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 Opposition to Plaintiffs' Motion for Preliminary Injunction

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INTRODUCTION

Federal law authorizes the Department of Health and Human Services ("HHS") to "assist States and their political subdivisions in the prevention and suppression of communicable diseases" and to "advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a). Under that authority, the Centers for Disease Control and Prevention ("CDC") has created a recommended schedule of vaccines for children and adults. That schedule does not preempt state or local policymaking on vaccines. It is guidance, and it represents the federal government's best judgment at that time on policy questions over which there is scientific debate.

Until last month, the recommended schedule was a high outlier in the international community. It had recommended vaccination for 18 diseases, departing from the recommendations in schedules from peer, developed countries. Recognizing this discrepancy, President Trump ordered a review of HHS's vaccine schedule and the judgments that peer countries have reached on the same question. The President directed HHS and CDC to consider other countries' recommended vaccine schedules and to modify CDC's schedule if appropriate. A comprehensive study was completed, and last month, CDC revised its recommendations for six vaccines ("the January 2026 action").

Also in the last year, HHS's new leadership adjusted the membership of a purely advisory entity called the Advisory Committee on Immunization Practices ("ACIP"). The body exists under the Secretary of Health and Human Services' authority to "appoint such advisory councils or committees . . . as he deems desirable . . . for the purpose of advising him." 42 U.S.C. § 217a(a). The committee members appointed by the Secretary in the last year are experts in vaccine science from diverse backgrounds. They are set to meet for one of their three annual

meetings later this month.

Plaintiffs ask this Court to block HHS's ability to receive and give advice on vaccine science and policy. Their proposed order is so broad it would even block Defendants from filing the administrative record in this case. They seek a court order preventing the Secretary's advisory committee from meeting and advising him. And they want a court order barring HHS from publishing anywhere or disseminating to anyone the vaccine schedule that its leadership—nominated by the democratically accountable President and confirmed by the democratically accountable U.S. Senate—view as the best science on questions over which reasonable minds might differ.

In urging this, Plaintiffs fail to satisfy any of the requirements for a preliminary injunction. To start, there is no likelihood of success on the merits. Plaintiffs' Administrative Procedure Act ("APA") challenge to the recommended vaccine schedule fails for multiple reasons: HHS's judgments about vaccine recommendations, including the January 2026 action, are committed to its discretion and outside the APA's ambit. The January 2026 action—modifying recommendations for six vaccines—also is not a final agency action subject to APA review. Regardless, on the merits, Plaintiffs have not identified anything about the January 2026 action that makes it arbitrary and capricious. Plaintiffs' challenge to the Secretary's ACIP appointments also fails. Plaintiffs allege a violation of the Federal Advisory Committee Act, but the Secretary's appointments satisfy that law's balance requirements, and his appointees are not subject to improper influence. Plaintiffs also cannot establish a likelihood of success on the merits because they lack standing.

Plaintiffs' extraordinarily unusual advice-banning proposed injunction is also plainly against the public interest. The injunction would prohibit ACIP from publicly meeting and HHS

from disseminating information about immunization recommendations. The reason for suppressing this information and denying opportunities for public debate: Plaintiffs disagree with ACIP's and CDC's recent recommendations. But the public expression of ideas may not be prohibited because a listener is offended. Our system of self-government relies on free and full debate of the issues; vaccine policy is no exception. Government officials, no less than private citizens or professional organizations, are entitled to participate in that debate, including by trying to persuade others about policy.

In stark comparison to the public harm that Plaintiffs' injunction would wreak, they themselves will not suffer immediate, irreparable harm in the narrow window before the Court rules on the merits. HHS will begin producing the administrative records for the claims in the operative Third Amended Complaint within a few weeks. Cross-motions for summary judgment can be briefed, and the case submitted for decision, promptly thereafter. Despite the sheer volume of Plaintiffs' declarations, the actual contents do not clearly establish that irreparable harm will occur within the next few months. Much ink is spelled in Plaintiffs' brief on alleged harms to third parties (*e.g.*, patients and unaffiliated organizations) and abstract concepts (*e.g.*, public health administration), on past expenses, and on speculation about events that would occur long after a merits ruling. Categorically, none of these theories of harm can support preliminary relief. Plaintiffs' motion should be denied.

BACKGROUND

I. January 2026 Vaccine Recommendations

In the United States, vaccines must be approved by HHS's Food and Drug Administration before they are distributed and marketed. 42 U.S.C. § 262(a). But policies about the prescribing and administering of vaccines are generally made at the state and local level through the exercise of the state police power. *See 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); *Preston v. United States*, No. CV 19-11034-MPK, 2022 WL 3093235, at *19 (D. Mass. May 25, 2022). At the federal level, Congress has directed that "[t]he Secretary [of Health and Human Services] shall . . . assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters, . . . and shall advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a). In implementing this mandate, HHS has in the past maintained a schedule of vaccines recommended for children and adults. This schedule is non-binding and made available to states and local authorities for their consideration.

A. On December 5, 2025, the President "direct[ed] the Secretary of [HHS] and the Director of [CDC] to review best practices from peer, developed countries for core childhood vaccination recommendations—vaccines recommended for all children—and the scientific evidence that informs those best practices." Presidential Mem., *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (Dec. 5, 2025), https://perma.cc/P67Y-8UQL. The President further ordered that "if they determine that those best practices are superior to current domestic recommendations," they shall "update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries while preserving access to vaccines currently available to Americans." *Id.*

B. On January 2, 2026, two senior HHS officials with expertise in vaccines, epidemiology, and public health, "in consultation with experts at CDC, FDA, NIH, and [the Centers for Medicare and Medicaid Services ('CMS')]," prepared "a scientific, evidence-based, data-driven response to the President's directive." ECF No. 185-19, at 1, 26–33. The assessment

"compare[d] the U.S. with peer nations, examine[d] vaccine uptake and trust, addresse[d] clinical and epidemiological considerations and knowledge gaps, analyze[d] vaccine mandates, and outline[d] recommendations and next steps for immediate and long-term action." *Id.*

The assessment observed that lockdowns during the COVID-19 pandemic "generated a drop in childhood vaccine uptake across all age groups" and that, "[w]hile the vaccination rates have rebounded, the created gaps have never been compensated for through catch-up vaccinations." *Id.* at 5. It also explained that "[a] fundamental principle of public health is trust," which requires public health agencies to "provid[e] accurate information and be[] honest when the scientific knowledge is incomplete." *Id.* at 6. This "fell apart during the COVID-19 pandemic," when "the public lost trust in the COVID-19 vaccine," which "also contributed to less adherence to the full CDC childhood immunization schedule, with lower rates of consensus vaccines such as measles, rubella, pertussis, and polio." *Id.* And "[w]hen vaccine uptake for certain diseases decreases below a certain percentage of the community, it may lead to disease transmission or cases of those diseases," as evidenced by recent U.S. measles outbreaks. *Id.* at 7.

The assessment noted that most "peer nations do not have childhood vaccination mandates" but "achieve very high voluntary vaccination rates while preserving informed consent" through "transparent and trustworthy public health authorities." *Id.* at 8. Indeed, "[s]ome peer countries have recognized that each additional vaccine may erode trust in the entire childhood immunization schedule, resulting in lower uptake of consensus childhood vaccines." *Id.* at 10. For example, "Danish health authorities have specifically expressed concerns about adding vaccines to the routine childhood immunization schedule when the opportunity for benefit in non-high-risk populations is low and/or when the disease does not pose a mortality or long-term disability risk." *Id.* Thus, "[a] new U.S. childhood schedule that removes the routine

recommendation for non-consensus vaccines could lessen coercion and increase public trust." *Id.* Furthermore, "[a] robust clinical trial and safety surveillance system is critical to ensure trust in the recommended childhood vaccine schedule." *Id.* at 11; *see* Restoring Gold Standard Science, Exec. Order No. 14303, 90 Fed. Reg. 22601 (May 23, 2025).

The assessment "compare[d] the U.S. childhood vaccination schedule to those of 20 peer nations: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Japan, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom." ECF No. 185-19, at 14. "In 2024," the assessment observed, "the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations." *Id.* at 15. "While a set of consensus vaccines are consistently recommended in all peer countries, several vaccines currently included in the childhood immunization schedule in the U.S. (hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries." *Id.* at 16. "Although these differences sometimes reflect the unique epidemiology of diseases in each region," the assessment found, "they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations." *Id.*

The assessment explained that "[o]ne way to restore trust in the U.S. childhood immunization schedule" and "help Americans make informed decision[s]" is "to better align the country with consensus vaccine components of the schedules of peer nations, while not restricting anyone's access to other immunizations." *Id.* at 16–17. Following CDC's existing vaccine recommendation structure, the assessment proposed three categories of recommendations. The first category—"Immunizations Recommended for All Children"—

contained vaccines "for which there is consensus among peer nations that all children should receive them." *Id.* at 17. This category included 11 vaccines: measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella (chickenpox). *Id.* at 18–19. The assessment found that "[f]ocusing on these vaccines is more likely to reverse the declining uptake of these vaccines." *Id.* at 19.

For the second category—"Immunizations Recommended for Certain High-Risk Groups or Populations"—the assessment did "not assess[] and [did] not propose any changes in vaccine recommendations for high-risk populations." *Id.* at 18. For the third category—"Immunizations Based on Shared Clinical Decision-Making"—vaccine "recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian." *Id.* After analyzing the risks and benefits, the practices of peer countries, and the state of the evidence, the assessment recommended six vaccines in this category: Hepatitis A, Hepatitis B, Rotavirus, Meningococcal Disease, Influenza, and COVID-19. *Id.* at 19–24.

The assessment emphasized that vaccines in each of those categories, which cover all the vaccines in the prior immunization schedule, "would still be available to anyone who wants them through their private health insurance, Medicaid, the Children's Health Insurance Program (CHIP), and/or the Vaccine for Children (VFC) Program." *Id.* at 25. Importantly, the assessment did not propose moving any currently recommended vaccines into the "Not Recommended" category. *Id.* at 18. And it encouraged CDC and ACIP to "continue [their] work revising recommendations based on the latest vaccine developments and scientific research." *Id.* at 25.

C. On January 5, 2026, the Director of NIH, the Administrator of CMS, and the Commissioner of Food and Drugs—all of whom are highly credentialed medical professionals—sent a memorandum to CDC's Acting Director. ECF No. 185-18, at 1. They proposed that CDC

adopt a revised childhood and adolescent immunization schedule based on the scientific assessment, as well as the Acting Director's discussion of "childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark" and "CDC and [FDA] officials with duties and responsibilities related to vaccine safety and efficacy, respectively." *Id.*

The memorandum summarized the scientific assessment's findings regarding "Decreased Vaccine Uptake and Trust," emphasizing that "[r]obust immunization programs are an essential public health tool, but those tools are only effective when there is public trust." *Id.* at 3. The three high-ranking HHS officials also summarized the assessment's discussion of "Knowledge Gaps Concerning Safety" and its comparison of the U.S. vaccine schedule to those of peer countries. *Id.* at 3–4. Noting that "[f]ocusing on" the consensus vaccines "is more likely to reverse the declining uptake of these vaccines," *id.* at 4, they recommended that CDC adopt the vaccine schedule proposed in the scientific assessment, *id.* at 4–8. And they confirmed that, consistent with the Presidential Memorandum, all the vaccines would "continue to be covered without cost sharing by private insurance and covered by Medicaid, Children's Health Insurance Program (CHIP), and the Vaccines for Children Program." *Id.* at 2–3; *see* HHS, *Fact Sheet: CDC Childhood Immunization Recommendations*, https://perma.cc/DSL3-HWAJ (last reviewed Jan. 5, 2026). On January 5, 2026, the Acting Director of CDC approved the revised childhood and adolescent immunization schedule. ECF No. 185-18, at 9.

II. The Advisory Committee on Immunization Practices

Congress has authorized the Secretary of Health and Human Services to "from time to time, appoint such advisory councils or committees . . . , for such periods of time, as he deems desirable with such period commencing on a date specified by the Secretary for the purpose of advising him in connection with any of these functions." 42 U.S.C. § 217a(a). Under this

authority, HHS has convened an advisory committee on vaccines called ACIP. The Federal Advisory Committee Act of 1972 ("FACA") imposes a variety of requirements on "advisory committee[s]" like ACIP. 5 U.S.C. app. 2 §§ 1-15. Among other things, the statute establishes "guidelines" that "shall be followed . . . in creating an advisory committee." *Id.* § 5(c). Advisory committee membership must "be fairly balanced in terms of the points of view represented and the functions to be performed." *Id.* § 5(b)(2). Members also may "not be inappropriately influenced by the appointing authority or by any special interest." *Id*. § 5(c).

In June 2025, Secretary Kennedy removed the then-serving ACIP members. Press Release, HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP, https://perma.cc/C5YC-Q7ZA (June 9, 2025). He has since appointed 14 new ACIP members,[1] who are "highly credentialed scientists, leading public-health experts, and some of America's most accomplished physicians . . . committed to evidence-based medicine, gold-standard science, and common sense." Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), https://perma.cc/49T9-C7NJ. All current ACIP members hold an M.D., Pharm.D., or Ph.D., have extensive relevant expertise, and represent a wide range of clinical and research backgrounds. *See* CDC, *ACIP Membership Roster*, https://perma.cc/74CV-D3NT (Jan. 14, 2026). Six seats on ACIP remain vacant.

ACIP meets about three times per year. ECF No. 185-21 at 4. ACIP is scheduled to next hold a public meeting on February 25–27, 2026. CDC, *ACIP Meeting Information* (Dec. 3, 2025), https://perma.cc/P4HQ-6X94. No agenda has been released yet.

III. Procedural History

Plaintiffs filed this action more than seven months ago on July 7, 2025, challenging a

[1] One of those members, Dr. Kulldorff, is no longer a member of the ACIP. For simplicity, Defendants will refer to the ACIP membership as discussed in Plaintiffs' motion.

Secretarial directive on COVID-19 vaccines for children and women. ECF No. 1, ¶¶ 111–28. The complaint has been amended three times, and plaintiffs now seek leave to amend the complaint a fourth time. The proposed Fourth Amended Complaint challenges (1) the Secretarial Directive, (2) the Secretary's ACIP appointments, (3) ACIP's June 2025 vote recommending that manufacturers discontinue the use of thimerosal as a preservative in influenza vaccines, (4) ACIP's September 2025 vote to recommend shared clinical decision-making for pediatric and adult COVID-19 vaccines, (5) ACIP's December 2025 vote to recommend shared clinical decision-making for the hepatitis B vaccine for certain infants, and (6) CDC's January 2026 adoption of a revised childhood and adolescent immunization schedule pursuant to a presidential memorandum. ECF No. 180-1, ¶¶ 146–83. Plaintiffs moved for a preliminary injunction. Consistent with the Court's direction at the recent status conference, Defendants limit this brief to their opposition to Plaintiffs' request for a preliminary injunction against the January 2026 action and future ACIP meetings. Defendants will respond to the balance of Plaintiffs' motion in a separate brief.

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Rather, a "plaintiff requesting a preliminary injunction 'must establish' that: (1) it is 'likely to succeed on the merits'; (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief'; (3) 'the balance of equities tips in its favor'; and (4) 'an injunction is in the public interest.'" *Planned Parenthood Fed'n of Am., Inc. v. Kennedy*, 162 F.4th 155, 166 (1st Cir. 2025) (quoting *Winter*, 555 U.S. at 20). The injunction "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion" on each factor. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (quoting 11A Wright *et al.*, Fed. Prac. & Proc. § 2948, 129–130 (2d ed.1995)); *see Becky's Broncos, LLC v.*

Town of Nantucket, 138 F.4th 73, 77 (1st Cir. 2025) ("The party seeking the preliminary injunction bears the burden of establishing that these four factors weigh in its favor." (quoting *Esso Standard Oil Co. (P.R.) v. Monroig-Zayas*, 445 F.3d 13, 18 (1st Cir. 2006))).

ARGUMENT

I. Plaintiffs Are Not Likely to Succeed on the Merits

In seeking a court-ordered ban on HHS receiving and giving advice on vaccines, Plaintiffs invite the Court to intrude into complex questions of science on which reasonable minds might disagree. These are questions under our system of government for scientists and policymakers to answer. They are not fit for judicial second-guessing. Unsurprisingly then, the APA does not license judicial review of CDC's vaccine recommendations. HHS's vaccine advice to states and localities is committed to agency discretion. It also is not a final agency action that determines rights or obligations or from which legal consequences flow. Even if Plaintiffs' challenge were cognizable under the APA, nothing about the recommendations falls outside the bounds of the substantial deference accorded to agencies under arbitrary-and-capricious review. The motion's challenge to ACIP's membership fares no better. That body is fairly balanced and has no influence problem as Plaintiffs' claim. Finally, Plaintiffs also cannot show a likelihood of success on the merits because they lack standing.

A. The January 2026 Action Is Unreviewable Because CDC's Vaccine Recommendations Are Committed to Agency Discretion by Law

Each of Plaintiffs' claims arise under the APA, but that statute does not apply where "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). That exception applies, as here, "when the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Union of Concerned*

Scientists v. Wheeler, 954 F.3d 11, 17 (1st Cir. 2020) (quotations omitted).[2]

CDC recommends immunization schedules under the delegated authority of the Secretary of HHS to "assist States and their political subdivisions in the prevention and suppression of communicable diseases" and "advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a). Beyond a general authorization to "assist" and "advise," section 243(a) provides no standard "for judging how and when [CDC] should exercise its discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The statute does not require CDC to issue immunization recommendations—or even mention immunization schedules—much less contain "requirements to guide [the court] in assessing the propriety of [the] agency's procedures" in exercising its authority under section 243(a). *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 159, 171 n.26 (1st Cir. 2021) (quoting *Union of Concerned Scientists*, 954 F.3d at 21). It certainly does not "constrain[]" CDC's discretion about whether to recommend immunization schedules and, if the agency so chooses, "the form and content" of such recommendations. *Dep't of Commerce v. New York*, 588 U.S. 752, 772 (2019).

A search "for a 'set of statutory or regulatory requirements to guide [the court] in assessing the propriety of'" the January 2026 action yields nothing. *Marasco & Nesselbush*, 6 F.4th at 171 n.26 (quoting *Union of Concerned Scientists*, 954 F.3d at 21). Plaintiffs cannot simply point to the arbitrary and capricious standard in 5 U.S.C § 706(2)(A). *See* PI Mem., ECF No. 184, at 25–34. That, of course, would reduce the exception to a nullity. Instead, the necessary

[2] Although this issue was not raised in Defendants' motion to dismiss the Third Amended Complaint, Plaintiffs' proposed Fourth Amended Complaint and preliminary injunction motion assert new claims. Regardless, this issue implicates sovereign immunity, *Cowels v. FBI*, 936 F.3d 62, 66 (1st Cir. 2019) (citing 5 U.S.C. § 702), which "is jurisdictional in nature," *FDIC v. Meyer*, 510 U.S. 471, 475 (1994), and "cannot be waived in litigation," *In re Rivera Torres*, 432 F.3d 20, 23 n.3 (1st Cir. 2005); *see* Fed. R. Civ. P. 12(h).

statutory or regulatory standards must exist "*apart from* 'the reasoned decision-making standards of the APA alone.'" *Marasco & Nesselbush*, 6 F.4th at 171 n.26 (quoting *Union of Concerned Scientists*, 954 F.3d at 21) (emphasis added). Here, they do not.

The absence of meaningful standards for CDC's issuance of immunization recommendations is highlighted by a contrast with FACA's fair balance and inappropriate influence provisions, 5 U.S.C. § 1004(b)(2)–(3), (c), which, the First Circuit held, provide "sufficient standards . . . for meaningful review," *Union of Concerned Scientists*, 954 F.3d at 20. The concepts of fair balance and avoiding inappropriate influence "tell [courts] what Congress intended the EPA to consider" in constituting advisory committees. *Union of Concerned Scientists*, 954 F.3d at 19–20. But beyond a general permission to "assist" and "advise" States about preventing communicable diseases and preserving public health, 42 U.S.C. § 243(a) does not "tell [courts] what Congress intended [CDC] to consider" about when and how to exercise that authority to give non-binding recommendations and advice. *Union of Concerned Scientists*, 954 F.3d at 19–20. Because section 243(a) "is drawn so that a court would have no meaningful standard against which to judge [CDC]'s exercise of discretion" in issuing immunization schedules, *id.* at 17 (quotations omitted), such actions are "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). Thus, the January 2026 action is unreviewable under the APA.

B. The January 2026 Action Is Not Final Agency Action

Plaintiffs' challenge to the January 2026 Action also fails because it is not final agency action. The APA provides for review only of "final agency action." 5 U.S.C. § 704. "As a general matter, two conditions must be satisfied for agency action to be 'final.'" *Bennett v. Spear*, 520 U.S. 154, 178 (1997). "First, the action must mark the 'consummation' of the agency's decisionmaking process." *Id.* "And second, the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Id.*

The January 2026 action was not final agency action because it is not one from which rights or obligations are determined or legal consequences flow. Again, the January 2026 Action was issued under an authority to merely "assist" and "advise" "States and their political subdivisions." 42 U.S.C. § 243(a). Nothing about the Action changes states' authority to regulate the prescription and administrative of vaccines, or to make policy decisions about which vaccines it may or may not require. CDC's recommendations remain non-binding for States and localities. *See Dalton v. Specter*, 511 U.S. 462, 469 (1994) (holding base closure recommendation was not final agency action). Plaintiffs suggest the January 2026 is final agency action because Plaintiffs "are forced to grapple with the daily and long-term public health and economic effects" of CDC's recommendation. PI Mem. 24. But even if those allegations were proven, a collateral consequence felt by a plaintiff does not by itself create final agency action. Plaintiffs' cases are readily distinguishable. The agency memorandum in *Biden v. Texas* "forbid[]" agency staff from "continu[ing] [a] program in any way." 597 U.S. 785, 808 (2022). Plaintiffs also analogize to *Student Loan Marketing Association v. Riley*, 104 F.3d 397 (D.C. Cir. 1997), but that case was "decided before *Bennett*" and does not "use[] the standard set out by the United States Supreme Court in *Bennett* for determining when agency action is 'final.'" *State v. Centers for Medicare & Medicaid Servs.*, No. 2:08-cv-881, 2010 WL 1268090, at *4 n.2 (M.D. Ala. Mar. 30, 2010).

Plaintiffs' lead argument in attempting to carry their burden on this element is that—even though the Court has not yet granted leave to amend the complaint—Defendants have "waived" any challenge to whether the January 2026 action is final agency action. PI Mem. 23. That is plainly wrong. Plaintiffs' quotations of Defendants' counsel's comments do not concede anything on finality. Nor could they: Defendants did not receive the proposed Fourth Amended Complaint

until *after* the status conference and of course were not required to list all potential defenses in the January 21, 2026, Joint Status Report. Thus, this final agency action argument is properly presented.

C. The January 2026 Action Was Reasonable and Reasonably Explained

Regardless, under the APA's standard of review, 5 U.S.C. § 706(2)(A), the court has "only a narrow role to play," *Dist. 4 Lodge of the Int'l Ass'n of Mechanists & Aerospace Workers Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 44 (1st Cir. 2021). The court "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). If the agency action is "supported by any rational view of the record," it must be upheld. *Littlefield v. DOI*, 85 F.4th 635, 643 (1st Cir. 2023) (quoting *Marasco & Nesselbush*, 6 F.4th at 172). A difference of opinion about how to evaluate the evidence has no place in arbitrary and capricious review. *See Dist. 4 Lodge*, 18 F.4th at 45–47. The court cannot "substitute its judgment for that of the agency" and must "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted).

Plaintiffs assert that the January 2026 action was arbitrary and capricious for four reasons. None has merit.

1. CDC Can Modify Immunization Recommendations Without Consulting ACIP

Plaintiffs argue that "Defendants failed to engage in reasoned decision-making" because the January 2026 action was not based on an ACIP recommendation. PI Mem. 26–28. For starters, the assessment underlying the January 2026 action *did consider* ACIP's September 2025 COVID-19 immunization recommendation and December 2025 Hepatitis B immunization

recommendation. ECF No. 185-19 at 20, 24. Regardless, no statute, regulation, or other agency policy requires ACIP consultation before CDC modifies an immunization recommendation. The President "direct[ed] the Secretary of Health and Human Services and the Director of the Centers for Disease Control and Prevention to review best practices from peer, developed countries for core childhood vaccination recommendations." Presidential Memorandum, *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries*, https://perma.cc/P67Y-8UQL (Dec. 5, 2025). And he left it to HHS and CDC's discretion in determining how to conduct that review.

As explained, the statute authorizing CDC and HHS to advise states and localities imposes no procedural constraints on the agency, let alone a requirement for ACIP consultation. *See* 42 U.S.C. § 243(a). Nor does FACA; rather, ACIP provides "advisory functions" only to the extent the Secretary and the CDC Director require advice for their own "[d]eterminations of action to be taken and policy to be expressed." 5 U.S.C. § 1008(b); 42 U.S.C. § 217a(a).

The Supreme Court rejected a similar argument in *Department of Commerce v. New York*, 588 U.S. 752, 776-77 (2019). There, it was argued that "the Secretary [of Commerce] should have deferred to the Bureau [of the Census] or at least offered some special justification for drawing his own inferences and adopting his own assumptions." *Id.* The Court instead recognized that "the Census Act authorizes the Secretary, not the Bureau, to make policy choices within the range of reasonable options." *Id.* at 777. Because Plaintiffs have identified *nothing* that requires CDC to consult with ACIP before issuing immunization recommendations, and CDC did not procedurally err by issuing the January 2026 action independently of ACIP. *See Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 719 F. Supp. 2d 26, 43 (D.D.C. 2010) ("Because the Board's precedent did not require an evidentiary hearing in connection with a

proposed rulemaking, the Board's decision not to conduct one was not arbitrary and capricious."), *aff'd*, 719 F. Supp. 2d 26 (D.C. Cir. 2011).[3]

2. The January 2026 Action Was Reasonably Explained

Plaintiffs also argue that Defendants did not "provide a satisfactory explanation" for the January 2026 action. PI Mem. 28. Not so. The Acting Director of CDC transparently and "reasonably explained" the bases for his decision, *Prometheus Radio Project*, 592 U.S. at 423: this includes the detailed scientific assessment prepared by two high-ranking HHS officials; "discussions with CDC, FDA, and peer, developed nation health officials"; and the unanimous recommendation of the Director of NIH, the Administrator of CMS, and the Commissioner of Food and Drugs. *See* ECF No. 185-18, at 9.

It is black-letter law that "an agency must have discretion to rely on the reasonable opinions of its own qualified experts." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). And when an agency makes a "scientific determination" that is "within its area of special expertise," "a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *see, e.g.*, *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009) (affording a "high level of deference" to FDA's "scientific judgment within its area of expertise") (quotations omitted)). Here, it was eminently reasonable for the Acting Director to rely on the detailed scientific assessment of HHS officials and the

[3] Relatedly, in taking the January 2026 action, there was no "inconsistency" with past policy that CDC needed to explain. PI Mem. 28. Such an explanation is only required when an agency adopts a "new policy," *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009), and the January 2026 action did not do that. That CDC "did not follow a [particular] legal or scientific process" or "detail[] a process and the[] reason for not undertaking it, when such a process is not required," is not "unreasonable." *Am. Wild Horse Campaign v. Stone-Manning*, No. 23-CV-117-KHR, 2024 WL 3872558, at *12 (D. Wyo. Aug. 14, 2024), *rev'd and remanded on other grounds sub nom. Am. Wild Horse Campaign v. Raby*, 144 F.4th 1178 (10th Cir. 2025).

recommendation of three HHS component heads—all highly experienced medical professionals.[4]

The scientific assessment described the impairment in vaccine uptake and trust since the COVID-19 pandemic and found that trust could be rebuilt by focusing the recommended-for-all-children category on vaccines for which there is an international consensus. *See* ECF No. 185-19. To identify consensus vaccines, the assessment compared the United Sates to 20 peer countries and found that the United States recommended more vaccines than its peers. *Id.* at 14–17. The assessment also analyzed vaccines' risks and benefits and the state of the evidence on those issues. *Id.* at 18–24. Based on this analysis, the assessment proposed a revised child and adolescent immunization schedule that recommended 11 vaccines for all children, six vaccines for certain high-risk groups or populations (which were unchanged), and six vaccines based on shared clinical decisionmaking—all of which would be covered by insurance for whoever wants them. *Id.* at 17–24. Thus, the scientific assessment and Acting Director's decision memorandum (ECF Nos. 185-18 and 185-19) "reasonably considered the relevant issues and reasonably explained" their recommendations. *Prometheus Radio Project*, 592 U.S. at 423; *see Littlefield*, 85 F.4th at 643.

Plaintiffs argue that the memorandum "does not state what Acting Director O'Neill discussed with health officials from Japan, Germany, and Denmark" or "with CDC and FDA officials." PI Mem. 30. It does. *See* ECF No. 185-18 ("[Y]ou discussed childhood immunization recommendations and policy . . . ."). And Plaintiffs offer no explanation why a more detailed memorialization of those discussions was required. Plaintiffs next claim that CDC did not

[4] Plaintiffs baselessly attempt to malign Drs. Høeg and Kulldorff, the assessment's authors. PI Mem. 29. Both are highly qualified researchers with extensive expertise in vaccines, epidemiology, and public health. *See* ECF No. 185-19, at 25-26. Additionally, Drs. Høeg and Kulldorff "consult[ed] with experts at CDC, FDA, NIH, and CMS." *Id.* at 1.

"explain why Japan, Germany, and Denmark serve as good immunization models for the United States." PI Mem. 30. But the assessment broadly "compare[d] the U.S. childhood vaccination schedule to those of *20* peer nations," not just those three countries. ECF No. 185-19, at 14 (emphasis added). And it acknowledged that "[c]ountries differ in terms of both disease exposure and health care system" and that the differences between countries' immunization schedules "sometimes reflect the unique epidemiology of diseases in each region." *Id.* at 16. Yet the differences in immunization schedules "more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations." *Id.* Thus, CDC reasonably accounted for "uncertain science and knowledge gaps" and national differences when comparing the United States to 20 peer countries. *Id.*; *see Prometheus Radio Project*, 592 U.S. at 423.

Plaintiffs' suggestion that the scientific assessment and decision memorandum should have been "peer-reviewed," PI Mem. 30, has no basis in the APA. Nor does the APA require "new" evidence to support the recommendations. *Id.* In any event, many of the 179 references cited in the assessment were from 2025. *See* ECF No. 185-19, at 26–33.

Plaintiffs wrongly claim the January 2026 action caused "dramatic changes to the CDC schedules" and thus could not restore trust in public health. PI Mem. 31. Actually, the modified recommendations were "not a significant departure from the current recommended immunization construct." ECF No. 185-18, at 3. All the vaccines on the prior immunization schedule remained on the revised schedule and remained covered by insurance. *See id.* The primary change was to shift the recommendations for six vaccines (Hepatitis A, Hepatitis B, Rotavirus, Meningococcal B and AWCY, and Influenza) from "recommended for all children" to "shared clinical decision-making." *Id.* CDC determined that "[i]dentifying the consensus vaccines on the schedule would

help Americans follow the schedule"—*i.e.*, foster trust in the recommendations—"while making all vaccines available for parents also wanting non-consensus immunizations." *Id.* at 5; *see* ECF No. 185-19 at 10, 16–17, 19.

Plaintiffs argue that CDC needed "surveys, studies, or data" to show that this approach would restore trust. PI Mem. 31. However, the assessment cited data showing that its recommended approach yielded high voluntary vaccination rates in peer nations. ECF No. 185-19, at 8-9. Furthermore, "[i]t is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion." *State Farm*, 463 U.S. at 52. And when an agency "is making predictions, within its area of special expertise, . . . a reviewing court must generally be at its most deferential." *Balt. Gas & Elec. Co.*, 462 U.S. at 103. CDC is entitled to that deference here. *Prometheus Radio Project*, 592 U.S. at 425 (upholding agency decision to "rel[y] on the data it had (and the absence of any countervailing evidence) to predict" future effect of agency action); *Dist. 4 Lodge*, 18 F.4th at 45–47.

Plaintiffs cannot undermine the reasonableness of that decision through post hoc, extra-record declarations about the purported effect of the January 2026 action on trust. PI Mem. 31 & n.77. "This sort of Monday morning quarterbacking" has no place in APA review. *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 547 (1978). Review occurs only "on the basis of the information available to the agency when it made the [challenged] decision." *Id.*; *see Berkey Int'l, LLC v. EPA*, No. CV 24-1106 (CVR), 2024 WL 3517721, at *2–3 (D.P.R. July 24, 2024) (under "the likelihood of success on the merits prong, the Court must limit itself to using the agency's administrative record").

3. CDC Reasonably Considered the Relevant Factors

Plaintiffs claim CDC failed to consider various "essential factors." PI Mem. 32. As

explained above, the authority under which Defendants made the January 2026 action does not set specific factors for agency consideration. *See* 42 U.S.C. § 243(a). It instead leaves it to Defendants' discretion to determine the appropriate factors in advising states and localities on public health. In any event, Plaintiffs' argument is premature. The administrative record, which will show the full scope of what the agency considered, is still being compiled. Regardless, from the face of the assessment, the Court can see that the factors Plaintiffs mention either were considered or did not need to be.

Plaintiffs state that CDC did not consider "data establishing that any of the vaccines on the schedule are harmful." PI Mem. 32. But the assessment observed that the influenza vaccine "has been linked to Guillain Barré syndrome" and that "the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents." ECF No. 185-19, at 24. The assessment also noted "a scarcity of reliable safety data" for the influenza vaccine and that "reliable safety data is limited" for the Hepatitis A vaccine. *Id.* at 20, 24. Regarding effectiveness data, PI Mem. 32, the agency noted the lack of adequate placebo-controlled randomized trials for the Hepatitis A, meningococcal disease, and influenza vaccines, and that there was *"*no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza*.*" ECF No. 185-19, at 20–23.

Plaintiffs provide no legal support for the purported requirements that CDC supplement its findings with "evidence from the FDA" regarding safety or effectiveness, "consultations with professional organizations," or "practice guidelines published by . . . professional organizations." PI Mem. 32. The agency also need not analyze "epidemiological" or "socioeconomic" data comparing the United States to peer countries or other information about peer countries such as their "screening programs for diseases." *Id.* As the assessment noted, "[c]ountries differ in terms

of both disease exposure and health care system," and the differences between countries' vaccine schedules "sometimes reflect the unique epidemiology of diseases in each region." ECF No. 185-19, at 16. But these differences "more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations." *Id.*

CDC recognized that vaccines can "provide material benefits against the target disease," *id.* at 18–19; *contra* PI Mem. 32, and that "[w]hen vaccine uptake for certain diseases decreases below a certain percentage of the community, it may lead to disease transmission or cases of those diseases," ECF No. 185-19, at 7; *see also id.* at 3, 5–8; *contra* PI Mem. 32. The agency also observed that peer countries "achieve very high voluntary vaccination rates while preserving informed consent" through "transparent and trustworthy public health authorities" and immunization schedules that are more focused on consensus vaccines. ECF No. 185-19, at 8, 10; *contra* PI Mem. 32. Informed by the success of peer countries, the assessment explained that "[o]ne way to restore trust in the U.S. childhood immunization schedule" and "reverse the declining uptake of [consensus] vaccines" is "to better align the country with consensus vaccine components of the schedules of peer nations, while not restricting anyone's access to other immunizations." ECF No. 185-19, at 16–17, 19 (footnote omitted).

Plaintiffs also had no "reliance interests" in the CDC recommendations in place before January 2026. *Contra* PI Mem. 33–34. Vaccine recommendations are never permanent. As Plaintiffs note, "[e]ven after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations." PI Mem. 26 n.68. Indeed, the potential for revision or withdrawal of an immunization recommendation is baked into the ACIP Charter. *See* ECF No. 185-21, at 3. Because vaccine recommendations are designed to change over time, neither

Plaintiffs nor anyone else had reliance interests in the recommendations remaining the same in perpetuity. *See Bell Atl. Tel. Companies v. FCC*, 79 F.3d 1195, 1205 (D.C. Cir. 1996) (agency's adjustments to price cap index did "not upset petitioners' reliance interests" because agency had announced it would review the price cap system and thus "Petitioners could not have reasonably assumed that the price cap index would not be altered"); *see also FDA v. Wages & White Lion Invs., L.L.C.*, 604 U.S. 542, 569 (2025) ("[i]t is unclear what, if any, daylight exists between" the "change-in-position doctrine" and a "conception of 'fair notice'" requiring consideration of "*reasonable* reliance interests" (emphasis added)).

Finally, CDC *did* consider the potential effects on "health insurance coverage and cost-sharing obligations under the Affordable Care Act" or access under the Vaccines for Children program. PI Mem. 34. All vaccines on the immunization schedule "continue to be covered without cost sharing by private insurance and covered by Medicaid, the Children's Health Insurance Program (CHIP), and the Vaccines for Children Program." ECF No. 185-18, at 2–3; *see* HHS, *Fact Sheet: CDC Childhood Immunization Recommendations*, *supra*.

Thus, CDC "reasonably considered the relevant issues and reasonably explained" the January 2026 action. *Prometheus Radio Project*, 592 U.S. at 423. Plaintiffs' disagreement with CDC's assessment of the evidence cannot overcome the "high level of deference" given to the agency's "scientific judgment within its area of expertise." *Rempfer*, 583 F.3d at 867 (quotations omitted); *see Balt. Gas & Elec.*, 462 U.S. at 103; *Dist. 4 Lodge*, 18 F.4th at 45–47. Moreover, the Court cannot "substitute its judgment for that of the agency" regarding how best to protect the public health. *State Farm*, 463 U.S. at 43 (citation omitted). At bottom, CDC's policy decision remained well "within a zone of reasonableness," *Prometheus Radio Project*, 592 U.S. at 423, and that is all the APA requires.

D. ACIP Is Operating in Compliance With FACA

Separate from their attack on the January 2026 action, Plaintiffs challenge ACIP's current compliance with FACA. 5 U.S.C. § 1004(b)(2)–(3), (c); *see* PI Mem. 34–42. They claim its membership is not fairly balanced and that it is subject to inappropriate influence. This challenge also fails.

1. ACIP Is Fairly Balanced

FACA "require[s] the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." 5 U.S.C. § 1004(b)(2). This does not require advisory committee membership to be split exactly evenly on either side of an issue, but "preserve[s] wide agency discretion" in striking a balance among committee members. *Union of Concerned Scientists*, 954 F.3d at 20. There are "different balances that can be struck in a committee's membership" and "many different points of view that [an agency] might take into account in forming its committees." *Id.* at 19. "[T]he 'fairly balanced' requirement falls short of mathematical precision in application" and "involve[s] some balancing of interests by the agency." *Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 434 (D.C. Cir. 1989) (Edwards, J., concurring in part and dissenting in part). "[T]he difficulty of determining what precisely constitutes a 'fair balance' may incline courts to be deferential in reviewing the composition of advisory committees and may defeat a plaintiff's claims in a given case." *Id.*; *see id.* at 424 (Friedman, J., concurring in the judgment) ("The determination of how the 'fairly balanced' membership of an advisory committee, in terms of the points of view represented and the functions the committee is to perform, is to be achieved, necessarily lies largely within the discretion of the official who appoints the committee."); *NAACP Legal Def. & Educ. Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 144 (D.D.C. 2020).

Plaintiffs argue that ACIP is not fairly balanced because they say 10 of the 14 current ACIP members (5 authorized seats are vacant) purportedly hold "anti-vaccine" views and "preconceived hypotheses that vaccines are categorically unsafe." PI Mem. 37. That is legally irrelevant because "Congress intended 'balance' to be judged by the members' employment status and background, not their professed personal opinions." *Pub. Citizen*, 886 F.2d at 437 (Edwards, J., concurring in part and dissenting in part). "Nothing in the Act or its legislative history even slightly indicates that Congress intended the presence or absence of balance to turn on an inquiry into the opinions of individual members." *Id.* Here, the ACIP members have a wide variety of employment histories and backgrounds, satisfying the fair balance requirement. *See infra* pp.26–27.

Moreover, even if Plaintiffs' characterization were relevant and factually accurate, ACIP's composition would not violate FACA. A 10-4 split is within the agency's wide discretion in striking a balance among ACIP members. *See Union of Concerned Scientists*, 954 F.3d at 19–20; *Pub. Citizen*, 886 F.2d at 434 (Edwards, J., concurring in part and dissenting in part); *id.* at 424 (Friedman, J., concurring in the judgment); *NAACP*, 496 F. Supp. 3d at 144. And six of the 19 authorized seats on ACIP are unfilled, *see* ECF No. 185-21, at 5, leaving Secretary Kennedy room to add more viewpoints.

In any event, Plaintiffs mischaracterize ACIP's members. As an ACIP member noted, "the committee's discussions clearly demonstrate that members are not opposed to vaccines" and that "the robust scientific debate, mutual respect among members, and inclusion of external experts reflect a thoughtful, open-minded approach rather than any predetermined stance." ACIP, September 18-19, 2025 ACIP Meeting Summary, at 88, https://perma.cc/Q5AE-PN4R.

Indeed, ACIP's new members have taken actions supportive of vaccines. In June 2025,

ACIP recommended that adults and children "receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." ACIP, June 25-26, 2025 ACIP Meeting Summary, at 72–74, https://perma.cc/WEP5-K2LD. Then in September 2025, ACIP voted unanimously to recommend the COVID-19 vaccine based on shared clinical decision-making. ACIP, September 18-19, 2025 ACIP Meeting Summary, *supra*, at 88–89. And in December 2025, ACIP voted to recommend the Hepatitis B vaccine based on shared clinical decision-making "for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus." CDC, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, https://perma.cc/3KQC-PJG6 (Dec. 5, 2025). ACIP's votes *to recommend vaccines* belie Plaintiffs' accusation that the current ACIP members are unilaterally "anti-vaccine." Thus, Plaintiffs are not likely to show ACIP is "[un]fairly balanced in terms of the points of view represented," 5 U.S.C. § 1004(b)(2), by categorically painting its members with a broad and nebulous "anti-vaccine" brush, which does not accurately represent the members' complex and nuanced perspectives and their committee voting records.

Plaintiffs also attack ACIP members' credentials. Contrary to those characterizations, PI Mem. 39, ACIP's members have extensive expertise relevant to vaccine recommendations from a wide range of clinical and research backgrounds. All current ACIP members hold an M.D., Pharm.D., or Ph.D., and they include:

- an obstetrician and gynecologist with "clinical education roles and publication on COVID-19 vaccine safety for pregnant women" (Dr. Biss);
- a former NIH section chief with "experience in clinical research, public health policy, and federal service" whose "work has informed U.S. public health guidelines, particularly in maternal and child health" and who "has authored more than 250 peer-reviewed publications" (Dr. Hibbeln);
- an MIT professor with expertise in "vaccine safety" who "co-authored studies examining

the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes" (Dr. Levi);

- an adjunct professor at Louisiana State University who is "a vaccinologist, scientist, and biochemist known for his early contributions to mRNA vaccine technology" with "expertise span[ning] molecular biology, immunology, and vaccine development" and who "is the author of more than 100 peer-reviewed publications" (Dr. Malone);

- the former Chief of the Division of Pediatric Infectious Diseases at Tufts Medical Center, who is an "internationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety" and who previously served on ACIP, FDA's Vaccine and Related Biologic Products Advisory Committee, and the National Vaccine Advisory Committee and was Head of HHS's National Vaccine Injury Compensation Program (Dr. Meissner);

- a former member of FDA's Vaccines & Related Biological Products Advisory Committee with experience in public health research, bioethics, and vaccine safety, as well as a doctorate in public health and nursing (Dr. Pebsworth);

- an epidemiologist who is a professor in the Department of Population and Quantitative Health at Case Western Reserve University, with "more than two decades of research experience on tuberculosis and infectious diseases and 115 peer reviewed publications," who "has collaborated extensively in genetics, biostatistics, and immunology" (Dr. Stein); and

- an obstetrician and gynecologist specializing in Maternal-Fetal Medicine who "has held academic appointments at Harvard Medical School, the University of South Florida, and Tufts University School of Medicine" and who has "published extensively in peer-reviewed journals and participated in FDA advisory panels" (Dr. Urato).

ACIP Membership Roster, *supra*.

Plaintiffs' argument that the Secretary did not follow HHS's Federal Advisory Committee (FAC) Membership Balance Plan, PI Mem. 36–41, is premature before an administrative record for Plaintiffs' FACA claim is available. If anything, though, the Plan *hurts* Plaintiffs' argument because the current ACIP has expertise in all areas set out in that Plan—"immunization practices," "public health," "the use of vaccines and immunologic agents," and "vaccine development, evaluation, safety and delivery." PI Mem. 39; *see ACIP Membership Roster*, *supra*.

Plaintiffs' reliance on *NAACP Legal Defense and Education Fund, Inc. v. Barr*, 496 F. Supp. 3d 116 (D.D.C. 2020), *see* PI Mem. 41, also is misplaced. There, a commission to study

law enforcement issues "[c]onsist[ed] entirely of current and former law enforcement officials," with no member from "a criminal defense, civil rights, or community organization background." *NAACP*, 496 F. Supp. 3d at 122. ACIP's membership is far different, including individuals with extensive relevant experience from a wide variety of clinical and research backgrounds. Given the Court's "highly deferential review" and the "wide agency discretion" in balancing advisory committee membership, ACIP easily satisfies FACA's functional balance requirement. *Union of Concerned Scientists*, 954 F.3d at 19–20; *see Cargill, Inc. v. United States*, 173 F.3d 323, 335 n.24, 336 (5th Cir. 1999).

2. ACIP Is Not Inappropriately Influenced

Plaintiffs' last contention is that the Secretary "failed to avoid inappropriate influence through the ACIP Appointments." PI Mem. 41. This accusation fares no better than its predecessors. FACA provides that, "in creating an advisory committee," agency heads shall ensure there are "appropriate provisions to 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." 5 U.S.C. § 1004(b)(3), (c); *see* 41 C.F.R. § 102-3.105(g) (agency heads must "[d]evelop procedures" to assure that advisory committee recommendations will not be inappropriately influenced). As with the "fairly balanced" requirement, FACA "preserve[s] wide agency discretion" in protecting against inappropriate influence. *Union of Concerned Scientists*, 954 F.3d at 20.

Plaintiffs do not argue that, when ACIP was originally created, there were inadequate "provisions" or "procedures" in place to protect against inappropriate influence. 5 U.S.C. § 1004(b)(3), (c); 41 C.F.R. § 102-3.105(g). Nor do they argue that there were inadequate

provisions or procedures in place when Secretary Kennedy appointed ACIP members.[5] In fact, the ACIP Charter and Membership Balance Plan help ensure that the ACIP membership is fairly balanced and not inappropriately influenced. Instead, Plaintiffs assert that ten ACIP members "have publicly stated views on vaccines that align with the Secretary's anti-vaccine views." PI Mem. 41. But even if true, that says nothing about whether there are "appropriate provisions" or "procedures" in place to ensure that ACIP's recommendations are not inappropriately influenced. 5 U.S.C. § 1004(b)(3), (c); *see* 41 C.F.R. § 102-3.105(g).

Similarly, Plaintiffs assert that four ACIP members "are members or otherwise affiliated with openly anti-vaccine organizations." PI Mem. 41. Again, even if true, that itself does not establish the absence of "appropriate provisions" or "procedures" in place to avoid inappropriate influence. 5 U.S.C. § 1004(b)(3), (c); *see* 41 C.F.R. § 102-3.105(g). That four out of 14 (and 19 authorized) ACIP members are, in Plaintiffs' view, affiliated with "anti-vaccine organizations," does not signal a failure to protect against inappropriate influence. To turn it around, if four ACIP members were affiliated with "pro-vaccine organizations," such as the Organizational Plaintiffs, Plaintiffs would not claim undue influence. This requirement "is designed to protect against 'the danger of allowing special interest groups to exercise undue influence upon the Government through the[ir] *dominance* of advisory committees which deal with matters in which they have vested interests.'" *Pub. Citizen*, 886 F.2d at 425 (Friedman, J., concurring in the judgment) (quoting H.R. Rep. No. 1017, at 6, *reprinted in* 1972 U.S. Code Cong. & Admin. News at 3496)) (emphasis added). Four members do not "domina[te]" a committee of 14, much less 19. *Id.*

[5] Plaintiffs argue that "[a]dvisory committee members whose professional interests or job prospects are directly affected by the committee's output raise a strong potential for inappropriate influence." PI Mem. 36. But they do not argue that any current ACIP members fit this description.

("[t]he appellants ha[d] not shown that the original Committee was dominated or 'inappropriately influenced' by food industry representatives" where "[o]nly six of the 18 members were employed by the food industry").

Plaintiffs cannot make up for their lack of evidence with a speculative accusation that ACIP is simply "a rubber stamp for Defendants' agenda to create and spread public health misinformation." PI Mem. 42; *see Ayoub v. CitiMortgage, Inc.*, No. 15-cv-13218-ADB, 2018 WL 1318919, at *8 (D. Mass. Mar. 14, 2018) (requiring a plaintiff to provide "evidence" showing a likelihood of success on the merits). As "Special Government Employees," *see* ECF No. 185-21, at 5, ACIP members are entitled to a presumption that they "have properly discharged their official duties," *United States v. Chem. Found.*, 272 U.S. 1, 14-15 (1926), and exercised their "independent judgment" in advising CDC, 5 U.S.C. § 1004(b)(3), (c). Plaintiffs have not presented "clear evidence" to the contrary. *See Chem. Found.*, 272 U.S. at 14-15; *Ayoub*, 2018 WL 1318919, at *8. Plaintiffs are not likely to succeed on the merits of their FACA claim under either a "fairly balanced" or an "inappropriate influence" theory.

E. Plaintiffs Lack Standing to Challenge the January 2026 Action and the February 2026 ACIP Meeting

Regardless of Plaintiffs' APA allegations, their claims fail at the threshold because they have not carried their burden to establish standing. "At the preliminary injunction stage," Plaintiffs "must make a 'clear showing' that" they are "'likely' to establish each element of standing." *Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (quoting *Winter*, 555 U.S. at 22). That is, Plaintiffs "(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, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Because standing is assessed "claim-by-claim," *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016), Plaintiffs must show a

cognizable injury traceable to each "challenged action," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).

Plaintiffs assert standing based on (1) the harm alleged in the Third Amended Complaint and (2) being denied participation in ACIP workgroups. PI Mem. 21–23. Both theories fail. Article III standing doctrine "prevents the federal courts from becoming a vehicle for the vindication of the value interests of concerned bystanders." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024) (quotation omitted). And that is all this suit is.[6]

1. The Theories of Harm in the Third Amended Complaint Do Not Support Standing

a. Organizational Plaintiffs Lack Standing

Defendants respectfully submit that the Court's analysis of standing in the motion to dismiss decision is inconsistent with Supreme Court precedent. The Court found that the American Academy of Pediatrics ("AAP") has organizational standing because it "divert[ed] resources away from its usual tasks and initiatives aimed at children's health" to "address the Challenged Actions." ECF No. 168 at 10–11. But the Supreme Court unanimously rejected this theory in *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024). There, the plaintiff-organizations alleged the challenged actions "impaired" their "ability to provide services and achieve their organizational missions." *Id.* at 394 (quotation omitted). That theory, the Court said, "would mean that all the organizations in America would have standing to challenge almost every federal policy that they dislike, provided they spend a single dollar opposing those

[6] Plaintiffs suggest it is "the law of the case" that they have standing because this Court denied Plaintiffs' motion to dismiss. PI Mem. 23. Not so. The Court's motion to dismiss decision was an "interlocutory ruling[]" that "do[es] not constitute the law of the case" because "the Civil Rules authorize district courts to revise their own orders and decisions at any time before entering final judgment." *Daumont-Colon v. Cooperativa de Ahorro y Credito de Caguas*, 982 F.3d 20, 26 (1st Cir. 2020) (quotations omitted) (citing Fed. R. Civ. P. 54(b)).

policies." *Id.* at 395.

Instead, the Supreme Court ruled, an organization must show that the challenged action imposes an "impediment" to the organization's business activities. *Id.* For example, in *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), an organization that "operated a housing counseling service" could sue a defendant that "gave [the organization]'s employees false information about apartment availability" and thus "perceptibly impaired [the organization]'s ability to provide counseling and referral services for low- and moderate-income homeseekers." *All. for Hippocratic Med.*, 602 U.S. at 395 (citing *Havens*, 455 U.S. at 368, 379). But *Alliance for Hippocratic Medicine* cautioned that "*Havens* was an unusual case, and this Court has been careful not to extend the *Havens* holding beyond its context." *Id.* at 396. As a rule, an organization "cannot manufacture its own standing" by spending resources in response to the challenged action, such as on "public advocacy and public education," to "the detriment of other spending priorities." *Id.* at 394–95.

Plaintiffs' own evidence demonstrates this case is analogous to *Alliance for Hippocratic Medicine*, not *Havens Realty*. The challenged actions have not impaired AAP's ability to publish "immunization recommendations," "clinical practice guidelines," and "policies on a broad range of topics that impact" children's health. ECF No. 185-27, ¶¶ 8, 18. Although AAP may choose to revise its clinical practice guidelines in response to the challenged actions, *id.*, ¶ 31, there is no "impediment" to AAP's ability to publish such guidelines, *All. for Hippocratic Med.*, 602 U.S. at 395—something it has been doing for decades.

Defendants do not "discredit" or "discount the importance" of AAP's guidance and immunization schedules by characterizing them as educational materials. ECF No. 168, at 12. On the contrary, the point is simply that "AAP operates to support the professional needs of its

members through the publication" of such information. ECF No. 185-27, ¶ 8. Advising members and updating guidelines to account for new information—whether the publication of a new study or the modification of CDC's immunization recommendations—is part of AAP's normal operations. *See, e.g.*, *id.* (AAP's normal operations "[i]nclude[] the *maintenance* and publication of the AAP Red Book, which contains current guidance on the diagnosis, treatment, and prevention of over 200 childhood infectious diseases" (emphasis added)); AAP, Red Book Online, https://publications.aap.org/redbook (because "the pediatric infectious disease landscape is changing continuously," "*Red Book Online* is consistently updated with the latest recommendations from the AAP" so "pediatric healthcare professionals have access to the most current information").

No resources spent on these activities are diverted from AAP's mission of "obtain[ing] optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults." ECF No. 185-27, ¶ 6. Rather, these resources directly further that mission. The same is true for the other Organizational Plaintiffs. *See infra* pp. 39–40.

The Organizational Plaintiffs largely advance the "doctor standing" theory rejected in *Alliance for Hippocratic Medicine*. Doctors cannot challenge any governmental action by theorizing that it might cause more patients to "show up at emergency rooms or in doctors' offices with follow-on injuries." 602 U.S. at 391. For example, "virtually all drugs come with complications, risks, and side effects," and "[a]pproval of a new drug may therefore yield more visits to doctors to treat complications or side effects." *Id.* at 392. But "doctors have never had standing to challenge FDA's drug approvals simply on the theory that use of the drugs by others may cause more visits to doctors." *Id.* Such "an unprecedented and limitless approach . . . would allow doctors to sue in federal court to challenge almost any policy affecting public

health." *Id.* at 391–92.

b. Plaintiffs Lack Associational Standing

The Court should also revisit its conclusion that the Organizational Plaintiffs have associational standing because their "member-doctors" have standing to sue in their own right. ECF No. 168, at 16. Regarding financial injury to the member-doctors, the Court said it was "predictable that the changes in recommendations would and will cause insurers to change their billing for the COVID vaccine." ECF No. 168 at 15. If the Court was referring to Plaintiffs' allegation that some insurers do not reimburse for vaccines with shared clinical decision-making recommendations, ECF No. 139, ¶ 91, that practice would be contrary to law, *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). And a third-party insurer's independent decision to violate the law is certainly not traceable to the challenged actions. *See Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976).

Or if the Court was referring to Plaintiffs' allegations that their members cannot bill for additional time spent on vaccine counseling, *see* ECF No. 139, ¶¶ 90, 102–07, that too is solely due to the independent actions of third parties. Plaintiffs do not contend the challenged actions altered the "Current Procedural Terminology ('CPT') codes" that their members "use to bill for the professional services . . . to patients," ECF No. 185-28, ¶ 11, or ordered the member-doctors to provide uncompensated services. Reimbursement policies for patient visits and consultations are set by "independent actors"—*i.e.*, insurers. *All. for Hippocratic Med.*, 602 U.S. at 383, 391 (quotation omitted). Proving the point, one declarant describes how "a new CPT code" exists "that providers can use for billing SCDM discussions even when a patient refuses a vaccine." ECF No. 185-28, ¶ 19. It is now a matter of whether a "health care payer"—*not CDC*—"accepts or recognizes this CPT code or . . . will reimburse for it." *Id.*; *see* ECF No. 185-31, ¶ 13 (at least

"one insurer paying" under the new code). So whether any particular member-doctor will suffer financial injury rests on "speculation" about future visits of individual patients, the policies of independent insurers, and the doctor's own willingness to spend uncompensated time with a patient. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted).

2. Being Denied Participation in ACIP Workgroups Does Not Give Plaintiffs Standing

Plaintiffs argue that Defendants "deprived [them] of their legal right to participate in ACIP activities," PI Mem. 22, by ending the participation of liaison organizations in ACIP workgroups in July 2025, ECF No. 180-1, ¶ 82. But Plaintiffs' FACA claim challenges the Secretary's *appointments* to ACIP, not the removal of liaison organizations from ACIP workgroups. ECF No. 139, ¶ 8; ECF No. 180-1, ¶¶ 156–68. Thus, Plaintiffs' alleged injury from being "deprived . . . of their legal right to participate in ACIP" workgroups, PI Mem. 22, is not "fairly traceable to *the challenged conduct*," *Spokeo*, 578 U.S. at 338 (emphasis added); *see Lujan*, 504 U.S. at 560–61. For the same reason, they also cannot establish redressability.

Plaintiffs also do not explain how the liaison organizations suffer a cognizable injury when they still participate in ACIP *meetings* just not *workgroup*s. For example, liaison representatives participated in the September 2025 ACIP Meeting. *See, e.g.*, ACIP, September 18-19, 2025 ACIP Meeting Summary, *supra*, at 42–43, 50, 81-82, 93, 99-104. Indeed, although the ACIP Charter provides for "non-voting liaison representatives," it does not require that they participate in workgroups. ACIP Charter, https://perma.cc/8W76-JTTS (Dec. 3, 2025); *see also* ACIP Secretariat, *ACIP: Work Groups*, Standard Operating Procedures, at 4, https://perma.cc/8NK4-T4SK (Aug. 2018) (work groups "*may include* . . . ACIP liaison representatives" (emphasis added)). The cases Plaintiffs cite, in which parties were denied membership altogether on an advisory committee, PI Mem. 22, do not apply to this situation of a

non-voting liaison representative. Accordingly, Plaintiffs have not clearly shown a cognizable injury to support standing for the FACA claim.

II. The Public Interest Strongly Disfavors Plaintiffs' Attempt to Suppress Differing Viewpoints About Vaccine Policy

Plaintiffs' motion should also be denied because the public interest disfavors Plaintiffs' extraordinary proposal to enjoin HHS from giving non-binding recommendations to states and localities and from holding advisory meetings. "In exercising [its] sound discretion," the Court must "pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). Here, both "the balance of equities and consideration of the overall public interest in this case tip strongly in favor of" CDC and HHS. *Id.* at 26.

"The right of citizens to inquire, to hear, to speak, and to use information . . . is a precondition to enlightened self-government and a necessary means to protect it." *Citizens United v. Fed. Election Comm'n*, 558 U.S. 310, 339 (2010). Thus, there is a significant "public interest in having free and unhindered debate on matters of public importance." *Rosaura Bldg. Corp. v. Municipality of Mayaguez*, 778 F.3d 55, 66 (1st Cir. 2015) (quoting *Pickering v. Bd. of Educ.*, 391 U.S. 563, 573 (1968)). Yet Plaintiffs ask this Court to preliminarily enjoin CDC and HHS "from convening, holding, or conducting the ACIP meeting currently scheduled for February 25–[27], 2026, as well as any subsequent ACIP meetings." ECF No. 183-1 at 3 (Proposed PI order). Plaintiffs also want this Court to prohibit CDC and HHS from "publishing [or] disseminating" the "immunization schedule" adopted in January 2026, as well as any "guidance documents, decision memorandum, work product, or public-facing materials that reflect" this action. *Id.* Plaintiffs are not shy about their motivation: Plaintiffs disagree with "statements" of "health-related information" by "speakers" at past ACIP meetings, and the

decision of CDC's Acting Director to change recommendations for several childhood vaccines in January 2026. PI Mem. 4-5, 12; *see, e.g.*, ECF No. 185-27, ¶ 46 (objecting to "anti-vaccine rhetoric" during ACIP meetings); ECF No. 185-35, ¶ 11.

Plaintiffs try to mask their intent under the guise of countering "misinformation." PI Mem. 43-44. But that label is just an "opinion[] which reflect[s] subjective judgments about the nature" of the information. *Cheng v. Neumann*, 51 F.4th 438, 447 (1st Cir. 2022). Put simply, Plaintiffs do not own a monopoly on scientific debate. "[T]he public expression of ideas may not be prohibited merely because the ideas are themselves offensive to some of their hearers." *Bachellar v. Maryland*, 397 U.S. 564, 567 (1970) (quotation omitted). Ideas about vaccine policy are no exception, regardless of how strenuously Plaintiffs disagree with some of them.

Beyond the substantial harm to the public debate, the Federal Government also would suffer great injury. "The government can 'say what it wishes' and 'select the views that it wants to express.'" *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 187 (2024) (quoting *Pleasant Grove City v. Summum*, 555 U.S. 460, 467-68 (2009)). That means officials at CDC and HHS may "share [their] views" about vaccine policy "freely" and "forcefully in the hopes of persuading others to follow [their] lead." *Id.* at 188. If Plaintiffs can muzzle those officials though, based on a disagreement about the substance and rollout of vaccine policy, the consequence is clear: The part of government charged with assisting and advising on matters of disease prevention will "barely function" with respect to immunization practices. *Id.* at 187.

Given the significant harms from preventing government officials from expressing policy views and from depriving the American public of opportunities to meet, discuss, and learn about vaccine policy, the equities heavily disfavor Plaintiffs' request for preliminary relief.

III. Plaintiffs Will Not Suffer Irreparable Harm Before The Court Rules On The Merits

On the other side of the ledger, Plaintiffs have not clearly shown they will suffer

immediate, irreparable harm unless the Court grants extraordinary relief. *See Winter*, 555 U.S. at 20; *Mazurek*, 520 U.S. at 972. Given the sheer verbosity of Plaintiffs' declarations, we begin by stripping away the theories of harm that categorically cannot support preliminary relief. First, only "irreparable harm *to the movant* rather than to one or more third parties" counts. *CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 622 (1st Cir. 1995). So all allegations of harm to third-party patients (*e.g.*, PI Mem. 51), third-party entities like "State, local, tribal, and territorial health departments" (*e.g.*, ECF No. 185-25, ¶ 26), and abstract notions such as "public health administration" (*e.g.*, ECF No. 185-25, ¶ 21) are irrelevant to this analysis.

Also immaterial is the harm that Plaintiffs "already suffered." *Gonzalez-Droz v. Gonzalez-Colon*, 573 F.3d 75, 81 (1st Cir. 2009). That includes the "time, staff attention, and financial resources" that "Plaintiff Organizations and their members" previously spent addressing ACIP matters or the January 2026 action. PI Mem. 44; *see, e.g.*, ECF No. 185-26, ¶ 20 ("responding to emails" about the January 2026 action); ECF No. 185-28, ¶ 15 ("discuss[ing] how" the January 2026 action "would impact [their] practice"). Such "expenses" of "time and resources," even if "substantial," are "already behind" Plaintiffs and thus cannot predicate a motion for prospective, preliminary relief. *Gonzalez-Colon*, 573 F.3d at 81.

As for future harm, the "long-term" does not matter, only "the interim period" before this Court resolves the merits. *Water Keeper All. v. U.S. Dep't of Def.*, 271 F.3d 21, 34 (1st Cir. 2001). After all, "[t]he purpose of a preliminary injunction is merely to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981). And in this APA case, that occurs when the Court rules on the parties' forthcoming motions for summary judgment. *See Juarez Morales v. Noem*, 791 F. Supp. 3d 100, 104 (D. Mass. 2025). This ruling is not far off. Defendants will begin producing the administrative

records for the claims in the operative Third Amended Complaint within a few weeks. *See* ECF No. 182. The parties can then brief cross-motions for summary judgment promptly thereafter. Plaintiffs cannot demonstrate irreparable harm in the narrow window of time between the Court's disposition of this motion and its final resolution of this case on summary judgment.

With those analytical parameters set, we address in turn each category of plaintiff—the Individual Plaintiffs, the Organizational Plaintiffs, and the practitioner-members of the Organizational Plaintiffs. The Individual Plaintiffs assert generalized "anxiety" about the "risk" of illness and about the prospect of "future vaccinations" for their children. ECF No. 185-49, ¶¶ 24-25; *see* ECF No. 185-50, ¶¶ 19-21; ECF No. 185-53, ¶¶ 31-32. However, "irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). With "no evidence" to substantiate the Individual Plaintiffs' fears, they have not demonstrated irreparable harm. *City of Lowell v. Enel N. Am., Inc.*, 705 F. Supp. 2d 116, 120 (D. Mass. 2010).

Turning to the Organizational Plaintiffs, they purportedly "will have to continue to divert" resources "from their primary missions . . . to address the confusion, misinformation, and distrust stemming from" the January 2026 action and "the February ACIP meeting." PI Mem. 45. But review of the declarations reveals that any future resources used to address developments in federal vaccine policy would be in service of, *not a diversion from*, the Organizational Plaintiffs' missions.

Whether in support of or in opposition to the recent actions of ACIP and CDC, the American Public Health Association ("APHA") will still engage in "professional and public education on how to improve community health" and "promot[ing] effective policy and practice"

when it advises members about vaccines in the coming months. ECF No. 185-25, ¶¶ 10-11. Likewise, the AAP does not take "resources away from core child-health initiatives" by publishing its own immunization schedule, preparing guidance documents, and answering members' questions. ECF No. 185-27, ¶¶ 22, 26; *see* ECF No. 185-35, ¶¶ 14-19. That is right in the wheelhouse of AAP's mission of attaining well-being and health for children through "publication of . . . policies on a broad range of topics," including a book with "AAP's immunization recommendations." ECF No. 185-27, ¶ 8. The same is true for the Infectious Diseases Society of America,[7] the Massachusetts Chapter of the American Academy of Pediatrics,[8] and the other Organizational Plaintiffs. Put simply, any resources the Organizational Plaintiffs will spend on advocacy and education about immunization policy will help them "accomplish [their] primary mission" and therefore not constitute irreparable harm. *New York v. McMahon*, 784 F. Supp. 3d 311, 362 (D. Mass. 2025).

The Organizational Plaintiffs also are not irreparably harmed by their difference of opinion with CDC's current immunization recommendations. Private organizations like AAP, the American College of Physicians, and the American Academy of Family Physicians have long published their own vaccine recommendations. *See* ECF No. 185-27, ¶ 8 (discussing AAP's *Red Book*); L. Reed Walton, et al., *The history of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 Vaccine 405, 409-10 (2015). These groups' views historically

[7] *Compare* ECF No. 185-36, ¶ 13 (offering "training, education, and resources regarding immunization"), *with id.* ¶ 40 (responding "to questions from members and the public surrounding" past ACIP votes and the January 2026 action).

[8] *Compare* ECF No. 185-42, ¶ 6 (providing "state-specific logistical guidance and evidence-based educational resources" to "pediatric health professionals"), *with id.* ¶ 23 (updating "website to reflect the AAP guidelines" and considering "additional materials and possible webinars to support physicians who administer the COVID-19 vaccine").

were not always in lockstep with CDC; there was "disagreement." *See* Walton, *History of ACIP*, *supra*, at 408-09 (discussing differences between recommendations, including for the measles, mumps, and rubella vaccine). Yet no group accused CDC then of inflicting irreparable harm based on a difference of opinion—because there was no harm. So too now.

Shifting to the doctor-members of the Organizational Plaintiffs, the evidence does not clearly show they "need . . . *immediate* relief" either. *Matos ex rel. Matos v. Clinton Sch. Dist.*, 367 F.3d 68, 74 (1st Cir. 2004). To be clear, neither ACIP nor the January 2026 action are imposing a "directive" that overrides practitioners' "medical judgment." ECF No. 185-45, ¶ 16; *see* ECF No. 185-27, ¶ 51. ACIP and CDC made recommendations; they have not issued commands. Other entities, such as States and professional organizations, have made recommendations too. *See, e.g.*, ECF No. 185-42, ¶ 22; ECF No. 185-43, ¶ 44; ECF No. 185-37, ¶ 22. The declarations confirm that providers are exercising their judgment to act consistent with the standard of care and the law, which for some means maintaining prior practice under State or professional guidelines. *See* ECF No. 185-51, ¶ 25; ECF No. 185-37, ¶ 22; ECF No. 185-42, ¶ 22; ECF No. 185-29, ¶ 8; ECF No. 185-30, ¶ 9.

Those doctor-members who choose to follow CDC's latest recommendations, including shared clinical decision-making for some vaccines, are hardly burdened in their "ability to provide" care. PI Mem. 45. As declarants concede, there is no "uniform standard meaning" of shared clinical decision-making. ECF No. 185-30, ¶ 10. For one declarant, it "means briefly discussing the benefits of a vaccine that I recommend the patient receive and risks of not being vaccinated." *Id.* Another describes the process beginning "by referencing the topic of the Covid vaccine and my recommendation that patients receive it," "solicit[ing] the patient or patient's parent for their perspective and engag[ing] in a conversation based on what is communicated."

ECF No. 185-32, ¶ 14; *see, e.g.*, ECF No. 185-31, ¶ 11.

Many conversations last only a few minutes. *See* ECF No. 185-33, ¶ 8 (2-3 minutes); ECF No. 185-27, ¶ 38 (3-5 minutes); ECF No. 185-32, ¶ 16 (5 minutes). Frequently, it is less because "[m]any [patients] do not wish to even engage in a discussion." ECF No. 185-31, ¶ 10. But creating space for a basic dialogue between physician and patient about whether to receive a vaccine hardly amounts to irreparable harm; nor does the fact that "[p]arents" are "asking more questions" about vaccines, ECF No. 185-43, ¶ 52. Those sorts of interactions are part and parcel of a physician's ordinary clinical responsibility. Certainly no patient would view this exchange as an irreparable harm to the physician.

Other purported harms mentioned by declarants are "largely self-inflicted" and categorically "not irreparable." *S.F. Real Est. Invs. v. Real Est. Inv. Tr. of Am.*, 692 F.2d 814, 818 (1st Cir. 1982). For example, the January 2026 action does not require any practitioner to establish a new protocol of special 30-minute visits for shared clinical decision-making. ECF No. 185-28, ¶ 18. A professor at Yale School of Medicine, who used to crib from the "CDC website" and ACIP, is hardly harmed by now "independently . . . identify[ing] the most accurate and fact-driven sources for instructional purposes." ECF No. 185-39, ¶ 8. And declarants voluntarily spend time "counseling colleagues" despite knowing that time "is not separately reimbursable." ECF No. 185-30, ¶ 13; *see* ECF No. 185-38, ¶ 12.

Plaintiffs also assert "safety concerns for physicians" and the fear of being "subject to liability" from a private lawsuit or "Board of Medicine" inquiry. PI Mem. 45. However, "irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears of what the future may have in store." *Charlesbank*, 370 F.3d at 162. And the declarants' concerns are purely speculative. *See* ECF No. 185-32, ¶ 20; ECF No. 185-45,

¶ 16; ECF No. 185-29, ¶ 25; ECF No. 185-31, ¶ 8. With "no evidence" to ground this "possible parade of horribles," Plaintiffs have not established irreparable harm. *City of Lowell*, 705 F. Supp. 2d at 120.

IV. Plaintiffs' Proposed Preliminary Injunction is Overbroad

If the Court finds Plaintiffs have carried their burden to satisfy each of the *Winter* factors for interim relief, it still should decline to enter the order proposed by Plaintiffs. "[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). "[I]n equity, 'the broader and deeper the remedy the plaintiff wants, the stronger the plaintiff's story needs to be.'" *Trump v. Casa, Inc.*, 606 U.S. 831, 854 (2025) (quoting S. Bray & P. Miller, Getting into Equity, 97 Notre Dame L. Rev. 1763, 1797 (2022)).

A. If the Court finds a defect in the January 2026 action, it should at most enter a stay of that action under the APA. *See* 5 U.S.C. § 705 ("On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court . . . may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings."). Plaintiffs quibble with the *process* through which Defendants responded to the December 2025 Presidential Memorandum and modified its recommended vaccine schedule. They have not identified any legal reason that the previous vaccine schedule cannot be changed, nor are Defendants aware of one. Instead, Plaintiffs argue, for example, that the schedule should have been reviewed by the ACIP and that it should have been supported by different reasoning.

If the Court agrees, it should not enter an injunction that would prevent Defendants from making future modifications to the schedule or attempting to cure any defects that this Court identifies. And any injunction certainly should not prevent HHS from deliberating on and

discussing vaccine science within the Department, with other agencies, and with the States and localities that Congress has authorized HHS to advise. In asking the Court to "FURTHER ENJOIN[]" Defendants "from publishing, disseminating, or relying upon any CDC immunization schedule, guidance documents, decision memorandum, work product, or public-facing materials that reflect or implement the enjoined actions," ECF No. 183-1 at 3, Plaintiffs appear to desire that outcome. That unusual proposal is totally unworkable and only highlights the wrongness of Plaintiffs' desire to stifle HHS's views. Its terms would prevent Defendants from filing the administrative record for this case. And it would require Defendants to violate the Freedom of Information Act's disclosure requirements if a request were made for records not subject to withholding under that law's exceptions. *See* 5 U.S.C. § 552.

B. Plaintiffs' proposed injunction as to its FACA allegations is also wrong.

Plaintiffs' proposed order asks the Court to enjoin Defendants "from convening, holding, or conducting the ACIP meeting currently scheduled for February 25-26, 2026, as well as any subsequent ACIP meetings of the current ACIP membership." ECF No. 183-1 at 4. That suggested injunction is vastly overbroad when compared to Plaintiffs' FACA allegations, which center on specific appointments to the Committee. If the Court finds a balance problem under FACA, it should stay the appointment of (or enjoin the service of) only as many appointees as would be necessary to achieve the balance that Plaintiffs can show FACA requires. Likewise, if the Court finds an influence problem, only the influenced members should have their service affected.

Plaintiffs argue that only *some* of Secretary Kennedy's appointees hold anti-vaccine views, and even then, they do not argue that no vaccine skeptic may serve on the ACIP. To the extent the Membership Balance Plan is relevant, Plaintiffs admit that not all of Secretary

Kennedy's appointments were inconsistent with it. PI Mem. 39. Plaintiffs do not come close to proving that all 14 of HHS's recent appointments to ACIP are unlawful. Thus, any injunction should be tailored to the specific appointments that Plaintiffs prove are legally problematic.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' preliminary injunction motion.

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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.

February 9, 2026

/s/ Isaac C. Belfer
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