UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 25-11916-BEM**
ROBERT F. KENNEDY, JR., *et al.*,	)	
Defendants.	)	

MEMORANDUM AND ORDER ON DEFENDANTS' MOTION TO DISMISS

MURPHY, J.

This case concerns various actions the Government has taken since May 2025 to alter its recommendations related to the COVID vaccine and to replace members of the Advisory Committee on Immunization Practices, the committee that provides recommendations to the Centers for Disease Control and Prevention on vaccinations and immunization schedules. Plaintiffs challenge these actions as arbitrary and capricious in violation of the Administrative Procedure Act and contend that the reconstitution of the Advisory Committee on Immunization Practices violated the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et seq*. Before the Court now is Defendants' motion to dismiss. For the reasons set forth below, the Court will deny the motion.

I. Background

A. Factual Background

The following summary is drawn from the third amended complaint, and all well-pleaded facts are accepted as true for purposes of the motion to dismiss. *See McKee v. Cosby*, 874 F.3d

54, 59 (1st Cir. 2017). Additionally, 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 official government websites, *Gent v. CUNA Mut. Ins. Soc'y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010).

1. The Parties

Plaintiffs are seven professional medical organizations (collectively, "Organizational Plaintiffs"),[1] and three individuals (collectively, "Individual Plaintiffs," and with Organizational Plaintiffs, "Plaintiffs").[2]

Defendants are the U.S. Department of Health and Human Services ("HHS"); the Secretary of HHS, Robert F. Kennedy, Jr. ("Secretary Kennedy"); the Centers for Disease Control and Prevention (the "CDC"); the Acting Director of the CDC, Jim O'Neill ("Director O'Neill"); and Does 1 through 50.[3]

2. Statutory Framework

Congress requires the Secretary of HHS to conduct an "evidence-based campaign" aimed at combating misinformation and increasing rates of vaccination. 42 U.S.C. § 245(a). To assist in this public health mission, the CDC relies on the Advisory Committee on Immunization Practices ("ACIP"). Dkt. 139 ("Compl." or "Complaint") ¶¶ 29–32.[4] ACIP, a federal advisory committee

[1] Those organizations are the American Academy of Pediatrics ("AAP"), the American College of Physicians, Inc. ("ACP"), the American Public Health Association ("APHA"), the Infectious Diseases Society of America ("IDSA"), the Massachusetts Public Health Association d/b/a the Massachusetts Public Health Alliance ("MPHA"), the Society For Maternal-Fetal Medicine ("SMFM"), and the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP").

[2] Jane Doe 1, Jane Doe 2, and Jane Doe 3. Individual Plaintiffs were each granted leave to proceed under pseudonyms on July 8, 2025, Dkt. 22; July 24, 2025, Dkt. 66; and September 5, 2025, Dkt. 105, respectively.

[3] Plaintiffs allege that Does 1 through 50 are each "responsible in some manner for the conduct alleged here and for the injuries suffered by Plaintiffs." Dkt. 139 ("Compl.") ¶ 26.

[4] *See also General Committee-Related Information*, CDC, (Aug. 12, 2025), https://www.cdc.gov/acip/about/index.html [https://perma.cc/36Y9-X69B].

constituted under the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et seq.* ("FACA"), is responsible for developing and issuing evidence-based recommendations for the use of vaccines in the United States. Compl. ¶¶ 29–34.[5] In 2018, ACIP adopted the Evidence to Recommendation ("EtR") framework "to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation."[6] *Id.* ¶ 60. These recommendations for whether and how vaccines are listed on the CDC's immunization schedules are provided to the CDC Director to decide whether to adopt and publish them in the official immunization schedules, which guide healthcare providers and state public health authorities. *Id.* ¶¶ 29–34.

3. May 2025 Directive

On May 27, 2025, Secretary Kennedy publicly announced, via video statement and a backdated directive, an order for the CDC to remove from the routine CDC Schedules the recommendation that pregnant women and "healthy" children receive the COVID vaccine (the "May 2025 Directive"). *Id.* ¶¶ 6, 32. The CDC subsequently designated the vaccine for these

[5] *See also supra* note 4.

[6] *ACIP Evidence to Recommendation User's Guide*, CDC, at 3 (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf [https://perma.cc/C7ER-N2A6].

groups as "Shared Clinical Decision Making" ("SCDM").[7] *Id.* ¶¶ 6, 64. Plaintiffs allege that this action was taken *sua sponte*, without consulting CDC leadership, ACIP, or any public health data, and without utilizing the allegedly mandatory EtR framework. *Id.* ¶¶ 6, 65–67. The change from a routine recommendation to SCDM—a designation that Plaintiffs claim is typically reserved for vaccines where the risk/benefit analysis is less clear or complex, especially for certain age groups—allegedly led to immediate, widespread confusion among healthcare providers and patients. *E.g.*, *id.* ¶¶ 2, 21, 84–85, 87, 89, 94, 98–103.

4. ACIP Reconstitution

On June 9, 2025, Secretary Kennedy terminated all 17 existing members of ACIP, effective immediately. *Id.* ¶¶ 8, 47–48. Plaintiffs describe Secretary Kennedy's explanation for the terminations as "pretextual."[8] *Id.* ¶ 50. Following this mass termination, Secretary Kennedy appointed new members through a process that Plaintiffs allege circumvented the established,

[7] According to the CDC, "[u]nlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are 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*, CDC (Jan. 7, 2025) https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html [https://perma.cc/3QBY-RXFN]. The CDC had previously designated only four other vaccines as SCDM. In those instances, the designation was made after application of the EtR framework and limited to specific age groups with certain risk characteristics. Compl. ¶¶ 7, 75; Dkt. 146-17 ¶ 10 ("For example, when the ACIP considered expanding the HPV (human papillomavirus) vaccine use to adults between 27 and 45 years of age, the EtR framework indicated uncertainties related to the public health problem and acceptability in this age group, variable individual benefits, and high costs associated with use of resources if the recommendation was routine. Accordingly, the HPV vaccine was designated as SCDM for adults between 27 to 45 years of age."). On those four prior occasions, Plaintiffs allege that the "CDC has issued detailed explanation of its underlying rationale and guidance on healthcare providers' engagement in SCDM with patients," explanation that was not similarly issued for the COVID vaccine. Compl. ¶¶ 7, 75.

[8] Secretary Kennedy described the terminated ACIP members as having "been plagued with persistent conflicts of interest," as having "become little more than a rubber stamp for any vaccine," as being "corrupt," and as "directly work[ing] for the vaccine industry." Compl. ¶ 49 (alteration in original) (quoting Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025, 4:00 PM), https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112). Plaintiffs allege that such allegations are demonstrably false, as the referenced reports analyzed "years in which none of the 17 terminated members were on the ACIP" and that research concluded that ACIP conflicts were at historically low levels for years preceding the terminations. *Id.* ¶ 50 (quoting *Conflicts of Interest on CDC Vaccine Panel Were at Historic Lows Before RFK Jr. Dismissal*, U. S. CAL. SCHAEFFER CTR. (Aug. 18, 2025), https://schaeffer.usc.edu/research/cdc-acip-vaccine-conflicts-rfk-jr/ [https://perma.cc/X4RD-3XTB]).

rigorous application and vetting procedures. *Id.* ¶¶ 50–51. Plaintiffs assert that the new appointments were based on the candidates' alignment with Secretary Kennedy's "anti-vaccine agenda" and that the new members lacked the qualifications or experience previously required for membership, thereby compromising the scientific integrity and objectivity of the committee.[9] *Id.* ¶¶ 8, 45, 52–56, 76. Plaintiffs contend that the resulting ACIP is no longer "fairly balanced" as required by FACA. *Id.* ¶ 8. Furthermore, Secretary Kennedy terminated the participation of members of liaison organizations, including some members of Organizational Plaintiffs (specifically, AAP and ACP), from ACIP workgroups on the stated basis that liaison organizations constitute "special interest groups."[10] *Id.* ¶ 57.

5. Threatened Legal Liability

Plaintiffs contend that, in response to Defendants' changes to the immunization schedule, they "have had to divert resources to develop new infrastructures, processes, and guidance to fulfill their mission to their members." *Id.* ¶ 86. This includes counseling Organizational Plaintiffs' member-doctors who have been directly impacted, *see e.g.*, *id.*; Dkt. 118 ¶¶ 4–6, and publishing their own immunization schedules, Compl. ¶ 86. The same day that AAP published its own immunization schedule, Secretary Kennedy stated: "AAP today released its own list of corporate-friendly vaccine recommendations . . . AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." *Id.* (quoting Robert F. Kennedy, Jr. (@SecKennedy),

[9] Plaintiffs further allege that Secretary Kennedy required ACIP members to be registered Republican or Individual and have made no prior public criticisms of the President or Secretary Kennedy. Compl. ¶ 52.

[10] Plaintiffs state that liaison members do "important work undertaking detailed evidence reviews of the safety and effectiveness of vaccines that helps to inform the group's votes." Compl. ¶ 57 (quoting Brenda Goodman, *HHS further constrains certain vaccine advisors to the CDC, limiting their input in evidence reviews*, CNN (Aug. 1, 2025), https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc [https://perma.cc/D2GQ-2ZNH]).

X (Aug. 19, 2025, 5:17 PM), https://x.com/SecKennedy/status/1957914911415153107 [https://perma.cc/RRE6-V8Y5]).

6. ACIP September 2025 Vote

In September 2025, the newly constituted ACIP voted to change the COVID vaccine recommendation for adults under the age of 65 from a routine recommendation to an SCDM designation. *Id.* ¶ 73. Plaintiffs allege that this determination failed to follow the required EtR framework, lacked a clear evidence-based justification, and did not include the necessary detailed implementation guidance that the CDC typically issues to accompany an SCDM designation. *Id.* ¶¶ 74–82. Plaintiffs also allege that this action further compounded confusion and diminished the utility of the national immunization schedule. *E.g.*, *id.* ¶¶ 2, 21, 84–85, 87, 89, 94, 98–103.

B. Procedural Background

Plaintiffs filed suit on July 7, 2025. Dkt. 1. In the Complaint, Plaintiffs allege that Defendants' changes to the vaccine recommendations and reconstitution of ACIP (collectively, the "Challenged Actions") violate section 706(2)(A) of the Administrative Procedure Act ("APA") because they were arbitrary and capricious (Count I), and that the reconstitution of ACIP violates section 706(2)(A) of the APA because it was contrary to law (Count II). Compl. ¶¶ 108–126.[11] On September 3, 2025, Defendants moved to dismiss the Complaint under Rules 12(b)(1) and 12(b)(6). Dkt. 144; *see also* Dkt. 145 ("Mem."); Dkt. 146 ("Opp."); Dkt 146 ("Reply"). The Court held a hearing on December 17, 2025, and took the matter under advisement.

[11] In light of the Court's allowance of the Plaintiffs' filing of the third amended complaint, the Court denies as moot Defendants' previously filed motion to dismiss, Dkt. 102.

II. Standard of Review

With respect to a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(1), the plaintiff bears the burden of establishing subject matter jurisdiction. *Justiniano v. Soc. Sec. Admin.*, 876 F.3d 14, 21 (1st Cir. 2017). To survive a motion to dismiss under Fed. R. Civ. P. 12(b)(6), a complaint must contain sufficient factual matter, disregarding all "conclusory" statements, to "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). "When faced with motions to dismiss under both 12(b)(1) and 12(b)(6), a district court, absent good reason to do otherwise, should ordinarily decide the 12(b)(1) motion first." *Katz v. Pershing, LLC*, 806 F. Supp. 2d 452, 456 (D. Mass. 2011), *aff'd*, 672 F.3d 64 (1st Cir. 2012). Whether a motion is brought under Rule 12(b)(1) or 12(b)(6), "the reviewing court must take all of plaintiff's allegations as true and must view them, along with all reasonable inferences therefrom, in the light most favorable to plaintiff." *Verlus v. Experian Info. Sols., Inc.*, 2025 WL 836588, at *1 (D. Mass. Mar. 17, 2025). Although the First Circuit has held that the Rule 12(b)(6) plausibility standard ordinarily "does not apply to a complaint for judicial review of final agency action," *Atieh v. Riordan*, 727 F.3d 73, 76 (1st Cir. 2013),[12] the First Circuit has recognized an exception where the Government alleges that the plaintiff's claim is legally flawed, *id.* at 76 n.4.

III. Jurisdiction

The Constitution gives courts power to hear only "Cases" and "Controversies." U.S. CONST. art. III, § 2, cl. 1. "Essential to defining this fundamental limitation on 'the judiciary's proper role in our system of government' are the doctrines of standing and mootness." *Nat'l Ass'n of Gov't Emps., Inc. v. Yellen*, 120 F.4th 904, 909 (1st Cir. 2024) (quoting *Hein v. Freedom From*

[12] Not all circuits follow this approach. In the D.C. Circuit, for example, courts "regularly review motions to dismiss APA actions under the plausibility standard." *Asante v. Azar*, 436 F. Supp. 3d 215, 222 n.2 (D.D.C. 2020).

Religion Found., Inc., 551 U.S. 587, 598 (2007)). "These 'intertwined doctrines' mandate that a plaintiff have a 'personal stake' at the outset of an action (standing) and throughout all stages of review (mootness)." *Id.* (citations omitted). Defendants challenge whether Plaintiffs have satisfied both of these requirements.

A. Standing

A plaintiff's standing to sue is "part of the common understanding of what it takes to make a justiciable case." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 102 (1998). Therefore, "the absence of standing sounds the death knell for a case." *Microsystems Software, Inc. v. Scandinavia Online AB*, 226 F.3d 35, 39 (1st Cir. 2000). Establishing standing requires a showing that a plaintiff "has suffered, or will suffer, an injury that is '[1] concrete, particularized, and actual or imminent; [2] fairly traceable to the challenged action; and [3] redressable by a favorable ruling.'" *Murthy v. Missouri*, 603 U.S. 43, 57 (2024) (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013)). This requirement prevents "federal courts [from] operat[ing] as an open forum for citizens 'to press general complaints about the way in which government goes about its business.'" *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 393–94 (2024) (quoting *Allen v. Wright*, 468 U.S. 737, 760 (1984)).

Importantly, "standing in no way depends on the merits of the plaintiff's contention that particular conduct is illegal." *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 734 (1st Cir. 2016) (quoting *Warth v. Seldin*, 422 U.S. 490, 500 (1975)). "For standing purposes, we accept as valid the merits of [plaintiff's] legal claims." *Fed. Election Comm'n v. Cruz*, 596 U.S. 289, 298 (2022). The "only question is, putting the merits aside, whether [plaintiffs] plausibly allege[] [they were] injured under [their] theory of the underlying legal claim." *Laufer v. Acheson Hotels, LLC*, 50 F.4th 259, 267 (1st Cir. 2022), *vacated and remanded on other grounds*, 601 U.S. 1 (2023). "[I]f at least one plaintiff has standing, the suit may proceed." *Capen v. Campbell*, 134 F.4th 660, 668

(1st Cir. 2025) (quoting *Biden v. Nebraska*, 600 U.S. 477, 489 (2023)). Defendants contend that no Plaintiff has standing to bring this case. Mem. at 14–23. The Court disagrees.

1. Organizational Plaintiffs

Like an individual plaintiff, "[a]n organization with individual members may establish Article III standing by satisfying the three elements of such standing based on an 'injury in fact' of its own." *Doe v. Trump*, 157 F.4th 36, 47 (1st Cir. 2025) (quoting *All. for Hippocratic Med.*, 602 U.S. at 393–94). An organization may also "establish 'associational standing' to sue in a 'representational capacity.'" *Id.* (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). Defendants contend that Organizational Plaintiffs have not established either form of standing.[13]

a. Organizational Standing

Organizational standing allows an organization to sue when, like an individual, it has "'alleged . . . a personal stake in the outcome of the controversy' as to warrant [its] invocation of federal-court jurisdiction." *Louis v. Saferent Sols., LLC*, 685 F. Supp. 3d 19, 32 (D. Mass. 2023) (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378–79 (1982)). An organization must "show that the defendant's actions cause a 'concrete and demonstrable injury to the organization's activities' that is 'more than simply a setback to the organization's abstract social interests.'" *Id.* (quoting *Nat'l Ass'n of Consumer Advocs. v. Uejio*, 521 F. Supp. 3d 130, 142 (D. Mass. 2021)). This is "'not a demanding standard,' as 'only a perceptible impairment of an organization's activities is necessary for there to be an injury in fact.'" *Id.* (quoting *Nat'l Ass'n of Consumer Advocs.*, 521 F. Supp. 3d at 142). Defendants contend that, of the Organizational Plaintiffs, only

[13] Neither party argues that the standing analysis differs for each claim, and the Court see no reason to analyze Plaintiffs' standing for each claim separately.

AAP has purported to demonstrate organizational standing, Mem. at 17, and that AAP has in turn failed to establish an injury in fact, *id.* at 17–18.

AAP is a "professional organization for pediatric medicine" and seeks to promote children's health. Compl. ¶ 12. Founded in 1930, its stated mission is "to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults." Dkt. 146-5 ¶ 6. Among various theories of harm, AAP has alleged that it has had to devote significant time and resources to counseling many of AAP's 67,000 members in light of the Challenged Actions. Compl. ¶ 86; Dkt. 118-9 ¶¶ 4–6. This work has allegedly come at the cost of AAP's diverting resources away from its usual tasks and initiatives aimed at children's health. Dkt. 118-9 ¶ 9. This is sufficient injury to AAP's core business activities for the purposes of organizational standing.

Despite Defendants' argument to the contrary, the Supreme Court's decision in *Alliance for Hippocratic Medicine* does not suggest a different result. In *Alliance for Hippocratic Medicine*, the "plaintiff doctors and medical associations" sought to challenge "FDA's regulations [that] appl[ied] to doctors prescribing mifepristone and to pregnant women taking mifepristone," despite not prescribing or using mifepristone themselves. 602 U.S. at 385. Thus, the plaintiffs challenged only FDA regulations that permitted *others* to prescribe mifepristone but did not implicate the plaintiffs' own practices. *Id.* The Supreme Court explained that "general legal, moral, ideological, and policy concerns do not suffice on their own to confer Article III standing." *Id.* Further, the Supreme Court held that the organizations could not manufacture standing simply because they incurred costs in objecting to an action with which they disagreed on ideological grounds. *Id.* at 394 ("[A]n organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate

against the defendant's action."). Instead, such costs must have been incurred because a defendant's "actions directly affected and interfered with [the organization's] core business activities." *Id.* at 395 (citing *Havens*, 455 U.S. at 379).

Defendants argue that AAP's "educational and advocacy work" to respond to the Challenged Actions is merely "a continuation of [its] 'ongoing activities.'" Mem. at 17. But AAP has alleged more than that. Similarly to *Havens*, AAP alleges that its ability to provide its regular programming and resources to both its members and others has been impaired by the need to specifically address the Challenged Actions and to divert resources in response to Defendants' actions. *Havens*, 455 U.S. at 379. AAP—and additional Organizational Plaintiffs[14]—has alleged that it needed to divert resources away from its usual business activities because of the Challenged Actions, including by counseling member-doctors who have been directly impacted (such as through direct counseling and webinars). Compl. ¶ 86; Dkt. 118-9 ¶¶ 4–6; *cf. Friends of the Earth v. Sanderson Farms, Inc.*, 992 F.3d 939, 943 (9th Cir. 2021) ("Once [the defendant's] misleading advertisements were brought to the attention of the [plaintiff organizations], they simply continued doing what they were already doing—publishing reports on and informing the public of various companies' antibiotic practices."). Furthermore, Defendants mischaracterize AAP's immunization schedules by calling them mere "educational and advocacy work." Mem. at 17. AAP "[maintains] and publi[shes] . . . the AAP Red Book [containing] . . . AAP's immunization recommendations" as part of its efforts "to support the professional needs of its members." Dkt. 146-5 ¶ 8. AAP's recommendations to physicians on vaccine use predate the creation of

[14] *See, e.g.*, Compl. ¶ 100 (detailing SMFM's efforts to counsel its members in response to the Challenged Actions); Dkt. 146-34 ¶¶ 17–18 (same); Dkt. 146-19 ¶ 27 (detailing APHA's efforts to counsel its members in response to the Challenged Actions); Dkt. 146-32 ¶ 22 (detailing MPHA's efforts to counsel its members in response to the Challenged Actions); Dkt. 146-39 ¶ 9 (detailing how SMFM members sought assistance from SMFM after the May 2025 Directive was issued).

ACIP by more than 25 years. Compl. ¶ 27 (citing L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 405 (Jan. 2015), https://pubmed.ncbi.nlm.nih.gov/25446820/). There is no basis for the Court at this juncture to discredit that characterization or discount the importance such work has on the organization's efforts to support its members in furtherance of its mission.

In sum, this type of diversion of resources goes beyond mere advocacy as to be sufficient for organizational standing.[15] *See, e.g.*, *Nat'l Coal. Against Violent Athletes v. Dep't of Educ.*, 2020 WL 13876913, at *4 (D. Mass. Dec. 3, 2020) (holding that the organizational plaintiff had standing in part because the organization had pointed to clients who were seeking its legal help for cases before the U.S. Department of Education and had alleged that the guidance documents it was challenging would disfavor its clients in those cases, thus frustrating its advocacy mission and diverting its resources); *African Cmtys. Together v. Trump*, 2019 WL 5537231, at *3–4, *4 n.5 (D. Mass. Oct. 25, 2019) (finding that the organizational plaintiff had alleged an injury in fact to challenge the President's decision to terminate Deferred Enforced Departure for Liberians based on allegations that the organization diverted resources to protect those particular immigrants facing imminent removal). That AAP's counseling of its members involved issues of a similar nature to the organization's prior work merely supports the conclusion that the Challenged Actions "directly affected and interfered with [AAP's] core business activities." *All. for Hippocratic Med.*, 602 U.S. at 395.

[15] Notably, Plaintiffs plausibly allege injuries that are more than just an "effect of [a challenged action] on the organizations' lobbying activities" or purely the impairment of its "issue-advocacy." *Equal Means Equal v. Ferriero*, 3 F.4th 24, 30 (1st Cir. 2021) (alteration in original) (quoting *People for the Ethical Treatment of Animals v. U.S. Dep't of Agric.*, 797 F.3d 1087, 1093–94 (D.C. Cir. 2015)) (cited in Mem. at 17).

Simply put, there is no question that, but for the change in vaccine recommendations and ACIP appointments, AAP would not have expended the resources that it did, such as to counsel its members. Again, this is "not a demanding standard" and requires "only a perceptible impairment of an organization's activities." *Louis*, 685 F. Supp. 3d at 32 (quoting *Nat'l Ass'n of Consumer Advocs.*, 521 F. Supp. 3d at 142). AAP has demonstrated organizational standing to make both claims.[16]

b. Associational Standing

Having concluded that at least one Organizational Plaintiff has demonstrated organizational standing for each claim, the Court need not address whether any Organizational Plaintiff has associational standing to decide the motion under Rule 12(b)(1). *See, e.g.*, *President & Fellows of Harvard Coll. v. U.S Dep't of Health & Hum. Servs.*, 798 F. Supp. 3d 77, 114 (D. Mass. 2025). But "[b]ecause the Plaintiffs' standing theories may affect the relief this Court can offer, this Court proceeds to analyze [associational] standing as well." *Am. Ass'n of Univ. Professors v. Rubio*, 780 F. Supp. 3d 350, 379 (D. Mass. 2025).

"[A]n association may have standing solely as the representative of its members even in the absence of injury to itself." *Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp.*, 799 F.2d 6, 10 (1st Cir. 1986). Associational standing allows an organization to sue on behalf of its members when "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt*, 432 U.S. at 343; *see also In re Fin. Oversight & Mgmt. Bd. for P.R.*, 110 F.4th

[16] "So long as one plaintiff has standing to seek a particular form of global relief, the court need not address the standing of other plaintiffs seeking the same relief." *Comfort v. Lynn Sch. Comm.*, 418 F.3d 1, 11 (1st Cir. 2005) (en banc). Thus, the Court need not rule on whether the remaining Organizational Plaintiffs have organizational standing to sue at this stage.

295, 308 (1st Cir. 2024). Only one member of an organization need have individual standing for that organization to satisfy the first *Hunt* factor. *See Draper v. Healey*, 827 F.3d 1, 3 (1st Cir. 2016). Defendants challenge only the first element, contending that Organizational Plaintiffs have not established standing because they have failed to establish that any one of the organizations' members has suffered or will suffer injury sufficient for individual standing.[17] Mem. at 18–23.

i. Financial Injury

Organizational Plaintiffs first contend that their members have shown injury-in-fact through the financial injuries they have suffered as a result of the Challenged Actions. Opp. at 18. Specifically, Organizational Plaintiffs argue that their members have suffered financial harm that "includ[es] engaging in SCDM conversations without compensation, absorbing the full cost of purchasing vaccine doses that go unused due to the Directive's suppression of vaccine uptake, and being able to see fewer patients per day due to the increased amount of time spent with patients discussing vaccines." *Id.* (citing to declarations from members). Defendants argue that such injuries are not "fairly traceable" to Defendants because the injuries depend on the independent actions of various third parties, including insurers, patients, and vaccine manufacturers.[18] Mem. at 19–21; Reply at 10–11.

The Supreme Court has recently reiterated the guidelines that frame a causation (and redressability) analysis where, as here, an unregulated plaintiff asserts standing based on the actions of a regulated third party. "When the plaintiff is not the object of a government regulation[,] causation and redressability often depend on how regulated third parties not before

[17] To reiterate, establishing standing requires a showing that a plaintiff "has suffered, or will suffer, an injury that is '[1] concrete, particularized, and actual or imminent; [2] fairly traceable to the challenged action; and [3] redressable by a favorable ruling.'" *Murthy*, 603 U.S. at 57 (quoting *Clapper*, 568 U.S. at 409).

[18] Defendants do not argue that the financial injuries as alleged are insufficiently "concrete, particularized, and actual or imminent." *Murthy*, 603 U.S. at 57 (quoting *Clapper*, 568 U.S. at 409).

the court will act in response to the government regulation or judicial relief." *Diamond Alt. Energy, LLC v. Env't Prot. Agency*, 606 U.S. 100, 112 (2025). In such a scenario, "[c]ourts must distinguish the 'predictable' from the 'speculative' effects of government action or judicial relief on third parties." *Id.* (quoting *All. for Hippocratic Med.*, 602 U.S. at 383). The Supreme Court explained that "[w]ith respect to causation (and redressability), a court must conclude that third parties will likely react to the government regulation (or judicial relief) in predictable ways that will likely cause (or redress) the plaintiff's injury." *Id.* (cleaned up) (quoting *All. for Hippocratic Med.*, 602 U.S. at 383).

Although Defendants argue that *Diamond Alternative Energy* involved a much more "straightforward" chain of causation, Reply at 13, the Court concludes that Plaintiffs' theory of causation is sufficiently traceable to Defendants' actions to survive a motion to dismiss. It is more than mere speculation how relevant third parties will (and did) react to Defendants' changes in vaccine recommendations. For standing purposes, it was certainly predictable that the changes in recommendations would and will cause insurers to change their billing for the COVID vaccine. *See Diamond Alt. Energy*, 606 U.S. at 112 ("[A] court must conclude that third parties will likely react to the government regulation . . . in predictable ways that will likely cause (or redress) the plaintiff's injury." (cleaned up) (quoting *All. for Hippocratic Med.*, 602 U.S. at 383)); *see also Weaver's Cove Energy, LLC v. R.I. Coastal Res. Mgmt. Council*, 589 F.3d 458, 467 (1st Cir. 2009) ("The plaintiff need not show that 'the defendant's actions are the very last step in the chain of causation' for the injury." (quoting *Bennett v. Spear*, 520 U.S. 154, 169 (1997))); *cf. All. for Hippocratic Med.*, 602 U.S. at 385–86 ("Because the plaintiffs [did] not prescribe, manufacture, sell, or advertise mifepristone or sponsor a competing drug, the plaintiffs suffer[ed] no direct monetary injuries from FDA's actions relaxing regulation of mifepristone."). As such, because

the billing changes flow directly from the changes in recommendations, the financial injuries from those changes are fairly traceable to Defendants' actions. *See Weaver's Cove*, 589 F.3d at 467–68 (holding that plaintiff had standing because defendant's actions "directly affected" the later regulatory process that required defendant's actions, even if other barriers still remained). This would be sufficient to confer individual standing for the member-doctors, and is thus sufficient to confer associational standing for Organizational Plaintiffs to make both claims.

ii. Threat of Legal Action

Additionally, Plaintiffs argue that Secretary Kennedy's threat of legal action constitutes sufficient injury to confer standing on Organizational Plaintiffs' members. Opp. at 19. Defendants contend that "administering the vaccine to a patient is not 'contrary to' CDC's recommendation that patients and providers discuss the vaccine" and thus any legal liability "is entirely speculative." Reply at 13. In essence, Defendants argue that there is no real legal risk, and so any perceived threat of legal action is illusory.

Defendants misstate the inquiry. It does not matter that, according to Defendants, any litigation against a doctor for administering the COVID vaccine would fail. Instead, it is the very clear threat that such an action would be brought in the first place that creates harm. *See 303 Creative LLC v. Elenis*, 600 U.S. 570, 588–89, 597 (2023) (holding that wedding website designer who preemptively proclaimed she would not design a website for a same-sex couple had standing even though no same-sex couple had tried to engage her services because a credible threat of legal consequences existed). If Organizational Plaintiffs' member-doctors follow AAP's recommended immunization schedule and recommend the COVID vaccine in a manner that "diverge[s] from the CDC's official list"—which is plausibly understood in context as recommending the COVID vaccine in the first place—then based on Secretary Kennedy's statement, those doctors could face

"liability under the 1986 Vaccine Injury Act."[19] Compl. ¶ 86 (quoting Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, 5:17 PM), https://x.com/SecKennedy/status/1957914911415153107 [https://perma.cc/RRE6-V8Y5]). That the CDC's recommendations changed again in September 2025 merely adds to the confusion. Simply put, Defendants' focus on the success of any potential legal action does not diminish Secretary Kennedy's credible threat of the initiation of such legal action in the first place.[20] This threat is sufficient to confer standing.

2. Individual Plaintiffs

Defendants argue that Individual Plaintiffs have not alleged harms that are concrete and particularized, and that all of the harms alleged are past harms that fail to confer standing for prospective relief. Mem. at 15–17. However, the Court need not resolve this dispute at the current juncture, having determined that Organizational Plaintiffs have standing to assert both claims. *See, e.g.*, *Town of Chester v. Laroe Estates, Inc.*, 581 U.S. 433, 439–40 (2017) ("[W]hen there are multiple plaintiffs[,] [a]t least one plaintiff must have standing to seek each form of relief requested in the complaint."); *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 264 & n.9 (1977) ("[We] have at least one individual plaintiff who has demonstrated standing . . . . Because of the presence of this plaintiff, we need not consider whether the other plaintiffs have standing to maintain the suit."); *Capen*, 134 F.4th at 668 ("[I]f at least one plaintiff has standing, the suit may proceed." (quoting *Biden*, 600 U.S. at 489)). Consequently, even if Individual

[19] Amicus Curiae Defend Public Health further details open questions of liability for pharmacists who administer the COVID vaccine. *See* Dkt. 155-1 at 16–22.

[20] Tellingly, Defendants do not attempt to disavow Secretary Kennedy's threats. *See 303 Creative LLC v. Elenis*, 6 F.4th 1160, 1174 (10th Cir. 2021) ("Although not dispositive, non-disavowal of future enforcement remains a relevant factor for courts to consider in determining standing."), *rev'd on other grounds*, 600 U.S. 570 (2023) (upholding 10th Circuit's decision with respect to standing analysis).

Plaintiffs lack standing, the presence of Organizational Plaintiffs is sufficient to allow the claims to proceed.

B. Mootness

"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) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)). "The Supreme Court has placed the 'heavy burden of persuasion' with respect to mootness on the party advocating for it." *Town of Barnstable v. O'Connor*, 786 F.3d 130, 142 (1st Cir. 2015) (quoting *United States v. Concentrated Phosphate Exp. Ass'n*, 393 U.S. 199, 203 (1968)). "[T]he key question 'is whether the relief sought would, if granted, make a difference to the legal interests of the parties (as distinct from their psyches, which might remain deeply engaged with the merits of the litigation).'" *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 8 (1st Cir. 2021) (quoting *Air Line Pilots Ass'n, Int'l v. UAL Corp.*, 897 F.2d 1394, 1396 (7th Cir. 1990)).

Defendants argue that the CDC immunization schedule now reflects ACIP's recommendations from September 2025 and that any allegations related to the May 2025 Directive are irrelevant and therefore that part of the case moot. Mem. at 13–14. But Plaintiffs have alleged that ACIP's vote merely implemented Secretary Kennedy's determination that the COVID vaccine recommendation should be withdrawn and was done to effectuate the May 2025 Directive, perpetuating and increasing the harms Plaintiffs face.[21] Given the nature of Plaintiffs' allegations, the Court cannot conclude at this stage that the ACIP vote negated the May 2025 Directive such

[21] For example, Plaintiffs allege that Secretary Kennedy reconstituted ACIP's membership such that ACIP is no longer fairly balanced nor free of inappropriate influence. *E.g.*, Compl. ¶¶ 53–55. This alleged link between Secretary Kennedy's influence on ACIP and the similarities in the ACIP vote plausibly suggest that the vote did not moot the May 2025 Directive.

to narrow the claims. Furthermore, even if the Court were to view the ACIP recommendations as an entirely separate, intervening event, Defendants' cited evidence demonstrates only that the ACIP vote did not address the full scope of the May 2025 Directive, applying only to children and adults generally.[22] Defendants' evidence makes no mention of the recommendation for pregnant women at all. Further, ACIP's meeting minutes indicate that the group explicitly chose not to vote on any changes to the recommendations for pregnant women. *See Meeting of the Advisory Committee on Immunization Practices (ACIP)*, CDC, at 84, https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf [https://perma.cc/JS8G-98HD] (last visited Dec. 19, 2025). Accordingly, at least the portion of the Directive with respect to recommendations for pregnant women was not impacted by the ACIP vote and is thus still effective. Thus, the Court concludes that Defendants have not met their burden to demonstrate that Plaintiffs' challenge to the Directive is moot.[23]

IV. Merits

An agency decision must be set aside under the APA when it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). As noted, in the First Circuit, a Rule 12(b)(6) motion may be appropriate, and dismissal of an APA claim warranted, where the "underlying premise of the complaint is legally flawed." *Atieh*, 727 F.3d at

[22] *See* Reply at 5–6 (first citing *ACIP Recommends COVID-19 Immunization Based on Individual Decision-Making*, HHS, (Sept. 19, 2025), https://www.hhs.gov/press-room/acip-recommends-covid19-vaccination-individual-decision-making.html [https://perma.cc/BP2T-97ZS]; then citing *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, CDC (Oct. 6, 2025), https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html [https://perma.cc/SD3P-G2V7]).

[23] Because the Court concludes that the challenge to the May 2025 Directive was not mooted by the ACIP vote or CDC's changes to the immunization schedules, the Court need not address the parties' arguments regarding voluntary cessation. However, the Court notes that Defendants have provided no indication that the allegedly wrongful behavior would not occur again. *See Already*, 568 U.S. at 92 (explaining that it is a defendant's "burden to show that it 'could not reasonably be expected' to resume its" challenged conduct (*quoting Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000))).

76 n.4. Such a circumstance may arise where the plaintiff is unable to identify any regulatory or statutory authority with which the government action has allegedly failed to comply. *Roe v. Mayorkas*, 2023 WL 3466327, at *11 (D. Mass. May 12, 2023). Defendants contend that Count II must be dismissed "because none of the challenged actions are contrary to law." Mem. at 13.

"FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest."[24] *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020) (holding that FACA's fair "balance and inappropriate influence provisions" are reviewable under the APA). The "congressional command that [advisory] committees be fairly balanced," *id.* at 20–21, implements one of FACA's "principal purpose[s] . . . to enhance the public accountability of advisory committees," *Pub. Citizen v. Dep't of Justice*, 491 U.S. 440, 459 (1989).

Indeed, "[b]alanced membership" is one of the key "policies to be followed by Federal departments and agencies in establishing and operating advisory committees consistent with the [FACA]." 41 C.F.R. §§ 102-3.30, 102-3.30(c). "[F]actors [that] should be considered in achieving a 'balanced' advisory committee membership should include," *inter alia*, the "economic or scientific impact of the advisory committee's recommendations"; the "types of specific perspectives required"; and the "need to obtain divergent points of view on the issues before the advisory committee." *Id.*, pt. 102-3, subpt. B, app. A, III (Key points and principles).

Defendants argue that Count II fails on the merits because Plaintiffs have not alleged "'well-pleaded facts' that plausibly show [the new ACIP] members were appointed solely based on their views." Mem. at 24. Plaintiffs conversely describe the decision of the First Circuit in

[24] There is no dispute among the parties that FACA applies to ACIP.

Union of Concerned Scientists v. Wheeler, 954 F.3d 11, 20 (1st Cir. 2020) as "dispositive." Opp. at 21.

In *Union of Concerned Scientists*, the First Circuit held that FACA's fairly balanced and inappropriate influence provisions are reviewable under the APA, and that the plaintiffs had plausibly alleged that a new EPA directive "skewed the composition of EPA committees in favor of regulated industries." 954 F.3d at 20–21. Contrary to Defendants' argument, Reply at 14, it does not matter that *Union of Concerned Scientists* involved a directive *precluding* a category of people from serving on EPA advisory committees, as opposed to affirmatively *favoring* a category of people (as alleged here). Instead, what matters is that the agency policy, as alleged, "alter[ed] the balance and the role of [the impacted group] on EPA advisory committees." *Union of Concerned Scientists*, 954 F.3d at 20; *see also id.* at 19 ("[F]or example, if the agency announced that only persons paid by a regulated interested business could serve on a committee, we would expect that FACA's fair balance and inappropriate influence standards would supply a meaningful tool for reviewing such a new policy.").

So is true in Plaintiffs' Complaint. Here, Plaintiffs have alleged that all but one ACIP member has professed strong opposition to the COVID vaccine and/or mRNA vaccines generally—in alignment with Secretary Kennedy's own views—and/or lacks the relevant experience and credentials for membership, suggesting that new members were appointed solely based on their views as aligned with Secretary Kennedy's.[25] Compl. ¶¶ 53–55. These facts as

[25] Specifically, Plaintiffs allege that after Secretary Kennedy fired all 17 members of ACIP, Compl. ¶¶ 6, 47–48, and appointed 12 new members of ACIP, *id.* ¶ 53, of ACIP members, at least 8 share the same view, or nearly so, with regards to the COVID vaccine and/or mRNA vaccines generally, and another 3 lack relevant experience and credentials for membership, *id.* ¶¶ 54–55.

alleged are sufficient to plausibly suggest the committee is neither fairly balanced nor free of inappropriate influence.

But, even if the members were not appointed *solely* based on their views, it does not follow that the membership is fairly balanced. Plaintiffs allege that these appointments skewed the composition of ACIP in favor of COVID-vaccine and/or mRNA-vaccine deniers in order to comport with Secretary Kennedy's personal views. Given ACIP's role in providing recommendations on vaccines to the CDC,[26] the Court cannot conclude that views supportive of the COVID vaccine and/or mRNA vaccines more generally are not the type of legitimate views that FACA requires balancing in appointing members. At this stage of the litigation, Plaintiffs have plausibly alleged that the current ACIP composition does not comport with FACA's requirements. Thus, the allegations are sufficient to survive a motion to dismiss.

V. Conclusion

For the foregoing reasons, Defendants' motion to dismiss, Dkt. 144, is DENIED.

So Ordered.

/s/ Brian E. Murphy
Brian E. Murphy
Judge, United States District Court

Dated: January 6, 2026

[26] Kalwant Smagh, *Amendment to the Charter of the Advisory Committee on Immunization Practices*, CDC, at 1 (April 1, 2024) https://www.cdc.gov/acip/downloads/acip-charter.pdf [https://perma.cc/6CNV-L5XR].