. 146-30, ¶ 22. Dr. LaRocque recommends the vaccine to patients “based on [her] professional training and experience, and on the published peer-reviewed research in infectious diseases.” ECF No. 146-25, ¶ 9.

¹¹ Similarly, if a patient chooses not to get vaccinated and then develops COVID-19, *e.g.*, ECF No. 146-35, ¶ 2, that is traceable to the patient’s independent choice. It also does not injure the healthcare provider. *See All. for Hippocratic Med.*, 602 U.S. at 393 n.5; Defs.’ Mem. 18.

Third, the Plaintiff Organizations argue their members are harmed by “the Secretary’s threat of legal liability for administering vaccines contrary to CDC guidance.” Pls.’ Opp. 15. But as Defendants explained, administering the vaccine to a patient is not “contrary to” CDC’s recommendation that patients and providers discuss the vaccine.¹² Defs.’ Mem. 16–17. The National Childhood Vaccine Injury Act of 1986 does not create liability for providers who administer COVID-19 vaccines, and the notion that Plaintiffs’ members would face malpractice liability for administering COVID-19 vaccines, ECF No. 146-33, ¶ 14—which they assert *is* the standard of care—is entirely speculative, *see* Defs.’ Mem. 16–17.

Neither *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), nor *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139 (2010), aids Plaintiffs. *See* Pls.’ Opp. 16–17. Unlike *Diamond Alternative Energy*, where causation was so “straightforward” that “no party dispute[d]” it, 606 U.S. at 113, Plaintiffs’ theories of injury to their members require speculation about the decisions of countless independent third parties, including patients (who base healthcare decisions on many sources of information and considerations) and insurers (who set billing policies). In *Monsanto*, the farmer-respondents directly incurred costs “to conduct testing” and “take certain measures” against crop contamination in response to an agency’s deregulatory order. 561 U.S. at 154. Again, Plaintiffs’ theory of financial injury is far more attenuated, turning on the decisions of independent third parties.

III. Count II Fails to State a Claim for Relief

Plaintiffs’ allegation in Count II that “[t]he Secretary’s reconstitution of the ACIP” is “not in accordance with law,” TAC ¶ 120, fails to state a plausible claim for relief, Defs.’ Mem.

¹² Contrary to Plaintiffs’ purported uncertainty, ECF No. 146-5, ¶ 21, CDC has explained that shared clinical decision-making need not be conducted by a physician, but may be conducted by a variety of providers, including “pharmacists.” CDC, *ACIP Shared Clinical Decision-Making Recommendations*, <https://perma.cc/QE5B-D8WU> (Jan. 7, 2025); Defs.’ Mem. 6.

18–20. Plaintiffs avoid Defendants’ argument that the challenged actions did not violate 42 U.S.C. § 245(a) because they had nothing to do with “award[ing] competitive grants or contracts” for “a national, evidence-based [vaccine] campaign.” Defs.’ Mem. 18–19. Plaintiffs also do not respond to Defendants’ argument that the ACIP Charter does not provide “procedure[s] required by law,” 5 U.S.C. § 706(2)(D), and that, even if it did, the Secretary’s appointments were fully consistent with the Charter. Defs.’ Mem. 20. Plaintiffs have therefore “waived” any “objections” to these points. *Liberty Mut. Ins.*, 2023 WL 5435878, at *4.

Plaintiffs’ defense of Count II rests entirely on *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020), Pls.’ Opp. 17–19, a case far afield from ours. *Union of Concerned Scientists* involved an EPA directive preventing “grant recipients—who are mostly employed by universities and other nonprofit institutions—from sitting on the EPA’s” advisory committees, which “increased the participation of industry-affiliated scientists” on those committees. 954 F.3d at 13, 15. By contrast, Plaintiffs do not plausibly allege any policy that prohibits a category of people from serving on ACIP. Rather, the complaint speculates about the Secretary’s reasons for appointing ACIP members without any well-pleaded facts showing how the appointments violated the Federal Advisory Committee Act (“FACA”). *See* Defs.’ Mem. 19–20. Although Plaintiffs suggest the “sequence of events” is suspicious, Pls.’ Opp. 18–19, their timeline “do[es] not permit the court to infer more than the mere possibility” that ACIP’s recommendations were “inappropriately influenced” by the Secretary or that ACIP’s membership was not “fairly balanced.” *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009); 5 U.S.C. § 1004(b)(2)–(3), (c).

CONCLUSION

For the reasons discussed above and in Defendants’ opening brief, the Court should dismiss this case for lack of subject-matter jurisdiction and failure to state a claim.

December 12, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

December 12, 2025

/s/ Isaac C. Belfer
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