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-WGY

Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction

Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; United States Department of Health and Human Services; Marty Makary, in his official capacity as Commissioner of Food and Drugs; the Food and Drug Administration; Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health ("NIH"); NIH; Jim O'Neill, in his official capacity as Acting Director of Centers for Disease Control and Prevention ("CDC"); and CDC move this Court under Federal Rule of Civil Procedure 12(b)(1) to dismiss this action for lack of subject-matter jurisdiction. The grounds for this motion are fully set forth in an accompanying memorandum.

September 3, 2025

Respectfully submitted,

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LOCAL RULE 7.1 CERTIFICATE

Per Local Rule 7.1, counsel for Defendants state that they conferred with counsel for Plaintiffs by email on September 3, 2025, and counsel for Plaintiffs stated that they oppose Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction.

/s/ Isaac C. Belfer
Isaac C. Belfer

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.

September 3, 2025

/s/ Isaac C. Belfer
Isaac C. Belfer

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INTRODUCTION

On May 27, 2025, Secretary of Health and Human Services Robert F. Kennedy, Jr., issued a Secretarial Directive on Pediatric COVID-19 Vaccines for Children less than 18 Years of Age and Pregnant Women (the "Directive"). Ex. A.[1] The Centers for Disease Control and Prevention ("CDC") implemented the Directive through CDC's vaccination schedules, which now recommend "shared clinical decision-making" between the healthcare provider and the patient or parent/guardian about COVID-19 vaccines for pediatric patients, Ex. B at 2, 5, and make no recommendation—either for or against vaccination—for pregnant patients, Ex. C at 3.

Plaintiffs—three women and seven organizations—object to the Directive and want CDC to recommend routine COVID-19 vaccination for pediatric and pregnant patients. But a plaintiff cannot seek relief in federal court merely to vindicate her policy preferences. Instead, she must show standing to sue—*i.e.*, a concrete, actual or imminent injury in fact that is traceable to the challenged conduct and redressable by the requested relief. No Plaintiff has done so here.

Jane Doe 1 is concerned about future harm from COVID-19, but that harm is purely speculative, especially because she already received the vaccine and vaccine boosters. She wants another dose, but the Directive does not stand in the way, as healthcare providers (such as doctors, nurses, and pharmacists) still have discretion to prescribe or administer the vaccine according to their professional judgment. Jane Doe 1 cannot show standing by speculating that she will not receive another vaccine dose *and then* will get infected with the virus that causes COVID-19 *and then* will suffer physical injury. Similarly, Jane Doe 2's concern about future harm from COVID-19 is speculative, and she has also received the vaccine and vaccine boosters.

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[1] Exhibits designated with letters (*e.g.*, Ex. A) refer to exhibits to the Declaration of Isaac C. Belfer, filed with this motion. Exhibits designated with numbers (*e.g.*, Ex. 1) refer to exhibits in the Appendix of Evidence in support of Plaintiffs' preliminary injunction motion. ECF No. 75.

Finally, Jane Doe 3 speculates that she and her sons will suffer future harm because a single pharmacist declined to vaccinate her sons—a decision, moreover, based on the pharmacist's independent judgment and not traceable to the Directive. No individual plaintiff has standing.

The organizational plaintiffs also lack standing. *First*, the two organizations that assert standing in their own right, the Massachusetts Public Health Association ("MPHA") and the Society for Maternal-Fetal Medicine ("SMFM"), do not plausibly allege an injury. The Directive does not impede their operations, and they cannot show standing by engaging in education and advocacy about COVID-19 vaccines, which are their normal activities.

Second, the organizational plaintiffs do not have standing through their members. They allege the Directive interferes with their members' ability to provide the standard of care, which they believe is to recommend and administer the COVID-19 vaccine to children and pregnant women, but they concede their members still do that. Providing such care, moreover, is fully consistent with the Directive and CDC immunization schedules, which do not prohibit or even recommend against vaccinating children and pregnant women. The organizational plaintiffs also fail to show cognizable harm to their members' medical practices. It is not enough to allege their members must counsel patients about COVID-19 vaccines—which is their job—or to allege abstract impacts on the doctor-patient relationship. And although Plaintiffs claim the Directive will increase the number of COVID-19 patients and that their members will need to devote more resources to treating such patients, the Supreme Court recently held that standing theory rests on a causal chain that is "too speculative or otherwise too attenuated." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 390 (2024). *Finally*, the organizational plaintiffs try to invoke potential harm to their members' patients, but *Alliance for Hippocratic Medicine* rejected that very theory.

Thus, the Court should dismiss this case for lack of standing.

BACKGROUND

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

A. FDA Approves Vaccines

Vaccines are "biological product[s]." 42 U.S.C. § 262(i)(1). To seek permission to distribute and market a vaccine for use in the United States, a company submits a Biologics License Application ("BLA") to FDA. *Id.* § 262(a). FDA will approve a BLA if, among other things, the company demonstrates the vaccine is "safe, pure, and potent." *Id.* § 262(a)(2)(C)(i)(I).

B. CDC Recommends Vaccines

CDC does not approve vaccines; instead, it recommends who should receive them. This process generally starts with the Advisory Committee on Immunization Practices ("ACIP"), which advises the CDC Director "regarding use of vaccines and related agents for effective control of vaccine-preventable diseases." ACIP Charter at 1[2]; *see* 42 U.S.C. § 217a(a) (authorizing Secretary to appoint advisory committees). ACIP's 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* (MMWR)." ACIP Charter at 1.

CDC also develops immunization schedules based, in part, on ACIP's recommendations. *See generally* 42 U.S.C. § 243; CDC, *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations* (Sept. 17, 2024).[3] These schedules recommend (but do not require) specific vaccines for particular patient populations, depending on age group and medical

[2] https://www.cdc.gov/acip/downloads/acip-charter.pdf.

[3] https://www.cdc.gov/acip/about/role-in-vaccine-recommendations.html. On a Rule 12(b)(1) motion, the Court may consider "facts subject to judicial notice." *Cangrejeros De Santurce Baseball Club, LLC v. Liga De Beisbol Profesional De Puerto Rico*, 146 F.4th 1, 11 (1st Cir. 2025). The Court may take judicial notice of facts on government websites. *See Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (taking judicial notice of facts on CDC's website, which were "not subject to reasonable dispute" (quoting Fed. R. Evid. 201(b), (f))).

condition or indication. *See, e.g.*, Ex. B; Ex. C. One type of recommendation is "shared clinical decision-making," in which "vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian." Ex. B at 5.[4] And sometimes CDC makes no recommendation on whether a vaccine should be administered to a certain population. *See id.* at 2 ("No Guidance/Not Applicable" category); Ex. C at 2 (same).

C. Healthcare Providers Prescribe and Administer Vaccines

When FDA approves a drug or biological product, the approval is "for a particular medical use" or indication. *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 915 F.3d 1, 5 (1st Cir. 2019). From FDA's perspective, with few exceptions, healthcare professionals generally may choose to prescribe or use a legally marketed vaccine for an unapproved (or uncleared) use (also called an "off-label" use) when they judge that the unapproved use is medically appropriate for an individual patient. *See id.*; *cf. United States v. Facteau*, 89 F.4th 1, 15 (1st Cir. 2023).

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

FDA has approved several COVID-19 vaccines[5] for use in adults ages 65 years and older and people in certain younger age groups who have at least one underlying condition that puts

[4] *See* CDC, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

[5] For convenience, this brief will refer to the COVID-19 vaccines collectively as "the vaccine."

them at high risk for severe outcomes from COVID-19.[6]

On May 27, 2025, Secretary Kennedy issued the Directive. Ex. A[7]; *see* 42 U.S.C. §§ 242c(b)[8], 243. The Secretary noted that HHS "continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available [FDA] approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations." *Id.* After reviewing the "recommendation of the FDA and National Institutes of Health (NIH)," the Secretary "determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years" outweighed "the purported benefits of the vaccine." *Id.* Based on this analysis, the Secretary rescinded two prior Secretarial Directives from June 2022 that had "ratif[ied] CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years." *Id.*

After reviewing another FDA recommendation, Secretary Kennedy "determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby." *Id.* Thus, the Secretary rescinded "the CDC recommendation that pregnant women receive the COVID-19 vaccine." *Id.*

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[6] These age groups are 5 years through 64 years (Pfizer-BioNTech's vaccine, COMIRNATY), 12 years through 64 years (ModernaTX, Inc.'s vaccine, MNEXSPIKE), 6 months through 64 years (ModernaTX, Inc.'s vaccine SPIKEVAX), and 12 years through 64 years (Novavax, Inc.'s vaccine, NUVAXOVID). FDA, COMIRNATY, https://www.fda.gov/vaccines-blood-biologics/comirnaty (Aug. 27, 2025); FDA, MNEXSPIKE, https://www.fda.gov/vaccines-blood-biologics/mnexspike (Aug. 27, 2025); FDA, NUVAXOVID, https://www.fda.gov/vaccines-blood-biologics/vaccines/nuvaxovid (Aug. 27, 2025); FDA, SPIKEVAX, https://www.fda.gov/vaccines-blood-biologics/spikevax (Aug. 27, 2025).

[7] There are two versions of the Directive, one dated May 19, 2025, and the other dated May 27, 2025. Both were executed on May 27, 2025, and they are identical other than the date that appears. The first version signed was mistakenly dated May 19, 2025. HHS corrected the error the same day, and the Secretary executed a version correctly dated May 27, 2025.

[8] When the Directive was issued, the office of the Director of CDC was vacant.

CDC implemented the Directive as to pediatric vaccines in the Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger. Ex. B. The schedule now recommends vaccination for children ages six months to 17 years who are not moderately or severely immunocompromised based on "shared clinical decision-making" between "the health care provider and the patient or parent/guardian." *Id.* at 5. 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 in the Recommended Child and Adolescent Immunization Schedule by Medical Indication, *id.* at 4, and the Recommended Adult Immunization Schedule by Medical Condition or Other Indication, Ex. C at 3. The entry for the COVID-19 vaccine for pregnant women now indicates "No Guidance/Not Applicable." Ex. B at 4; Ex. C at 3.

Although the Directive affected CDC's recommended immunization schedules, it did not change FDA's approvals of COVID-19 vaccines or vaccine eligibility. Thus, providers may still prescribe and administer the vaccine to pediatric and pregnant patients, for either an approved or unapproved use, according to their professional judgment and consistent with applicable law.

III. Procedural History

Plaintiffs are three women and seven organizations who oppose the Directive. ECF No. 99, Second Amended Complaint ("SAC"), ¶¶ 15–24. They filed suit on July 7, 2025, ECF No. 1, and concurrently filed a preliminary injunction motion, ECF No. 16. They later filed an Amended Complaint and a new preliminary injunction motion. ECF Nos. 63, 73. On September 3, 2025, the Court granted Plaintiffs leave to file the Second Amended Complaint. ECF No. 96.

Defendants now move to dismiss under Rule 12(b)(1) for lack of standing.

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) (quotations omitted).

"There are two types of challenges to a court's subject matter jurisdiction: facial challenges and factual challenges." *Torres-Negron v. J & N Recs., LLC*, 504 F.3d 151, 162 (1st Cir. 2007). In a facial challenge, 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. By contrast, in a factual challenge, the Court may "weigh the evidence" to determine if jurisdiction exists. *Torres-Negron*, 504 F.3d at 163.

ARGUMENT

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 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 (quotations 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."[9] *Id.* at 382.

When plaintiffs allege future injury from government action that does not regulate them, "the causation requirement and the imminence element of the injury in fact requirement can overlap," both asking if it is "likely that the [challenged action] will cause a concrete and particularized injury in fact to the unregulated plaintiff?" *Id.* at 385 n.2. In this circumstance, standing "is ordinarily substantially more difficult to establish." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992) (quotations omitted). The plaintiff "must show a predictable chain of events leading from the government action to the asserted injury," and the links in the chain "must not be too speculative or too attenuated." *All. for Hippocratic Med.*, 602 U.S. at 383, 385. Plaintiffs cannot rely on "speculation about the unfettered choices made by independent actors not before the courts." *Id.* at 383 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 n.5 (2013)).

Because "standing is not dispensed in gross," *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021), it is "plaintiff-specific," and courts "must determine whether each particular plaintiff is entitled to have a federal court adjudicate each [asserted] claim," *Pagan v. Calderon*, 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").

[9] 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.

On its face, the Second Amended Complaint does not plausibly allege standing. But even looking beyond the complaint to the evidence accompanying Plaintiffs' preliminary injunction motion, the result is the same: No standing. Thus, under either a facial or a factual challenge to subject-matter jurisdiction, this case should be dismissed.

I. The Individual Plaintiffs Do Not Have Standing

Jane Doe 1 has not shown injury from the Directive. She is worried about the risk of future harm to herself or her unborn child from COVID-19, yet she "ha[s] been vaccinated against COVID-19 and ha[s] received COVID-19 vaccine boosters." Ex. 5, ¶ 7; *see* SAC ¶ 22. She alleges "her doctors have advised her to get another dose of the vaccine later in pregnancy" and that the Directive "will make [that] more difficult." SAC ¶¶ 22, 94.[10] However, the Directive does not disturb healthcare providers' discretion to administer the vaccine to pregnant women according to their professional judgment. *See supra* p. 6. Jane Doe 1 merely *speculates* about how unknown healthcare providers—"independent actors not before the court"—will "exercise their discretion," at some indefinite point in the future and under unknown circumstances, regarding whether to administer the vaccine to her.[11] *Clapper*, 568 U.S. at 401, 412, 414 n.5; *see All. for Hippocratic Med.*, 602 U.S. at 383, 385. Such speculation does not show Jane Doe 1's alleged injury is either "certainly impending" or "fairly traceable" to the Directive. *Clapper*, 568 U.S. at 401–02; *see Simon v. E. Kentucky Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976). For the

[10] Jane Doe 1 also alleges she must decide whether "to try to get the COVID-19 vaccine now" or "wait until later in [her] pregnancy" when it may be more effective. Ex. 5, ¶ 10. But she identifies no facts indicating her vaccine access in several months will be any different. Similarly, there is no basis for AAP member Dr. Scott-Vernaglia's speculation that her pediatric patients may be harmed if they "wait to receive their COVID-19 Booster until the fall of 2025." Ex. 15, ¶ 17.

[11] Insurers are also "independent actors not before the court" with "discretion" whether to cover the vaccine for pregnant women. *Clapper*, 568 U.S. at 401, 412, 414 n.5. Jane Doe 1 acknowledges she does not know whether they will cover the vaccine if she attempts to get another dose in the future. *See* Ex. 5, ¶ 9.

same reasons, Jane Doe 1 has not shown that any alleged difficulty in receiving the vaccine is likely redressable. *Spokeo*, 578 U.S. at 338. Even if the Directive were vacated, healthcare providers would still have discretion whether to administer the vaccine to pregnant women.

Jane Doe 1 also claims the Directive increases her risk of COVID-19, but this theory rests on a speculative and attenuated chain of possibilities. *First,* she argues the Directive "will decrease the rate at which people get the COVID-19 vaccine or a booster dose," Ex. 5, ¶ 6, but this is speculative because healthcare providers will still counsel patients about the vaccine in light of patients' medical history, *see, e.g.*, SAC ¶¶ 106, 109, 111, as CDC recommends for pediatric patients, Ex. B at 5. *Second*, Jane Doe 1 claims the number of people who get COVID-19 will increase, Ex. 5, ¶ 6, but this is also speculative: although the vaccine helps protect against serious symptoms, it does not prevent transmission of the virus or developing some symptoms.[12]

Third, Jane Doe 1 argues that more "people [will] come into the hospital when [she is] there who are either sick with COVID-19 or unknowingly spreading the SARS-CoV-2 virus when they are asymptomatic." Ex. 5, ¶ 6. But it is pure conjecture whether persons with COVID-19 will visit Jane Doe 1's hospital rather than visiting another facility or isolating at home. *Fourth*, she argues she will be exposed to "a higher risk of . . . getting COVID-19," Ex. 5, ¶ 6, yet it is speculative whether patients with COVID-19 would come into contact with Jane Doe 1 and transmit the virus to her. Even more speculative is Jane Doe 1's concern that she will "possibly pass[]" the virus to her "unborn child." *Id.* Each link in this chain of possibilities is highly speculative and attenuated, and thus Jane Doe 1 does not show an injury that is "certainly impending" or "fairly traceable" to the Directive. *Clapper*, 568 U.S. at 401–02, 414.

[12] *See* CDC, *COVID-19: How to Protect Yourself and Others*, https://www.cdc.gov/covid/prevention/index.html (Mar. 10, 2025).

Jane Doe 1 also claims to feel "stress and uncertainty," SAC ¶ 22; *see* Ex. 5, ¶ 7, but these feelings are not concrete injuries. *See Clapper*, 568 U.S. at 418 (a "subjective fear . . . does not give rise to standing"); *Wadsworth v. Kross, Lieberman & Stone, Inc.*, 12 F.4th 665, 668–69 (7th Cir. 2021) ("stress," "anxiety," and "confusion" are not concrete harms but "are quintessential abstract harms that are beyond [courts'] power to remedy"). They also are not fairly traceable to the Directive, instead reflecting Jane Doe 1's subjective fears based on her speculation about future vaccine access and the risk of getting COVID-19.

Jane Doe 2 fails to show standing for the same reasons. She is concerned about future harm to herself or her unborn child from COVID-19, Ex. 12, ¶ 6, but she "ha[s] been vaccinated against Covid and ha[s] received Covid vaccine boosters," Ex. 12, ¶ 6; *see id.* ¶ 19; SAC ¶ 9, and her concern is speculative, *see supra* pp. 9–10. She also claims she felt "confusion[] and stress" when she was trying to get the vaccine between May 30 and July 23, 2025, Ex. 12, ¶ 23; *see id.* ¶ 6, but such feelings are not concrete injuries, as discussed above. Moreover, those feelings ended when she got the vaccine in July and thus do not show "a sufficient likelihood of future injury" as required to "seek[] prospective relief." *All. for Hippocratic Med.*, 602 U.S. at 381.

Jane Doe 3 alleges she "is now faced with heightened risk of contracting Covid because a pharmacist refused to administer the Covid vaccine to her two teenage sons on August 14, 2025." SAC ¶ 101. Like the other Jane Does' allegations, this standing theory rests on a speculative and attenuated chain of possibilities: that her sons will be unable to get a vaccine from another healthcare provider, that they will get COVID-19, and that they will transmit the virus causing COVID-19 to her. *See All. for Hippocratic Med.*, 602 U.S. at 383, 385; *Clapper*, 568 U.S. at 410.

In addition, the pharmacist's decision not to administer the vaccine to Jane Doe 3's children—"because they are not in the eligible age group" of "over 60 or 65," SAC ¶ 24—is not

fairly traceable to the Directive. The Directive does not affect who is *eligible* for the vaccine, but simply who CDC *recommends* should receive it. And CDC does not recommend the vaccine only for people "over 60 or 65"; for example, it recommends the vaccine for children ages 6 months through 17 years based on shared clinical decisionmaking. Ex. B at 5. Lastly, as discussed above, Jane Doe 3's "fear and anxiety" and feeling "upset" are neither concrete injuries nor fairly traceable to the Directive. SAC ¶¶ 24, 101; *see supra* p. 11.

In sum, each Jane Doe has failed to show standing and should be dismissed.

II. 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 (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379, n.19 (1982)). In particular, an organization must show a concrete injury, such as an "impediment" to its operations, *All. for Hippocratic Med.*, 602 U.S. at 395, and cannot merely allege it is "continuing ongoing activities," *Friends of the Earth v. Sanderson Farms, Inc.*, 992 F.3d 939, 942 (9th Cir. 2021) (citing cases).

Standing on this basis is asserted only in two declarations, from members of MPHA and SMFM, but neither makes the required showing. The Pavlos Declaration states that MPHA has diverted resources "away from other strategic priorities in order to respond to" the Directive, including by "issu[ing] public statements, letters to the editor, and informational materials in an effort to maintain public confidence in vaccines" and "public health institutions." Ex. 21, ¶ 10. The Srinivas Declaration makes similar claims about SMFM. Ex. 30, ¶ 11.

MPHA and SMFM cannot show standing by spending resources on "public advocacy and public education" in response to the Directive "to the detriment of other spending priorities." *All. for Hippocratic Med.*, 602 U.S. at 394. The First Circuit rejected a similar theory of standing where the plaintiff organizations allegedly diverted resources "to identify and counteract" the

challenged agency action "by generating educational materials" and engaging in advocacy. *Equal Means Equal v. Ferriero*, 3 F.4th 24, 29–30 (1st Cir. 2021) (quotations omitted). Moreover, MPHA and SMFM are not injured by continuing their ongoing education and advocacy work. Ex. 21, ¶¶ 4–5; Ex. 30, ¶¶ 3, 5; *Friends of the Earth*, 992 F.3d at 942. Having failed to show an impediment to their operations or any other concrete injury, MPHA and SMFM have not established standing in their own right. *All. for Hippocratic Med.*, 602 U.S. at 395.

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

"[A]n association has standing to bring suit on behalf of its members when," among other things, "its members 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 categories of injury to their members: (1) interference with the standard of care, (2) harm to medical practices, and (3) injuries to members' patients. But none of these theories shows 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. Thus, the organizational plaintiffs do not have standing to sue on behalf of their members.

A. Alleged Interference with the Standard of Care

The organizational plaintiffs claim the Directive interferes with their members' ability to practice medicine to the standard of care. For example, the American Academy of Pediatrics ("AAP")[13] alleges that the Directive interferes with Dr. Galluci's ability "to provide the standard

[13] Plaintiffs do not offer facts to support the standing of the Massachusetts Chapter of AAP beyond what they offer for AAP.

of care recommended by the AAP," SAC ¶ 105, namely, that "all young children ages 6–23 months get vaccinated as well as children ages 2–18 years in certain risk groups." *Id.* ¶ 55.[14]

The medical standard of care, however, varies by state and is not determined by "advisory" recommendations from CDC or ACIP. *Avalo v. Sarkissian*, 83 Mass. App. Ct. 1135, 2013 WL 2631154, at *2 (2013) (unpublished); *contra* SAC ¶ 112 (MPHA). In Massachusetts, "[a] physician is held to the standard of care and skill of the average practitioner of the medical specialty in question." *Mitchell v. United States*, 141 F.3d 8, 13 (1st Cir. 1998); *see Preston v. United States*, No. CV 19-11034-MPK, 2022 WL 3093235, at *19 (D. Mass. May 25, 2022). Like "practice bulletins" from medical associations, *Woodman v. United States*, 602 F. Supp. 3d 265, 284 (D.N.H. 2022), ACIP recommendations are, at most, one data point to be considered when determining the applicable standard of care.

Here, the Directive has not prevented the organizational plaintiffs or their members from continuing to recommend and administer the vaccine to pediatric and pregnant patients.[15] *See, e.g.*, Ex. 11, ¶ 9 (AAP).[16] Indeed, the organizational plaintiffs are continuing to advise their members on what they consider the standard of care. For example, in August, AAP published its own pediatric immunization schedule, which departs from CDC's recommendations for pediatric COVID-19 vaccination. SAC ¶ 55; *see also id.* ¶ 104; Ex. 13, ¶ 22; SAC ¶ 115 (SMFM).

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[14] *See* Ex. 18, ¶¶ 9–11, 30–31 (American College of Physicians ("ACP")); SAC ¶ 107 (American Public Health Association ("APHA")); Ex. 19, ¶ 22 (APHA); Ex. 20, ¶¶ 27–28 (Infectious Diseases Society of America ("IDSA")); Ex. 28, ¶ 11 (MPHA); SAC ¶ 113 (SMFM); Ex. 30, ¶ 7 (SMFM).

[15] This disproves Plaintiffs' claims that the Directive prevents pediatric and pregnant patients from getting the vaccine, Ex. 18, ¶ 34 (ACP); Ex. 27, ¶ 26 (APHA); Ex. 17, ¶ 1 (SMFM), and that providers cannot advise pregnant women to receive the vaccine, SAC ¶ 108 (APHA); Ex. 27, ¶¶ 23–24 (APHA).

[16] *See also, e.g.*, Ex. 15, ¶ 7 (AAP); Ex. 20, ¶ 25 (AAP, ACP, IDSA); SAC ¶ 106 (ACP); Ex. 18, ¶ 11 (ACP); Ex. 26, ¶ 25 (ACP); Ex. 19, ¶¶ 12–13 (APHA); SAC ¶¶ 109, 111 (IDSA); Ex. 16, ¶ 11 (IDSA); Ex. 17, ¶ 6 (SMFM).

The organizational plaintiffs allege the Directive forces their members to choose between following the Directive and what the organizational plaintiffs consider the standard of care. *E.g.*, Ex. 11, ¶¶ 4, 9 (AAP).[17] The Directive, however, pertains only to CDC's *recommendations* and does not require or prohibit any action by healthcare providers. CDC's recommendations, moreover, are only recommendations, and do not bar healthcare providers from administering the COVID-19 vaccine to children or to pregnant women. For children, CDC recommends that healthcare providers and their patients or patients' parent/guardian engage in shared clinical decision-making about whether to administer the vaccine.[18] Ex. B at 5. For pregnant women, CDC makes no recommendation, either for or against the vaccine. Ex. C at 3. There is no conflict between these recommendations and a provider's decision to prescribe or administer the vaccine to pediatric or pregnant patients—what the organizational plaintiffs consider the standard of care.

Plaintiffs' claim that healthcare providers would face professional discipline or malpractice liability by recommending or administering the COVID-19 vaccine to pediatric and pregnant patients is pure conjecture, and Plaintiffs do not—and cannot—identify a single fact in support of their position. *E.g.*, Ex. 11, ¶¶ 4, 9 (AAP).[19] A provider might face those consequences if, among other things, she violated the standard of care. *E.g.*, *Mitchell*, 141 F.3d at

[17] *See also, e.g.*, SAC ¶ 106 (ACP); Ex. 18, ¶¶ 11, 30 (ACP); SAC ¶ 107 (APHA); Ex. 19, ¶ 21 (APHA); SAC ¶¶ 109–10 (IDSA); Ex. 14, ¶¶ 7, 10 (IDSA); Ex. 20, ¶¶ 17, 24 (IDSA); SAC ¶ 112 (MPHA); Ex. 21, ¶ 8 (MPHA); Ex. 28, ¶¶ 5, 11 (MPHA); SAC ¶¶ 114, 116 (SMFM); Ex. 17, ¶¶ 2, 10 (SMFM); Ex. 25, ¶¶ 14, 16 (SMFM); Ex. 30 ¶ 8 (SMFM).

[18] This shared clinical decision-making recommendation *encourages* consultation between healthcare providers and their patients about the COVID-19 vaccine; it does not create "barriers" to such consultation. SAC ¶ 104 (AAP). Moreover, this recommendation does not mean the vaccine is "suspect." *Id.* ¶ 105 (AAP); *see* Ex. 11, ¶ 8 (AAP); Ex. 28, ¶¶ 6, 10 (MPHA). Such an inference is unwarranted and would not be fairly traceable to the Directive.

[19] *See also, e.g.*, SAC ¶ 106 (ACP); Ex. 28, ¶¶ 5, 11 (MPHA); SAC ¶ 116 (SMFM); Ex. 25, ¶ 2 (SMFM).

13. But the standard of care reflects the "care and skill of the average practitioner of the medical specialty in question," *id.*, not necessarily what is recommended by ACIP and CDC, *Avalo*, 2013 WL 2631154, at *2. Indeed, Plaintiffs allege that recommending or administering the vaccine to pediatric and pregnant patients—precisely what Plaintiffs' members are doing—*is* the standard of care. *See, e.g.*, Ex. 11, ¶ 9 (AAP). Furthermore, Plaintiffs' theory improperly "rel[ies] on speculation about the unfettered choices made by independent actors not before the courts"—*i.e.*, that state medical boards will bring disciplinary charges or that patients will bring malpractice lawsuits. *All. for Hippocratic Med.*, 602 U.S. at 383 (quoting *Clapper*, 568 U.S. at 414 n.5).

B. Alleged Harm to Medical Practices

The organizational plaintiffs allege various harms to their members' medical practices: (1) time spent overcoming vaccine hesitancy, (2) harm to their doctor-patient relationships, (3) harm based on how insurers cover the vaccine, and (4) needing to treat more COVID-19 patients. None of these theories, however, shows a concrete injury that is fairly traceable to the Directive.

First, Plaintiffs allege the Directive has caused an "uptick in vaccine hesitancy" among patients, which healthcare providers must now spend time addressing in order to overcome. *E.g.*, SAC ¶ 105 (AAP).[20] This theory depends on the premise that the practice of medicine somehow does not include counseling patients regarding the medical care they are receiving. That premise is baseless. Irrespective of the Directive, counseling patients about the COVID-19 vaccine and addressing their concerns is part of being a healthcare provider; it is not an injury that establishes standing. Take the common example of a doctor who gives her patient diet advice. In explaining

[20] *See also, e.g.*, Ex. 11, ¶ 6 (AAP); SAC ¶ 107 (APHA); Ex. 19, ¶ 23 (APHA); Ex. 28 ¶ 12 (MPHA); SAC ¶ 113 (SMFM).

her advice, the 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.

Plaintiffs allege that spending more time counseling certain patients about the vaccine leaves less time for other patients. *E.g.*, SAC ¶ 104 (AAP); Ex. 24, ¶ 13 (AAP); Ex. 26, ¶ 34 (ACP). This is speculative—Plaintiffs have not shown, for example, that their members have had to turn patients away because they are too busy counseling other patients about the vaccine. Moreover, Plaintiffs have not shown that spending time on COVID-19 vaccine counseling necessarily would cause a net financial loss. For example, they do not allege their members cannot be compensated for additional time spent on such counseling, let alone that the Directive prevents such compensation. If a provider chooses not to bill for that time, Ex. 26, ¶ 34 (ACP), any loss of revenue is "self-inflicted" and not fairly traceable to the Directive. *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam).

Second, Plaintiffs allege the Directive has harmed their members' doctor-patient relationships, such as by reducing patients' trust in their doctors. *E.g.*, Ex. 15, ¶ 19 (AAP).[21] But these are paradigmatic abstract injuries that do not support standing. *All. for Hippocratic Med.*, 602 U.S. at 381. Plaintiffs also contend the Directive "dismantle[s] public trust in science- and medical-infrastructure," Ex. 15, ¶ 19 (AAP), and "erod[es] public trust in vaccines," Ex. 21 ¶ 9 (MPHA); Ex. 17, ¶ 14 (SMFM); Ex. 30, ¶¶ 9–10 (SMFM). Those alleged harms, however, are abstract (not concrete) and "generalized grievances" that are not particular to Plaintiffs' members. *All. for Hippocratic Med.*, 602 U.S. at 381 (quotations omitted).

[21] *See also, e.g.*, SAC ¶ 103 (ACP); *id.* ¶ 107 (APHA); *id.* ¶¶ 109–10 (IDSA); *id.* ¶ 113–14 (SMFM); Ex. 17, ¶ 10 (SMFM); Ex. 25, ¶ 16 (SMFM).

Third, Plaintiffs claim their members are harmed by how insurers cover the vaccine, but they do not plausibly allege any concrete injuries (either tangible or intangible) traceable to the Directive. Although Plaintiffs allege some members "face financial harm because some insurers do not cover [the] vaccines,"[22] SAC ¶ 106 (ACP), *the patient* is responsible for the vaccine cost if the insurer will not pay, Ex. 18, ¶ 31 (ACP). The *Directive* does not impose additional costs on Plaintiffs' members. And Plaintiffs can only speculate how third-party insurers will "exercise their discretion" in the future regarding whether to cover the vaccine for particular patients. *Clapper*, 568 U.S. at 401, 412, 414 n.5; *see Simon*, 426 U.S. at 42–43.

Dr. Galluci claims her office "spend[s] excessive time navigating unclear insurance coverage rules," SAC ¶ 105 (AAP); Ex. 11, ¶ 8, but that is a product of third-party insurers' practices, *not* the Directive. *See All. for Hippocratic Med.*, 602 U.S. at 383; *Clapper*, 568 U.S. at 414 n.5. And although Dr. Scott-Vernaglia claims there was "a period of just under two weeks" when her office paused its purchase of pediatric COVID-19 vaccines due to uncertain insurance coverage, that office has resumed purchases. Ex. 15, ¶ 13 (AAP). This short-term pause is not a cognizable injury, let alone the *future* injury required to seek prospective relief. *All. for Hippocratic Med.*, 602 U.S. at 381. It also is not traceable to the Directive because it is a "self-inflicted" harm in response to third-party insurers' practices. *Pennsylvania*, 426 U.S. at 664.[23]

The Columbus Department of Public Health (the "Department") alleges the Directive "prevents [it] from purchasing discounted Covid-19 vaccines" through the Vaccines for Children program. SAC ¶ 108 (APHA); *see* Ex. 27, ¶¶ 30–31 (APHA). But the Department cannot support

[22] However, Dr. Hopkins is "unaware as of the date of [his] declaration whether a patient's insurance has denied" coverage. Ex. 26, ¶ 30 (ACP).

[23] Similarly, any harm to patients who did not receive the vaccine during the two-week pause and returned to the office to receive it, Ex. 15, ¶¶ 13–15 (AAP), is neither a future injury nor traceable to the Directive. Moreover, doctors cannot assert harm to patients. *See infra* p. 20.

APHA's standing because it is not an independent legal entity that can sue. *See* Ex. 27, ¶ 29 (APHA); *Elkins v. Summit County, Ohio,* No. 5:06–CV–3004, 2008 WL 622038, at *6 (N.D. Ohio Mar. 5, 2008) ("Administrative units of a local government, such as a municipal police department, are not *sui juris* because they lack the power to sue, and cannot be sued absent positive statutory authority.").[24] Moreover, the Directive did not change the discounted rates for ordering pediatric COVID-19 vaccines through the Vaccines for Children Program, since CDC still recommends the vaccine for pediatric patients through shared clinical decision-making, Ex. B at 5. Thus, the Columbus Department of Public Health has not plausibly shown a concrete injury traceable to the Directive.

Finally, Plaintiffs speculate that unvaccinated people "will face increased illness" and "more severe illness," which will "require[] more of [doctors'] time and resources to treat." *E.g.*, Ex. 26, ¶ 35 (ACP).[25] But the Supreme Court rejected this standing theory in *Alliance for Hippocratic Medicine*, which held that doctors did not show standing by claiming the challenged action would lead to increased illness and require them to treat patients with that illness rather than other patients, because "[t]he causal link between [the challenged] actions and those alleged injuries is too speculative or otherwise too attenuated to establish standing." 602 U.S. at 390.

Drs. Scott-Vernaglia and Hopkins speculate that an increased number of COVID-19 patients seeking treatment from them will put them "at increased risk for contracting COVID-19" and transmitting it to their family members. Ex. 15, ¶ 23 (AAP); *see* Ex. 26, ¶ 36 (ACP). But that theory adds yet another layer of speculation to an already-speculative causal chain. *See All. for Hippocratic Med.*, 602 U.S. at 390.

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[24] *See Nieves v. City of Cleveland,* 153 F. App'x 349 (6th Cir. 2005); *Richardson v. Grady*, No. 77381, 2000 WL 1847588, at *2 (Ohio Ct. App. Dec. 18, 2000).

[25] *See* Ex. 22, ¶ 23 (AAP); Ex. 31, ¶ 20 (AAP); Ex. 27, ¶ 28 (APHA).

C. Alleged Injuries to Members' Patients

Plaintiffs attempt to assert injuries to their members' patients, 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 a patient "delays or refus[es] to receive the COVID-19 vaccination," Ex. 13, ¶ 12 (AAP),[26] and later develops severe COVID-19, that is not an injury to the healthcare provider.[27] Similarly, a doctor is not injured if her patient has difficulty accessing the vaccine. *E.g.*, SAC ¶ 103 (ACP).[28] Nor is a doctor injured by a patient's "confusion," "uncertainty," or "fear" about vaccine access or "CDC's COVID-19 recommendations . . . for children." *E.g.*, SAC ¶ 111 (IDSA); Ex. 13 (AAP), ¶ 15; Ex. 28 ¶ 6 (MPHA). Moreover, those feelings are abstract harms that are not even cognizable injuries to the patients, and they rest on speculation about how healthcare providers will exercise their discretion to administer the vaccine or how insurance companies will exercise their direction to cover it. *See All. for Hippocratic Med.*, 602 U.S. at 381, 393 n.5; *Clapper*, 568 U.S. at 401, 412, 414 n.5; *Simon*, 426 U.S. at 42–43.

CONCLUSION

For these reasons, the Court should dismiss this case for lack of subject-matter jurisdiction.

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[26] *See* Ex. 11, ¶ 9 (AAP); Ex. 26, ¶ 33 (ACP); Ex. 28 ¶¶ 9, 11 (MPHA); SAC ¶ 114 (SMFM); Ex. 17, ¶¶ 2, 9 (SMFM); Ex. 30, ¶ 7 (SMFM).

[27] Plaintiffs allege some patients are "refus[ing] a myriad of routine vaccinations" and so face a "severe risk of serious illness." Ex. 13, ¶ 13 (AAP); *see* Ex. 28, ¶ 8 (MPHA); Ex. 17, ¶ 14 (SMFM); Ex. 25, ¶ 21 (SMFM); Ex. 30, ¶¶ 9–10 (SMFM). That is not an injury to healthcare providers and also is not traceable to the Directive, which relates only to the COVID-19 vaccine.

[28] *See also, e.g.*, Ex. 26, ¶ 32 (ACP); SAC ¶ 111 (IDSA); Ex. 14, ¶ 12 (IDSA); Ex. 16, ¶¶ 10, 13 (IDSA); Ex. 17, ¶ 9 (SMFM).

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Respectfully submitted,

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