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

Memorandum 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

In October 2025, the Centers for Disease Control and Prevention ("CDC") recommended that pediatric and adult patients consult with their healthcare provider about whether to get a COVID-19 vaccine. In so doing, CDC adopted the recommendations made by the Advisory Committee on Immunization Practices ("ACIP") in September 2025. Plaintiffs—a collection of individuals and healthcare organizations—disagree with CDC's recommendations and, in turn, bring this action requesting that this Court implement their policy preferences. This Court, of course, cannot do so, and Plaintiffs' claims must be dismissed.

To start, it is unclear from the Third Amended Complaint whether Plaintiffs still challenge the May 27, 2025, Secretarial Directive on Pediatric COVID-19 Vaccines for Children less than 18 Years of Age and Pregnant Women (the "Secretarial Directive" or "Directive"). If they do, that claim is moot because the Directive has effectively been overtaken by subsequent events. The Directive addressed prior directives from the U.S. Department of Health and Human Services ("HHS"), and CDC's COVID-19 vaccine recommendations that were in effect in May 2025. CDC's immunization schedules were updated accordingly over the summer. Then, in September 2025, ACIP voted in favor of new COVID-19 vaccine recommendations for both pediatric and adult populations, which CDC adopted and implemented in new immunization schedules dated October 2025. Because the current schedules reflect CDC's adoption of the September 2025 ACIP recommendations, any issue with the Directive is no longer live.

Plaintiffs lack standing to challenge CDC's current recommendations and Secretary Kennedy's appointment of new ACIP members. Jane Does 1 to 3 have not shown any concrete, actual or imminent injury that is traceable to the challenged actions and redressable by the requested relief. The only organizational plaintiff that attempts to show standing in its own right is the American Academy of Pediatrics ("AAP"), which fails to show any impediment to its

operations—only a continuation of its ongoing education and advocacy. No organizational plaintiff has standing through its members because no member plausibly has standing. The Third Amended Complaint does not plausibly show that the challenged actions have interfered with a member's ability to provide the standard of care or financially harmed a member's medical practice. And although Plaintiffs assert injuries to their members' patients, the Supreme Court has squarely held that doctors cannot bootstrap themselves into Article III standing through their patients. Thus, the case should be dismissed in its entirety for lack of subject-matter jurisdiction.

Count II also should be dismissed for failure to state a claim. Plaintiffs' theory that the Secretary's appointment of new ACIP members violated several statutes and the ACIP Charter is legally baseless and unsupported by well-pleaded facts.

BACKGROUND

I. Legal Framework for Vaccine Approval, Recommendation, and Administration

Vaccines are "biological product[s]." 42 U.S.C. § 262(i)(1). To distribute and market a vaccine for use in the United States, a manufacturer must obtain FDA approval. *Id.* § 262(a). FDA will approve a marketing application if, among other things, the vaccine is "safe, pure, and potent." *Id.* § 262(a)(2)(C)(i)(I). A vaccine is approved by FDA "for a particular medical use" or indication. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019). Healthcare providers may prescribe or administer a vaccine both for that approved use and (with few exceptions) an unapproved or "off-label" use when medically appropriate for an individual patient. *See id.*; *cf. United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023).

The Secretary, acting through CDC, recommends who should receive the vaccines that FDA approves. 42 U.S.C. § 242c(b). This process generally starts with ACIP, which is established and maintained at the Secretary's discretion. *See* 42 U.S.C. § 217a(a). ACIP advises the CDC Director "regarding use of vaccines and related agents for effective control of vaccine-

preventable diseases." ACIP Charter, https://perma.cc/6CNV-L5XR, at 1.[1] Icts recommendations "are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in [CDC's] *Morbidity and Mortality Weekly Report*." *Id.*

CDC also develops immunization schedules based, in part, on ACIP recommendations it adopts. *See generally* 42 U.S.C. § 243; CDC, *General Committee-Related Information*, https://perma.cc/WEA8-L439 (Aug. 12, 2025). These schedules recommend (but do not require) specific vaccines for particular patient populations, depending on age group and medical condition or indication. *See, e.g.*, ECF No. 103-2; ECF No. 103-3. One type of recommendation is "shared clinical decision-making," in which the decision whether to vaccinate is "individually based and informed by a decision process between the health care provider and the patient or parent/guardian." CDC, *ACIP Shared Clinical Decision-Making Recommendations*, https://perma.cc/QE5B-D8WU (Jan. 7, 2025). And sometimes CDC makes no recommendation. *See, e.g.*, ECF No. 103-2 at 2 ("No Guidance/Not Applicable" category).

Generally, states set vaccination policy through their police powers. *Zucht v. King*, 260 U.S. 174, 176 (1922); *e.g.*, Mass. Gen. Laws Ann., pt. 1, tit. 16, ch. 111, §§ 6, 181, tit. 12, ch. 76, § 15 (2024). State law also determines the standard of care for healthcare providers. *See Preston v. United States*, No. CV 19-11034-MPK, 2022 WL 3093235, at *19 (D. Mass. May 25, 2022).

II. The Directive and Its Implementation by CDC

By spring 2025, FDA had approved several COVID-19 vaccines for use in adults ages 65 years and older and approved and authorized the vaccine for people in certain younger age

[1] On a Rule 12(b) motion, the Court may consider "facts subject to judicial notice," *Cangrejeros De Santurce Baseball Club, LLC v. Liga De Beisbol Profesional De P.R.*, 146 F.4th 1, 11 (1st Cir. 2025), including information on government websites, *Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010).

groups.[2] On May 27, 2025, Secretary Kennedy issued the Directive. ECF No. 103-1[3]; *see* 42 U.S.C. §§ 242c(b), 243. Based on recommendations from FDA and the National Institutes of Health ("NIH"), the Secretary rescinded two prior directives that had "ratif[ied] CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years" and rescinded CDC's "recommendation that pregnant women receive" the vaccine. ECF No. 103-1.

Over the summer, CDC implemented the Directive. ECF No. 103-2 (rev. Aug. 7, 2025); ECF No. 103-3 (same). The revised pediatric immunization schedule recommended vaccination for healthy children based on "shared clinical decision-making" between "the health care provider and the patient or parent/guardian." ECF No. 103-2 at 5. That meant where "the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances." *Id.* CDC implemented the Directive as to pregnant women by revising the pediatric and adult immunization schedules. *Id.* 4; ECF No. 103-3 at 3. As revised, the entry for the COVID-19 vaccine for pregnant women indicated "No Guidance/Not Applicable." ECF No. 103-2 at 4; ECF No. 103-3 at 3.

III. CDC Adopts New ACIP Recommendations and Publishes New Immunization Schedules Based on Those Recommendations

On June 9, 2025, Secretary Kennedy removed the then-serving ACIP members. ECF No. 139 ("TAC") ¶¶ 47–48. In June and September 2025, he appointed new ACIP members, who are "highly credentialed scientists, leading public-health experts, and some of America's most

[2] *See* FDA, *Coronavirus (COVID-19) | CBER-Regulated Biologics*, https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-regulated-biologics (Aug. 27, 2025).

[3] An initial version of the Directive was mistakenly dated May 19, 2025, despite being executed on May 27, 2025. However, the Secretary executed another copy correctly dated May 27, 2025.

accomplished physicians . . . committed to evidence-based medicine, gold-standard science, and common sense." *Id.* ¶ 53. All new ACIP members hold an M.D., Pharm.D., or Ph.D., and they include (1) "a Professor of Pediatrics at the Geisel School of Medicine at Dartmouth and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety" who "previously served as Chief of the Division of Pediatric Infectious Disease at Tufts-New England Medical Center and on [ACIP] and the FDA's Vaccine and Related Biologic Products Advisory Committee," (2) a former "professor of medicine at Harvard University," and (3) a former section chief at NIH. *Id.* ¶ 54; *see* CDC, *ACIP Membership Roster*, https://perma.cc/DW74-3MSZ (Sept. 16, 2025). ACIP members have also researched mRNA vaccines and authored "articles on the association between mRNA COVID-19 vaccines and adverse health outcomes." TAC ¶ 54.

On September 19, 2025, ACIP voted in favor of new recommendations for the COVID-19 vaccine, which the Acting Director of CDC then adopted. See HHS, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making*, https://perma.cc/BP2T-97ZS (September 19, 2025). On October 6, 2025, CDC's immunization schedules were updated to reflect the new ACIP recommendations. *See* CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making*[4] *for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, https://perma.cc/SD3P-G2V7 (Oct. 6, 2025) ("CDC Announcement").

For pediatric and adult patients, including pregnant women, the current CDC immunization schedules recommend that the COVID-19 vaccine be administered through shared clinical decision-making. CDC, Recommended Child and Adolescent Immunization Schedule for

[4] "Individual-based decision-making" is also known as "shared clinical decision-making." https://perma.cc/SD3P-G2V7.

Ages 18 Years or Younger, at 2, 4–5, https://perma.cc/TL5F-6E2P (rev. Oct. 7, 2025) ("Pediatric Immunization Schedule"); CDC, Recommended Adult Immunization Schedule for Ages 19 Years or Older, at 2–4, https://perma.cc/LQN9-ACLC (rev. Oct. 7, 2025) ("Adult Immunization Schedule"). That means the decision is "individually based and informed by a decision process between the health care provider and the patient or parent/guardian." *ACIP Shared Clinical Decision-Making Recommendations*. A health care provider is "anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists." *Id.*

There "is not a prescribed set of considerations or decision points in the decision-making process," and the decision "may be informed by" factors including "the individual's characteristics" and "the health care provider's clinical discretion." *Id.* Nonetheless, the schedules explain that "the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk according to the CDC list of COVID-19 risk factors." Pediatric Immunization Schedule at 5 (citing CDC, *Underlying Conditions and the Higher Risk for Severe COVID-19*, https://perma.cc/GT9J-FKD8 (Feb. 6, 2025) ("*Underlying Conditions*")); Adult Immunization Schedule at 4 (citing *Underlying Conditions*). Cost, however, is not a factor. Vaccines administered through shared clinical decision-making, when that is recommended by CDC, "generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible)." *ACIP Shared Clinical Decision-Making Recommendations* (citing 42 U.S.C § 300gg-13; 26 C.F.R. § 54.9815-2713(a)(1)(ii); 29 C.F.R.

§ 2590.715-2713(a)(1)(ii); 45 C.F.R. § 147.130(a)(1)(ii)).[5]

IV. Procedural History

Plaintiffs initially filed suit on July 7, 2025. ECF No. 1. In the operative Third Amended Complaint, Plaintiffs challenge CDC's current shared clinical decision-making recommendations for COVID-19 vaccines and the Secretary's appointment of new ACIP members. TAC ¶¶ 5–9. Defendants now move to dismiss the Third Amended Complaint under Rules 12(b)(1) and (6).

LEGAL STANDARD

Subject-matter jurisdiction, including standing, must "be established as a threshold matter." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94–95 (1998). The Court is "presume[d]" to "lack jurisdiction" unless Plaintiffs meet their "burden of establishing it." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 n.3 (2006) (quotation omitted). When, as here, defendants bring a facial challenge to subject-matter jurisdiction under Rule 12(b)(1), the Court examines whether the non-conclusory, non-speculative allegations in the complaint, on their face, "plausibly allege" subject-matter jurisdiction. *Brownback v. King*, 592 U.S. 209, 217 (2021); *see Cangrejeros De Santurce Baseball Club*, 146 F.4th at 11.

Under Rule 12(b)(6), the Court must dismiss the complaint unless Plaintiffs have "state[d] a plausible claim for relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). They must plead sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.*; *see also Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) ("Factual allegations must be enough to raise a right to relief above the

[5] *See* CDC Announcement ("Like routine recommendations, individual-based-decision-making allows for immunization coverage through all payment mechanisms including entitlement programs such as the Medicare, Medicaid, Children's Health Insurance Program, and the Vaccines for Children Program, as well as insurance plans regulated by the Affordable Care Act."); Centers for Medicare & Medicaid Services, *Affordable Care Act Implementation FAQs - Set 12*, Question 8, https://perma.cc/NL2N-3W9D (last modified Sept. 10, 2024).

speculative level."). "Threadbare recitals of the elements of a cause of action" or "unadorned, the-defendant-unlawfully-harmed-me accusation[s]" do not suffice. *Iqbal*, 556 U.S. at 678. The Court accepts as true Plaintiffs' "well-pleaded factual allegations" but not "conclusory statements" or "legal conclusions." *Id.* at 678–79.

ARGUMENT

The Third Amended Complaint should be dismissed for lack of subject-matter jurisdiction and failure to state a claim for relief. ***First***, because the CDC immunization schedules now reflect ACIP's recommendations from September 2025, as adopted by CDC's Acting Director, the May 2025 Directive no longer has any effect, and any challenge to it is moot. ***Second***, Plaintiffs lack standing across the board. ***Finally***, because none of the challenged actions are contrary to law, Count II does not state a plausible claim for relief.

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

The Third Amended Complaint is ambiguous about whether it challenges the Secretarial Directive. The Directive is not among the "three final agency actions" identified, TAC ¶¶ 5–9, and the claims for relief do not mention the Directive, *id.* ¶¶ 108–26. Yet, Plaintiffs demand the Secretary "explain" the Directive, *id.* ¶ 6, and ask the Court to "[d]eclare [it] unlawful and set [it] aside," *id.* at p. 55. To the extent Plaintiffs actually challenge the Directive, that claim is moot.

"A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotation omitted)). Here, "[t]ime and events have overtaken" the Directive and rendered "moot" any dispute with its reasoning. *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 6 (1st Cir. 2021).

On its face, the Directive addressed the COVID-19 vaccine recommendations then in effect (*i.e.*, on May 27, 2025). ECF No. 103-1. By August 2025, CDC had implemented the

Directive in revised immunization schedules. ECF No. 103-2; ECF No. 103-3. However, on September 19, 2025, ACIP voted in favor of new COVID-19 vaccine recommendations, which were adopted by CDC. *See supra* pp.4–7. And on October 6, 2025, CDC replaced the immunization schedules from this summer, which had implemented the Directive, with new schedules that reflected the September ACIP recommendations. *See* CDC Announcement.

Because the current, October 6 immunization schedules reflect the September ACIP recommendations—*not* the earlier Secretarial Directive—Plaintiffs' disagreement with the Directive is "no longer 'live.'" *Already*, 568 U.S. at 91 (quotation omitted). Even if the Court vacated the Directive, that would not change the September ACIP recommendations and thus the current CDC immunization schedules. Accordingly, Plaintiffs "lack a legally cognizable interest in the outcome" of their challenge to the Directive. *Id.* (quotation omitted).[6]

II. Plaintiffs Lack Standing to Assert Any of Their Claims

Article III standing doctrine "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). It "screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action." *All. for Hippocratic Med.*, 602 U.S. at 381. This "prevents the federal courts from becoming a vehicle for the vindication of the value interests of concerned bystanders." *Id.* at 382 (quotation omitted).

Plaintiffs must show they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable

[6] For the same reasons, Plaintiffs lack standing to challenge the Directive. To have standing to "seek[] prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of *future* injury." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024) (emphasis added). Because the Directive no longer has any effect on CDC's immunization schedules, it cannot cause Plaintiffs any future injury. *See id.*

judicial decision." *Spokeo*, 578 U.S. at 338. The "injury in fact" must be "'concrete,' meaning that it must be real and not abstract," and "also must be particularized," affecting the plaintiff "in a personal and individual way" and not "a generalized grievance." *All. for Hippocratic Med.*, 602 U.S. at 381 (quotation omitted). Moreover, "the injury must be actual or imminent, not speculative," and a plaintiff who "seeks prospective relief such as an injunction" must "establish a sufficient likelihood of future injury." *Id.* Additionally, traceability requires that "the plaintiff 's injury likely was caused or likely will be caused by the defendant's conduct."[7] *Id.* at 382.

Also, "standing is not dispensed in gross." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). It is "plaintiff-specific," so courts "must determine whether each particular plaintiff is entitled to have a federal court adjudicate each [asserted] claim," *Pagán v. Calderón*, 448 F.3d 16, 26 (1st Cir. 2006); *see Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016) (standing requires "plaintiff-by-plaintiff and claim-by-claim analysis").

A. The Individual Plaintiffs Do Not Have Standing

Jane Doe 1 allegedly was harmed because the "decision" about when to receive another vaccine dose during her pregnancy "weighed on" her. TAC ¶¶ 19, 83. But such "psychological consequence[s]" do not confer standing. *Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 485 (1982). Moreover, the purported weight of Jane Doe 1's decision was lifted before the Third Amended Complaint was filed, when she gave birth. *Id.* ¶ 19; *see Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473–74 (2007) (when a plaintiff "voluntarily amends the complaint, courts look to the amended complaint to determine jurisdiction"). And past harm does not show "a sufficient likelihood of *future* injury" to Jane Doe

[7] Traceability and redressability "are often flip sides of the same coin" because if the challenged action did not cause the plaintiff's injury, then enjoining that action typically will not redress that injury. *All. for Hippocratic Med.*, 602 U.S. at 380–81.

1 as required to sustain the "prospective relief" sought here. *All. for Hippocratic Med.*, 602 U.S. at 381 (emphasis added). Furthermore, Jane Doe 1 purportedly experienced these harms *before* CDC's COVID-19 vaccine recommendations were updated in October 2025 to "shared clinical decision-making." *See supra* pp.5–7; *see, e.g.*, ECF No. 118-1, ¶¶ 9, 16 (Jane Doe 1's declaration dated September 23, 2025). Thus, she cannot show traceability to the actions challenged in the Third Amended Complaint—namely, CDC's current recommendations for the COVID-19 vaccine and the Secretary's appointment of new ACIP members. *Spokeo*, 578 U.S. at 338.

Jane Doe 2 was allegedly harmed in June and July 2025 when trying to get a COVID-19 vaccine booster during her pregnancy. TAC ¶ 84. However, she got a booster on July 23 and gave birth in October. *Id.* ¶ 20; ECF No. 118-2, ¶ 27. These harms are thus entirely in the past and not fairly traceable to the current immunization schedules challenged in the Third Amended Complaint. Nor are they "likely to be redressed by a favorable judicial decision," *Spokeo*, 578 U.S. at 338, because the prospective relief Plaintiffs request, TAC at pp. 55–56, will not remedy Jane Doe 2's purported past physical harm or recoup lost time and "gasoline expense," *id.* ¶ 84.

Although Jane Doe 2 allegedly "still suffers with the physical manifestations of stress as a result of the uncertainty of being able to get the Covid-19 vaccine while pregnant," *id.* ¶ 20, a "psychological consequence" to disagreeable conduct does not confer standing, *Valley Forge Christian Coll.*, 454 U.S. at 485. Likewise, any "psychic satisfaction" from a favorable ruling "is not an acceptable Article III remedy because it does not redress a cognizable Article III injury." *Steel Co.*, 523 U.S. at 107. Moreover, the prospective relief Plaintiffs seek cannot change Jane Doe 2's experiences while pregnant or redress any continuing harm they allegedly caused.

Jane Doe 3 alleges her sons became "upset" and "fearful" after a pharmacist declined to vaccinate them in August 2025. TAC ¶¶ 21, 85. But her sons received the vaccine in September

2025, ECF No. 118-3, ¶ 16, and she does not allege any ongoing or imminent injury, *see All. for Hippocratic Med.*, 602 U.S. at 381. Additionally, feeling "upset" and "fearful" are not concrete injuries. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013) (a "subjective fear . . . does not give rise to standing"); *Wadsworth v. Kross, Lieberman & Stone, Inc.*, 12 F.4th 665, 668–69 (7th Cir. 2021). And her sons' inability to receive the vaccine in August 2025 was not "fairly traceable to [Defendants'] challenged conduct" in the Third Amended Complaint. *Spokeo*, 578 U.S. at 338. Again, CDC's current immunization schedule recommends COVID-19 vaccines for pediatric patients based on shared clinical decision-making. *See supra* pp.5-7.

B. The Organizational Plaintiffs Do Not Have Standing in Their Own Right

Organizations may "'sue on their own behalf'" if, like individuals, they show "injury in fact, causation, and redressability." *All. for Hippocratic Med.*, 602 U.S. at 393–94 (quotation omitted). An organization must show a concrete injury, such as an "impediment" to its operations, and "cannot manufacture its own standing" merely "by expending money to gather information and advocate against the defendant's action." *Id.* at 394–95. Only AAP attempts to show its own standing here, but it falls far short of the standard.

AAP published new immunization schedules and guidance documents, "[d]evelop[ed] a new policy statement" about COVID-19 vaccines, answered members' questions about the Directive, provided educational webinars, and held "meetings to align advocacy, clinical, and communications efforts." ECF No. 118-9, ¶ 4; *see* TAC ¶ 86. None of these activities reflect an "impediment" to AAP's operations. *All. for Hippocratic Med.*, 602 U.S. at 395. Rather, this sort of educational and advocacy work is a continuation of AAP's "ongoing activities," which include publishing "immunization recommendations," "clinical practice guidelines," and "policies on a broad range of topics that impact" children's health. *Friends of the Earth v. Sanderson Farms, Inc.*, 992 F.3d 939, 942 (9th Cir. 2021) (citing cases); ECF No. 75-13, ¶¶ 8,

18. And both Supreme Court and First Circuit precedent are clear that an organization cannot conjure standing "by generating educational materials" and engaging in advocacy to "counteract" the challenged agency action. *Equal Means Equal v. Ferriero*, 3 F.4th 24, 29–30 (1st Cir. 2021) (quotation omitted); *see All. for Hippocratic Med.*, 602 U.S. at 394.

C. The Organizational Plaintiffs Do Not Have Standing Through Their Members

An association may sue "on behalf of its members when," among other things, they "would otherwise have standing to sue in their own right." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). Here, the organizational plaintiffs allege three theories of injury to their members: (1) interference with the standard of care, (2) harm to medical practices, and (3) injuries to members' patients. No theory survives scrutiny. Thus, no organizational plaintiff plausibly alleges that "at least one identified member" would "have standing to sue in their own right." *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009); *Hunt*, 432 U.S. at 343.

1. Alleged Interference with the Standard of Care

Plaintiffs allege the challenged actions "have frustrated the ability of clinicians and other public health members to advise the communities that they serve regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and death, thus compromising [Plaintiffs'] members' ability to practice consistent with their standard of care." TAC ¶ 92; *see id.* ¶¶ 89–90, 96, 98. But Plaintiffs concede their members continue to "counsel[] patients that, based on the evidence, the Covid-19 vaccine is safe and beneficial." *E.g.*, *id.* ¶ 88. And the organizational plaintiffs continue to advocate about the appropriate standard of care. *Id.* ¶¶ 89, 100. Thus, the complaint itself proves that Plaintiffs' members remain free to advise their patients about the COVID-19 vaccine according to their professional judgment. Although some patients may decide not to receive the vaccine, *e.g.*, *id.* ¶ 88, the "unfettered choice[]" of patients—

"independent actors not before the court[]"— about whether to get vaccinated cannot confer standing on Plaintiffs. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted).

Plaintiffs further allege the challenged actions "put[] physicians in the conflicting position of either advising patients on what they believe is the proper standard of care or adhering to inconsistent federal guidance." TAC ¶ 87; *see id.* ¶¶ 89, 91. Again, there is no inconsistency between the current "federal guidance" (*i.e.*, pediatric and adult patients may receive the vaccine based on shared clinical decision-making) and what Plaintiffs' members consider the standard of care (*i.e.*, administering the vaccine to their pediatric and adult patients). To the contrary, they are fully consistent: CDC recommends that patients consult with their healthcare provider so the provider can advise the patient about the vaccine in accordance with their understanding of the standard of care.

Even if Plaintiffs' members have experienced harm to their ability to provide the standard of care, that harm would not be fairly traceable to the challenged actions. CDC does not require or prohibit any action by healthcare providers.[8] Far from creating "barriers" to doctors' providing the standard of care, TAC ¶ 89, or "undermin[ing] [doctors'] independent medical judgment," *id.* ¶ 97, CDC's shared clinical decision-making recommendations *encourage* doctors to interact with their patients and exercise their professional judgment.

2. Alleged Harm to Medical Practices

Plaintiffs allege the challenged actions "have led to an increase in vaccine hesitancy," which has "caused physician members to spend more time counseling patients regarding the effectiveness of the Covid-19 vaccines that, in turn, diverts time and resources from other patients." TAC ¶¶ 88–90; *see id.* ¶¶ 92, 98, 101. But counseling patients about COVID-19

[8] For example, doctors are not "required to discuss recommendations from the current ACIP and CDC." TAC ¶ 94.

vaccines and addressing alternative information, *id.* ¶ 95, is part of being a healthcare provider; it is not an injury that establishes standing. For example, in giving her patient diet advice, a doctor may need to account for conflicting information the patient read on the Internet. That conversation does not injure the doctor—it is the doctor's job.

According to Plaintiffs, their members are "not able to bill for the additional time" spent counseling their patients, calling around "to determine [vaccine] availability," or "counseling fellow practitioners" about the vaccine and so must "perform uncompensated work." *Id.* ¶¶ 90, 102–07. However, any financial injury is not fairly traceable to the challenged CDC immunization recommendations or ACIP membership. Rather, the "chain of causation is simply too attenuated," involving speculation about the decisions of numerous "independent actors." *All. for Hippocratic Med.*, 602 U.S. at 383, 391 (quotation omitted). Plaintiffs have conceded 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. 118-4, ¶¶ 13, 18.[9] Thus, the alleged injury to healthcare providers rests on "speculation" about how "independent" patients will exercise their "unfettered choice[]" whether to get vaccinated. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted). Plaintiffs' alleged injuries also rest on speculation about insurers' reimbursement decisions. And if, despite knowing he will not be compensated, a healthcare provider chooses to do additional work, such as helping other providers care for their patients, TAC ¶ 107, any harm is "self-inflicted" and not fairly traceable to the challenged actions. *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam).

Plaintiffs baldly allege that unknown members "face financial harm because some insurers do not cover vaccines that are designated [shared clinical decision-making] on the CDC

[9] *See* ECF No. 118-5, ¶ 14; ECF No. 118-6, ¶ 7; ECF No. 118-7, ¶ 10; ECF No. 118-8, ¶ 11.

immunization schedules." TAC ¶ 91. But insurers generally must cover COVID-19 vaccines administered through shared clinical decision-making. *See* 42 U.S.C. § 300gg-13; 26 C.F.R. § 54.9815-2713(a)(1)(ii); 29 C.F.R. § 2590.715-2713(a)(1)(ii); 45 C.F.R. § 147.130(a)(1)(ii)); *supra* pp.6–7. And any harm from contrary action is traceable to the insurer's independent decision about what to reimburse, not to CDC's recommendation.

Plaintiffs claim "[s]hared [clinical] decision-making implies that the Covid-19 vaccine is optional or suspect, making it harder to hold Covid-19 vaccine clinics, limiting [providers'] ability to order vaccines in bulk, and creating reimbursement challenges." TAC ¶ 90; *see id.* ¶ 104. But a shared clinical decision-making recommendation does not plausibly mean the vaccine is "suspect"—just that patients should consult with their healthcare provider. Moreover, any inefficiencies allegedly faced by medical practices, such as a limited ability to order vaccines in bulk, rest on "speculation" about whether "independent" patients will choose to get vaccinated. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted).[10]

It is implausible that providers fear "potential legal liability in light of the Secretary's" statement that "recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." TAC ¶ 90. A doctor's recommendation of the vaccine to a patient does not "diverge from" CDC's recommendation that patients engage in shared clinical decision-making with their healthcare providers. Moreover, the National Childhood Vaccine Injury Act of 1986 created the National Vaccine Injury Compensation

[10] If a doctor is "left with unused vaccines that she cannot return," TAC ¶ 104, that also is not traceable to the challenged actions, but instead to the doctor's vaccine ordering choices or the vaccine manufacturer's return policies.

Program, and that program does not apply to COVID-19 vaccines.[11] The program certainly does not *create* liability for providers who administer them. Plaintiffs' alleged fear of malpractice liability for prescribing or administering COVID-19 vaccines—which they assert *is* the standard of care—is entirely speculative. *See Twombly*, 550 U.S. at 555.

Plaintiffs claim the challenged actions have harmed their members' doctor-patient relationships, such as by reducing patients' trust in their doctors. *See* TAC ¶¶ 87–88, 92, 94, 99, 101. But these are paradigmatic abstract injuries that do not support standing. *All. for Hippocratic Med.*, 602 U.S. at 381. Even if patients are experiencing more "uncertainty[] and confusion," TAC ¶ 87, that is not an injury to the healthcare provider. And if a patient decides to stop seeing a provider, *id.* ¶ 103, any resulting financial injury is traceable to the patient's "independent action." *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976).

Finally, Plaintiffs cannot show standing based on their members' "ideological[] or policy objection" to the challenged actions. *All. for Hippocratic Med.*, 602 U.S. at 381. For example, Massachusetts Public Health Association members assert a "generalized grievance" based on their "abstract" interest in "maternal and child health, vaccine delivery, and pandemic response in Massachusetts." TAC ¶ 97; *All. for Hippocratic Med.*, 602 U.S. at 381.[12] Columbus Public Health asserts a similar generalized grievance, TAC ¶ 93, and, in any event, it is not an independent legal entity that can confer standing on the American Public Health Association

[11] Health Resources & Servs. Admin., *About the National Vaccine Injury Compensation Program*, https://www.hrsa.gov/vaccine-compensation/about (last reviewed Sept. 2025); Health Resources & Servs. Admin., *Frequently Asked Questions*, https://www.hrsa.gov/vaccine-compensation/faq (last reviewed Sept. 2025).

[12] Plaintiffs also allege the challenged actions "weaken the public health infrastructure MPHA members rely on to perform their jobs," TAC ¶ 97, but this allegation is "too vague to render the claim[] plausible," *Atlas Glass & Mirror, Inc. v. Tri-N. Builders, Inc.*, 997 F.3d 367, 372 (1st Cir. 2021) (quotation omitted).

("APHA"). *See* ECF No. 75-27, ¶ 29; *Nieves v. City of Cleveland,* 153 F. App'x 349 (6th Cir. 2005); *Elkins v. Summit County, Ohio,* No. 5:06–CV–3004, 2008 WL 622038, at *6 (N.D. Ohio Mar. 5, 2008). And the fact that an APHA member devotes time to advocacy in response to the challenged actions, TAC ¶ 105, does not support standing because it does not respond to any concrete, cognizable injury, *see Clapper*, 568 U.S. at 415–18.

3. Alleged Injuries to Members' Patients

Plaintiffs attempt to assert injuries to their members' patients, TAC ¶¶ 88, 90, 99, but doctors cannot "shoehorn themselves into Article III standing simply by showing that their patients have suffered injuries or may suffer future injuries," *All. for Hippocratic Med.*, 602 U.S. at 393 n.5. If patients are "presenting at [a healthcare provider's] practice as afraid, misinformed and at increased risk of preventable illness and death," TAC ¶ 99, that does not injure the healthcare provider. It also is not fairly traceable to CDC's recommendation that patients consult with their healthcare provider about the vaccine. Likewise, a patient's financial liability for vaccine costs, *id.* ¶¶ 88, 90, does not injure the healthcare provider, and Plaintiffs have not alleged any financial harm to their members from a patient's inability to pay for the vaccine.

The organizational plaintiffs do not have standing on their own or through their members.

III. Count II Fails to State a Claim for Relief

Beyond the jurisdictional deficiencies, Count II also should be dismissed under Rule 12(b)(6). Count II challenges "[t]he Secretary's reconstitution of the ACIP" as "not in accordance with law" under 5 U.S.C. § 706(2)(A), (D), which allegedly makes ACIP's September 2025 votes "null and void," TAC ¶ 120. These "legal conclusions" are not presumed true. *Iqbal*, 556 U.S. at 678. Moreover, Plaintiffs do not plausibly allege that the Secretary's appointment of new ACIP members violated any law. *See id.* at 679.

The Secretary's appointments and ACIP's September 2025 votes plainly did not violate

42 U.S.C. § 245(a), *see* TAC ¶ 121, because they had nothing to do with "award[ing] competitive grants or contracts to one or more public or private entities to carry out a national, evidence-based campaign" about vaccines. ACIP's composition also accords with the Federal Advisory Committee Act's ("FACA") admonition that "the membership of the advisory committee [be] fairly balanced in terms of the points of view represented and the functions to be performed." 5 U.S.C. § 1004(b)(2), (c). Plaintiffs argue ACIP is "imbalanced," TAC ¶ 121, because "ACIP's discussion and votes at the June and September, 2025 meetings . . . promoted an anti-vaccine agenda," *id.* ¶ 8. But FACA does not require that ACIP "address the vaccine's benefits" in what Plaintiffs consider "a balanced manner." *Id.* ¶ 82. Nor does Plaintiffs' characterization of ACIP members' comments and votes as "anti-vaccine" constitute the sort of "well-pleaded facts" that "permit the court to infer more than the mere possibility of misconduct." *Iqbal*, 556 U.S. at 679.

Plaintiffs further allege, "upon information and belief," that the Secretary appointed new ACIP members based "on whether their views on vaccines align with the Secretary's" and "required candidates for membership on the ACIP to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary." TAC ¶¶ 8, 52; *see* 42 U.S.C. § 217a-1. But "the phrase 'information and belief' does not excuse pure speculation." *Lavigne v. Great Salt Bay Cmty. Sch. Bd.*, 146 F.4th 115, 127 (1st Cir. 2025); *see Doe v. Am. Univ.*, No. 19- CV-03097 (APM), 2020 WL 5593909, at *11 (D.D.C. Sept. 18, 2020). Other than concluding that "[e]ight of the current ACIP members have stated views on vaccines that align with the Secretary's," TAC ¶ 55, Plaintiffs offer no "well-pleaded facts" that plausibly show those members were appointed solely based on their views, *Iqbal*, 556 U.S. at 679.

Plaintiffs allege that ACIP "is not acting independently[] and is being inappropriately influenced by the Secretary, as evidenced by the ACIP's discussion and votes at the June and

September, 2025 meetings that promoted an anti-vaccine agenda." TAC ¶ 8 (footnote omitted); *see* 5 U.S.C. § 1004(b)(3), (c) (agency head should "assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment"). But even if certain ACIP members made comments and cast votes that Plaintiffs consider "anti-vaccine," that says nothing about whether the ACIP members are being "inappropriately influenced" by Secretary Kennedy as opposed to exercising their "independent judgment." 5 U.S.C. § 1004(b)(3), (c). On that critical point, Plaintiffs can only speculate. *Iqbal*, 556 U.S. at 679; *see Twombly*, 550 U.S. at 555.

Finally, Plaintiffs allege the Secretary did not appoint ACIP members "based on relevant experience or credentials as required by the ACIP Charter." TAC ¶ 8. This gives the ACIP Charter undue legal authority. The Charter is not a statute or regulation and does not bind the Secretary. Accordingly, the ACIP Charter's description of the committee's members is not a "procedure required by law." 5 U.S.C. § 706(2)(D). Even if it were, though, the Secretary's appointments were fully consistent with the Charter. All the new ACIP members hold an M.D., Pharm.D., or Ph.D. and are "knowledgeable in the field[] of . . . public health." ACIP Charter at 4; *see supra* pp.4–5; TAC ¶ 54. The members with an M.D. or Pharm.D. are also "knowledgeable in the field[] of immunization practices" and may "have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine." ACIP Charter at 4. Several members also "have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety." *Id.*; *see supra* pp.4–5; TAC ¶ 54.

CONCLUSION

For these reasons, the Court should dismiss this case for lack of subject-matter jurisdiction and failure to state a claim.

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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.

November 19, 2025

/s/ Isaac C. Belfer
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