

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

AMERICAN ACADEMY OF PEDIATRICS, et al.

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY JR., et al.

Defendants-Appellants.

On Appeal from the United States District Court
for the District of Massachusetts

BRIEF FOR FEDERAL DEFENDANTS-APPELLANTS

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GLOSSARY

AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
APA	Administrative Procedure Act
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DOD	U.S. Department of Defense
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
HHS	U.S. Department of Health and Human Services
MBP	Membership Balance Plan
MTD Op.	Memorandum and Order on Defendants' Motion to Dismiss
NIH	National Institutes of Health
PI Op.	Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction
SCDM	Shared Clinical Decision-Making

INTRODUCTION

The stay order below transferred vaccine policy authority from the Executive Branch to a single district judge. By staying thirteen of fifteen ACIP appointments while simultaneously holding that the CDC Director cannot change the immunization schedule without ACIP's involvement, the court ensured that no one could make vaccine policy: the Director needs the ACIP, the ACIP lacks a quorum, and the government cannot reconvene it without judicial permission. Should a pathogen emerge tomorrow, the government's only path to respond would run through the district court.

This appeal challenges the FACA-based structural relief only. It does not seek to disturb the stay of the January 5 Memo, which rests on independent grounds, and it does not ask this Court to disturb the stay of the CDC-adopted ACIP votes in the interim; on remand, the district court may consider whether that relief is warranted under the counts that remain.

This case began in July 2025 as a focused challenge to one agency action: the Secretary's May 2025 Directive on COVID-19 vaccines for children and pregnant women. The complaint has since been amended four times. By the Fourth Amended Complaint, the case encompassed numerous actions, a FACA reconstitution claim, and a request to enjoin the ACIP from

meeting. The preliminary injunction motion followed. The district court granted relief. The FACA claim that supports the broadest relief, the stay of nearly the entire committee and the holding that the Director may not act without ACIP, lacks legal foundation.

The district court effectively recognized a freestanding cause of action under FACA to challenge individual advisory committee appointments—though FACA does not create one, the APA does not supply one, and no court has ever recognized one. It conducted a de novo credentialing review of each ACIP member’s qualifications and concluded member by member that they were insufficiently expert. That review exceeds what this Court authorized in *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020), conflicts with *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), and yields a remedy—staying appointments, leaving the committee unable to convene; and conditioning schedule changes on ACIP involvement, a precondition found in no statute—the Constitution forbids.

The APA already has a place for every fact in this case, and that placement exposes the error. The APA supplies the only cause of action, and it reaches only final agency action. If anything here is final agency action, it is the CDC Director’s adoption of a recommendation. The ACIP vote that

precedes it is not, and the appointments that precede that vote are further still from finality. If the advisory process was compromised, that bears on whether the Director's adoption was arbitrary and capricious, and Counts I, III, and IV are the vehicle for saying so. Count II instead asked the court to review the appointments themselves.

That is the root error, and the rest follows from it. Having adjudicated a non-final action, the court had no final action to measure under the deferential standard the APA supplies, so it credentialed appointees de novo. And because it had no final action to vacate and remand, it crafted a remedy to put the committee out of existence. Neither the standard nor the remedy is a separate misstep. Each is what happens when a court reviews what the APA does not reach.

The order as to Count II should be reversed.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1331 (federal question) and 5 U.S.C. § 702 (judicial review of agency action).

The district court entered its preliminary relief order on March 16, 2026. Dkt. 291; App. 816. The government filed a timely notice of appeal on April 15, 2026, under 28 U.S.C. § 1292(a)(1).

An interlocutory order is appealable under § 1292(a)(1) when it has the practical effect of granting an injunction and meets the conditions set out in *Carson v. American Brands, Inc.*, 450 U.S. 79, 83–84 (1981). All three are satisfied. First, the order has the practical effect of an injunction: it does not preserve the status quo but affirmatively restrains executive action—barring thirteen appointees from serving and commanding that the CDC Director not change the immunization schedule without ACIP involvement. *Abbott v. Perez*, 585 U.S. 579, 594–95 (2018); see *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 287–88 (1988). Second, the order threatens “serious, perhaps irreparable, consequence.” *Carson*, 450 U.S. at 84. It disables the federal vaccine-advisory apparatus—the ACIP cannot reach a quorum, and the CDC Director may not alter the immunization schedule without it. Third, the order “can be ‘effectually challenged’ only by immediate appeal.” *Id.* The injury is the ongoing disability itself, which compounds each day and would be largely complete—the influenza-vaccine cycle missed and months of

vaccine policy frozen—before any final judgment; review at the end of the case would come too late to undo the harm.

This Court therefore has appellate jurisdiction over the March 16 order insofar as it grants the FACA-based relief challenged in this appeal.

STATEMENT OF THE ISSUES

Each of the district court’s errors independently warrants reversal. Together, they yielded a federal judge effectively staffing an executive branch advisory committee. The issues presented are:

(1) Whether Count II states a justiciable claim: whether plaintiffs have Article III standing to challenge advisory committee appointments; and whether such appointments constitute “final agency action” under 5 U.S.C. § 704.

(2) Whether the district court applied the correct standard of review to the FACA fair-balance claim, and whether its de novo credentialing review of individual ACIP members exceeded the scope authorized by *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020).

(3) Whether staying thirteen appointments, leaving the committee unable to convene, and conditioning any schedule change on ACIP

involvement, is authorized by FACA or the APA, and whether it is consistent with *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025).

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. The ACIP and the Vaccine Recommendation Process

The Advisory Committee on Immunization Practices is an advisory committee established under FACA. Dkt. 185-21, at 2–3; App. 157–58. Since 1964, the ACIP has provided expert guidance on the clinical use of vaccines.

The ACIP’s recommendations are not self-executing. The CDC Director retains independent authority to adopt or reject them. By regulation, an ACIP recommendation “is considered in effect” only “after it has been adopted by the Director.” 45 C.F.R. § 147.130(a)(1)(ii). The HHS Secretary retains supervisory authority over the CDC Director.

In *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), the Supreme Court held that members of the U.S. Preventive Services Task Force were inferior officers because the Secretary could remove them at will and

could review and block their recommendations before they took effect. The same supervisory features mark the Secretary's relationship to the ACIP. The Secretary's control reaches the committee's structure itself: he issues and amends the ACIP charter, which authorizes up to nineteen voting members and which he amended in December 2025. Dkt. 185-21, at 5-6; App. 160-61. Setting and revising the committee's size and membership is direct supervision.

Historically, before the ACIP votes on a vaccine recommendation, a Workgroup reviews the scientific evidence using the GRADE framework and the Evidence to Recommendation framework. PI Op. at 6-7 & nn.13-14; App. 821. Once the ACIP votes, the CDC Director may adopt or reject the recommendation. Dkt. 185-21, at 2-3; App. 157-58.

Congress has incorporated ACIP recommendations into various statutes related to vaccine coverage. The Affordable Care Act requires insurers to cover vaccines recommended by the ACIP. 42 U.S.C. § 300gg-13(a)(2). Veterans' benefits are tied to the ACIP schedule. 38 U.S.C. § 1701(9)(G), (10). Medicaid plans must cover ACIP-recommended vaccines. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B). The Vaccines for Children

program purchases vaccines according to the ACIP's list. *Id.* § 1396s(d)(1), (e).

B. The ACIP Reconstitution

Exercising the Secretary's authority over the membership of the ACIP, Secretary Kennedy reconstituted the committee to broaden the scientific perspectives represented on it. On June 9, 2025, Secretary Kennedy terminated all 17 ACIP members. He announced and explained the decision publicly the same day, describing the reconstitution as a measure to restore public trust in the committee's vaccine recommendations. PI Op. at 7 n.15; App. 822 (citing Robert F. Kennedy, Jr., *RFK Jr: HHS Moves to Restore Public Trust in Vaccines*, Wall St. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112> and HHS press release). On June 11, the Secretary announced eight replacement appointments. PI Op. at 7; App. 822. Four more followed on September 11, and two more on January 13, 2026. *Id.* at 7–8; App. 822.

The committee's charter authorizes up to nineteen voting members, and several seats remained unfilled, so its membership could still change and the reconstitution remained ongoing rather than complete. Dkt. 185-21,

at 5; App. 160. The assembly was in fact still under way when the district court ruled: on February 27, 2026, the Secretary appointed two additional members, whom the district court assumed to be “sufficiently qualified.” PI Op. at 8 & n.17, 29 n.46; App. 823, App. 844. Those appointments brought the Secretary’s new appointees to sixteen; one had departed in December, so “[f]our seats on ACIP remain vacant.” Dkt. 272, at 14 & n.3; App. 657.

C. The Three ACIP Votes

The reconstituted ACIP held three meetings and took three challenged votes — each a recommendation the CDC Director remained free to adopt or reject. At the June 2025 meeting, the committee voted to recommend that manufacturers discontinue thimerosal as a preservative in influenza vaccines. PI Op. at 9; App. 824. The Secretary adopted this recommendation on July 23, 2025. *Id.* at n.21; App. 824.

At the September 2025 meeting, the ACIP voted to change the COVID-19 vaccine recommendation for adults and children from routine to SCDM. *Id.* at 9; App. 824. Acting CDC Director O’Neill adopted the recommendation on or about October 6, 2025. Dkt. 237, at 9; App. 299.

At the December 2025 meeting, the ACIP voted 8–3 to recommend individual-based decision-making for the hepatitis B birth dose for infants

born to mothers who test negative for the virus—reversing a recommendation that had been in place since 1991. PI Op. at 9; App. 824. Outside presenters spoke on the hepatitis B vaccine. *See* Dkt. 272, at 39–41; App. 682. The CDC adopted this recommendation on December 16, 2025. Dkt. 237, at 10; App. 300.

D. The Motion to Dismiss

On November 19, 2025, the government moved to dismiss under Rules 12(b)(1) and 12(b)(6). Dkt. 144; App. 83. On January 6, 2026, the district court denied the motion. *AAP v. Kennedy*, 814 F. Supp. 3d 150 (D. Mass. 2026). The court found organizational standing based on AAP’s diversion of resources and associational standing based on member doctors’ financial injuries, including changed billing, unused vaccine doses, and unreimbursed SCDM conversations. MTD Op. at 10–16; App. 128. The court did not analyze standing separately for each count, stating that “[n]either party argues that the standing analysis differs for each claim, and the Court see[s] no reason to analyze Plaintiffs’ standing for each claim separately.” *Id.* at 9 n.13; App. 127.

On the merits, the court framed Count II as an APA claim, citing this Court’s *Wheeler* decision for the proposition that FACA’s fair-balance and

inappropriate-influence provisions are reviewable under the APA. *Id.* at 20; App. 138. The court held that Plaintiffs had “plausibly alleged” a FACA violation under Rule 12(b)(6). *Id.* at 22; App. 140. It did not articulate the standard of review that would govern the fair-balance claim on the merits. And it did not assess whether individual ACIP appointments constitute final agency action under 5 U.S.C. § 704.

E. The January 5, 2026 Decision Memo

On January 5, 2026, Acting CDC Director O’Neill signed a Decision Memo aligning the U.S. Childhood Immunization Schedule with the schedules of peer developed countries, reducing routinely recommended vaccinations from 17 to 11. PI Op. at 10; App. 825. The Memo was issued pursuant to a December 5, 2025 Presidential Memorandum. PI Op. at 10 n.25; App. 825. The ACIP did not vote on the childhood schedule realignment. The Memo relied on an assessment authored by individuals outside the ACIP process, with input from the NIH Director, CMS Administrator, and an FDA official. PI Op. at 10 & n.24; App. 825.

F. The District Court’s Preliminary Relief Order

On March 16, 2026, the district court granted the preliminary injunction motion in part. PI Op.; App. 816. As to the January 5 Memo, the

court held it was both contrary to law—because the Director acted without consulting the ACIP—and arbitrary and capricious—because the agency abandoned its longstanding practice of obtaining ACIP recommendations without sufficient explanation. *Id.* at 14–22; App. 829.

As to the May 2025 Directive, the court found that Plaintiffs had not met their burden of establishing a justiciable claim, because the Directive was either not final agency action or had been mooted by subsequent actions. *Id.* at 22–25; App. 837.

As to the ACIP reconstitution, the court conducted a member-by-member credentialing review. It evaluated each appointee’s credentials and publications. It concluded that only six of fifteen members had “any meaningful experience in vaccines,” *id.* at 29; App. 844, and that the reconstitution violated FACA’s fair-balance requirement because “the appointment process, in general, and thus the full committee, was tainted,” *id.* at 43–44; App. 858–59. The court stayed thirteen of the fifteen appointments and all votes taken by the reconstituted ACIP. *Id.* at 28–34, 43–45; App. 843–49, App. 858–60.

Plaintiffs did not seek a stay of appointments. Their proposed order sought to enjoin five specific downstream agency actions and to bar future

ACIP meetings. Dkt. 183-1; App. 141. The government argued that, if the court found a FACA imbalance, it should stay only as many appointments as necessary to cure it. Dkt. 232, at 51; App. 288. The court did neither. It stayed all thirteen challenged appointments, including members it did not find unqualified, on its tainted-process theory, sweeping broader than the government's proposal and leaving the committee without a quorum.

The court also held that the CDC Director lacks authority to change the immunization schedule without at least considering ACIP's recommendations – while expressly reserving whether the Director's role is limited to “adopt[ing]” ACIP's formal recommendations, *id.* at 15 & n.31; App. 830 – reasoning that multiple federal statutes contemplate ACIP's involvement and that the Director's general authority to “assist” and “advise” cannot override those specific provisions. *Id.* at 15-18; App. 830-33.

The combined effect of the order: the Director cannot act because the court says he needs the ACIP; the ACIP cannot convene because the court stayed its membership appointments; and neither can respond to public health developments without returning to the district court. The result is a stay broader than necessary to cure any imbalance the court identified, together with an ACIP-involvement precondition that appears in no statute.

SUMMARY OF ARGUMENT

This appeal presents a single error and its consequences. The district court adjudicated a non-final action—the ACIP appointments—that the APA does not reach. The standard of review it applied and the remedy it imposed follow from that mistake. Plaintiffs’ lack of Article III standing shares that root, but it is an independent, jurisdictional defect that defeats Count II on its own.

I. Count II is not justiciable, for two independent reasons. First, Plaintiffs lack Article III standing: their alleged injuries trace to the Director’s adoption of recommendations, not to who sits on the committee, and disturbing the appointments redresses nothing. Second, the appointments are not reviewable final agency action. FACA creates no private right of action. The APA is the only vehicle, and it reaches only final agency action. Advisory committee appointments are the beginning of a deliberative process, not its consummation. *Wheeler* reviewed a formal, categorical directive barring an entire class of scientists from committee service—a different species of agency action than a series of discrete personnel decisions made at different times. Plaintiffs’ concrete injuries trace to the downstream CDC-adopted recommendations, which are independently

actionable under Counts I, III, and IV. Plaintiffs themselves told the district court that the ACIP “neither makes nor implements government decisions or policy” and that the “final agency decisions belong to the Secretary or the CDC Director[.]” Dkt. 276, at 4–5; App. 713–14. Count II is redundant.

II. Because the court reviewed a non-final action rather than a final one, it applied the wrong standard. *Wheeler* authorized outer-boundary, process-based review – whether the agency acknowledged the effects of its actions and offered a rational reason for the alteration of balance. The district court went far beyond this. It conducted a de novo credentialing trial, evaluating each appointee’s credentials and publications and concluding member by member that they lacked requisite expertise. This Court did not sanction that approach in *Wheeler*. No circuit has. Once a court moves past outer-boundary review, there is no principled stopping point, as the Ninth Circuit’s contrary holding in *Center for Policy Analysis on Trade & Health v. Office of U.S. Trade Representative (CPATH)*, 540 F.3d 940 (9th Cir. 2008), underscores.

III. Regardless of the merits, the relief the district court entered is independent reversible error. FACA limits advisory committees to “solely for advisory functions” and reserves all policy determinations to the

President or a federal government officer. The district court's order inverts this framework. It treats ACIP involvement as a precondition for any schedule change while staying thirteen of fifteen appointments, ensuring the ACIP cannot achieve a quorum.

The combined effect is to freeze federal vaccine policy: the Secretary cannot reconvene the current committee without judicial permission, the Director cannot act without the committee, and no one can make recommendations in response to a public health emergency. That result conflicts with *Kennedy v. Braidwood Management*, which treated the Secretary's removal power and authority to block recommendations as what rendered the Task Force's structure constitutional.

The proper remedy, if any, is to stay the specific challenged final agency actions and remand for the agency to follow its procedures.

STANDARD OF REVIEW

This Court reviews de novo questions of law, including the existence of a cause of action, Article III standing, and the final agency action requirement. *Redondo-Borges v. HUD*, 421 F.3d 1, 5 (1st Cir. 2005); *see also Wheeler*, 954 F.3d at 17 (justiciability under the APA reviewed de novo). The

scope of judicial review under FACA—what standard the district court should have applied to the fair-balance determination—is a legal question reviewed de novo.

The district court’s fashioning of preliminary injunctive relief is reviewed for abuse of discretion. But a preliminary injunction that rests on an error of law is necessarily an abuse of discretion. *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 10 (1st Cir. 2013); *see Asociación de Educación Privada de P.R., Inc. v. García-Padilla*, 490 F.3d 1, 8 (1st Cir. 2007) (questions of law underlying injunctive relief are reviewed de novo). Because the district court’s FACA-based relief rests on threshold legal errors, this Court’s review is effectively de novo.

ARGUMENT

I. Count II Fails at the Threshold.

Standing and final agency action independently defeat Count II. No federal court has jurisdiction over a freestanding challenge to individual advisory committee appointments. Standing is assessed claim by claim and remedy by remedy: a plaintiff with standing to press one claim does not thereby acquire standing to press another, or to obtain relief that redresses no injury of its own. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006);

Davis v. FEC, 554 U.S. 724, 734 (2008); accord *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016) (claim-by-claim analysis).

That principle is dispositive here: Plaintiffs’ sufficient standing for Counts I, III, and IV does not carry over to Count II. The government pressed that claim-by-claim analysis below. Dkt. 272, at 18–19; App. 661–62; Dkt. 232, at 37–43; App. 274–80.

A. No Article III Standing.

1. Plaintiffs lack Article III standing to pursue Count II. That defect stands on its own: it is jurisdictional and defeats the claim however this Court resolves other questions.

The flaw is one of traceability and redressability. The concrete injuries Plaintiffs and the district court identified—changed billing, unused doses, unreimbursed counseling—flow from the CDC-adopted recommendations, not from who sits on ACIP. The Director’s independent decision whether to adopt a recommendation severs those injuries from the committee’s composition, and disturbing the appointments does not redress them. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380–83 (2024). The Director’s adoption also is not the kind of “predictable” third-party reaction that can sustain traceability. *All. for*

Hippocratic Med., 602 U.S. at 383. Adoption is an independent, discretionary determination committed to the Director, and by regulation a recommendation has no effect at all unless and until the Director adopts it. 45 C.F.R. § 147.130(a)(1)(ii). Counts I, III, and IV reach the adoption decisions directly. Count II reaches nothing they do not. Plaintiffs confirmed the overlap below. Arguing the preliminary injunction, their counsel urged that because the committee was “improperly constituted,” the “votes ... should be set aside” —a downstream remedy they sought through the upstream composition claim. Dkt. 283, at 22 (Mar. 4, 2026 Hr’g Tr.); App. 750. That is Count II doing the work of Counts I, III, and IV.

2. Plaintiffs separately identify no judicially cognizable Article III interest in the qualifications of executive-branch personnel. The President appoints officers, and those officers appoint personnel. Courts do not review whether a cabinet secretary’s counselor is sufficiently qualified, whether a special assistant has the right credentials, or whether an advisory committee member’s CV meets a judicially imposed standard. These are executive staffing decisions. They are subject to political accountability—congressional oversight, appropriations, elections—not judicial review.

3. The district court cited *National Anti-Hunger Coalition v. Executive Committee of the President's Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983), for the proposition that a person with “a direct interest in the committee’s purpose” has standing whenever the fair-balance requirement “is ignored.” That case predates *Lujan*, 504 U.S. 555; *Spokeo, Inc. v. Robins*, 578 U.S. 330 (2016); and *Alliance for Hippocratic Medicine*. And it is incompatible with current Supreme Court standing doctrine. It is also dictum: the D.C. Circuit called the standing question “a close one that we need not resolve,” and in the footnote appended to that observation agreed with the government that the downstream injury actually asserted—a possible diminution of federal benefits—was “speculative and conjectural in the purest sense” and “would not confer standing.” *Nat’l Anti-Hunger Coal.*, 711 F.2d at 1073–74 & n.2. The portion of the footnote the district court relied on was unnecessary to the appeals court’s decision; the portion it did not cite rejects the very downstream-injury theory advanced here.

The district court’s remaining authorities do not fill the gap. The decisions recognizing FACA fair-balance standing—*NAACP Legal Defense & Educational Fund, Inc. v. Barr*, 496 F. Supp. 3d 116 (D.D.C. 2020), *America First Legal Foundation v. Cardona*, 630 F. Supp. 3d 170 (D.D.C. 2022), and *National*

Ass'n of Consumer Advocates v. Uejio, 521 F. Supp. 3d 130 (D. Mass. 2021), are district-court decisions that rested on asserted representational and informational injuries — the denial of a voice or a seat in the committee's own proceedings — and sought relief against the committee's operations. Plaintiffs' claimed injuries here are financial and downstream. To the extent they also invoke the termination of liaison organizations' participation on ACIP workgroups, *see* PI Op. at 25–26; App. 840–41, that theory fails on its own terms. No statute entitles any organization to a workgroup seat. An interest in being represented in the committee's deliberations is exactly the bare representational stake *TransUnion* forecloses; and staying the appointments of voting members restores no one's workgroup participation, so the relief entered does not redress the asserted injury. The government made this point below. Dkt. 232, at 42–43; App. 279–80.

Even those decisions relied on by the district court police the injury requirement. *Cardona* itself denied standing to a plaintiff whose “general interest in government transparency” was not “a direct interest in the committee's purpose.” 630 F. Supp. 3d at 180. And to the extent any of them would confer standing on a bare statutory interest in committee composition divorced from concrete, traceable, redressable harm, they cannot be squared

with *Alliance for Hippocratic Medicine*, 602 U.S. at 380–83, which postdates each. A bare statutory entitlement to a balanced committee, untethered to concrete harm, is “an injury in law,” not “an injury in fact.” *TransUnion LLC v. Ramirez*, 594 U.S. 413, 427 (2021); see *id.* at 431 (standing “is not dispensed in gross”). And an organization “cannot spend its way into standing” by diverting resources in response to government action it opposes. *All. for Hippocratic Med.*, 602 U.S. at 394–95.

The district court relied on *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), and pre-*Alliance for Hippocratic Medicine* district court authority. But *Havens* is distinguishable. There, the defendant’s discriminatory practices “perceptibly impaired” the organization’s core service activity—its housing counseling and referral services. 455 U.S. at 379. The unlawful conduct operated directly on that activity. Here, the government’s actions operated on the vaccine schedule, which affected third-party doctors and patients, which prompted AAP to spend money responding. That is the attenuated chain *Alliance for Hippocratic Medicine* rejected, cautioning that *Havens* was “an unusual case” not to be extended beyond its context. 602 U.S. at 394–96.

4. Associational standing fares no better. The district court found standing based on member doctors’ financial injuries—changed billing,

unused vaccine doses, unreimbursed SCDM conversations. MTD Op. at 14–16; App. 132. But they do not support standing for Count II. These injuries trace to the CDC-adopted schedule changes, not to who sits on the committee. No doctor lost reimbursement because person X was appointed to ACIP. Doctors lost reimbursement because the vaccine schedule changed. The appointments are several causal steps removed from the financial harm. Count II thus lacks both organizational and associational standing.

The district court’s own holding on Count I confirms the traceability problem for the most consequential challenged action. The court held the January 5 Memo unlawful because the CDC Director bypassed the ACIP entirely. If the committee was bypassed, its composition necessarily was causally irrelevant to the resulting injury. Plaintiffs’ alleged financial harms from the January 5 schedule changes trace to the Director’s decision, not to who sits on a committee the Director ignored. And for the three ACIP votes, the financial injuries trace to the CDC Director’s adoption of the recommendations, not to the committee’s composition standing alone. Counts I, III, and IV reach those adoption decisions directly.

Other courts have rejected similar causal chains in the FACA context. In *Physicians’ Education Network v. Department of HEW*, 653 F.2d 621, 623 (D.C.

Cir. 1981), the court held that economic injury from an advisory committee's output was insufficient because rescinding the committee's work product would not redress the downstream harm. In *Metcalf v. National Petroleum Council*, 553 F.2d 176, 186–87 (D.C. Cir. 1977), the court held that consumer injuries from an advisory committee's allegedly biased advice were “speculative and conjectural in the purest sense” and thus insufficient as injuries in fact, while noting—without needing to decide—the “obvious problems ... related to causation and redressability” of such claims. And in *Mulqueeny v. National Commission on the Observance of International Women's Year*, 549 F.2d 1115, 1121 (7th Cir. 1977), the court held it was “wholly conjectural” whether the relief the plaintiffs sought against an advisory body would alter the independent legislative decision they sought to influence. Although these cases long predate *Lujan*, they are consistent with the traceability and redressability requirements the Supreme Court later formalized, 504 U.S. at 560–61, and have never been called into question.

5. If FACA's fair-balance requirement creates a judicially enforceable right in third parties to challenge individual appointments, then every statute that touches executive personnel decisions becomes a hook for judicial review of those decisions. Any advocacy organization with an

interest in an advisory committee's subject matter could sue to challenge individual appointments, demand a credentialing trial, and obtain a court order dictating committee composition. That is true not just for the ACIP but for roughly a thousand federal advisory committees.

Metcalf warned against this result: accepting such injuries “as sufficient for standing” would require courts “to supervise the membership and funding of federal advisory committees on a continual basis and to alter the composition of these committees according to our subjective determinations as to ‘fair balance.’” 553 F.2d at 190. That is what the district court did here.

The district court's motion-to-dismiss ruling confirms the problem. The court did not analyze whether the financial injuries described above are traceable to the *appointments* as distinguished from the downstream agency actions independently challenged in other counts. It *declined* to analyze standing claim by claim, seeing “no reason to analyze Plaintiffs’ standing for each claim separately.” *Id.* at 9 n.13; App. 127.

This Court should conduct that analysis. For Counts I, III, and IV, the causal chain runs from changed recommendations to changed billing to financial harm. For Count II, injuries must trace to the appointments themselves. They do not.

B. No Reviewable Agency Action.

1. The threshold problem is more basic than finality: the reconstitution is not “agency action” the APA makes reviewable at all. The APA defines “agency action” to mean “the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof[.]” 5 U.S.C. § 551(13). Each is a discrete, circumscribed act. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62–64 (2004). Appointing members to an advisory committee—or reconstituting one through a rolling series of appointments over many months—is none of those categories, and APA review does not lie against an ongoing course of conduct rather than a discrete action. *Id.*; *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 890 (1990). Only if the appointments were “agency action” would finality matter. And they are not final either.

The government argued below that Count II fails to state a claim because the reconstitution did not violate any law. Dkt. 145, at 23–25; App. 114–16. This argument refines that position: even if the ACIP was not “fairly balanced,” *Wheeler* requires a reviewable agency action as the vehicle for enforcement, and no such vehicle exists for individual advisory committee

appointments. Whether Count II fails because it lacks merit or because it lacks a vehicle is a legal question this Court reviews de novo.¹

2. “FACA contains no private right of action.” *Wheeler*, 954 F.3d at 17.

Any cause of action, if one exists, must come from the APA.

In *Wheeler*, the APA supplied that cause of action: the EPA Directive was the agency action under review—its finality was not disputed—and FACA supplied the substantive legal standard against which the directive was to be measured. This Court held that allegations that the directive violated FACA’s fair-balance and inappropriate-influence requirements “plausibly state[d] claims for judicial review under the APA[,]” reversed the dismissal of those claims, and remanded. *Wheeler*, 954 F.3d at 20. *Wheeler* did not hold that FACA itself provides a cause of action but that a specific agency

¹ Plaintiffs’ proposed order did not request a stay of the appointments. Dkt. 183-1; App. 141. It sought to enjoin five downstream agency actions and to stop future ACIP meetings, and the government briefed against that relief—arguing in the alternative that any appointment-related relief should reach only as many appointments as necessary to cure any imbalance. Dkt. 232, at 51; App. 288. A stay of thirteen appointments appeared for the first time in the order under review. A party cannot waive an argument against relief no one requested. To the extent this Court views the final agency action question as distinct from those preserved arguments, it is a purely legal question resolvable on the existing record. See *Singleton v. Wulff*, 428 U.S. 106, 121 (1976).

action—the directive—could be reviewed under the APA for compliance with FACA. *Wheeler* thus confirms that FACA’s fair-balance requirement is reviewable, but only through a reviewable final agency action. What defeats Count II is the absence of such an action here, not doubt about FACA’s enforceability.

The district court confirmed *Wheeler*’s framework in its motion-to-dismiss ruling, citing it for the proposition that FACA’s fair-balance and inappropriate-influence provisions are reviewable under the APA. MTD Op. at 20; App. 138. Plaintiffs agree. Their memorandum in support of the preliminary injunction stated: “The APA provides a cause of action for review of agency decisions that violate federal law, including FACA.” Dkt. 237 at 42; App. 332. But having identified the APA as the vehicle, the district court never then asked whether individual appointments satisfy the APA’s final agency action requirement. They do not.

Because all agree the APA supplies the cause of action, its constraints apply—including the requirement of a reviewable final agency action. There is none. Appointment decisions cannot satisfy *Bennett v. Spear*, 520 U.S. 154, 178 (1997), because they do not determine “rights or obligations.” No legal consequences flow from placing someone on an advisory committee.

Nor are ACIP recommendations final agency action. They are advisory inputs to a downstream decisionmaker. That is the structure the Supreme Court held insufficient in *Dalton v. Specter*, 511 U.S. 462, 469–71 (1994) (base closure recommendations not final agency action because they were “more like a tentative recommendation than a final and binding determination” (quoting *Franklin v. Massachusetts*, 505 U.S. 788, 798 (1992))); see *Bennett*, 520 U.S. at 178 (explaining that the recommendations in *Dalton* were “in no way binding on the President, who had absolute discretion to accept or reject them”). That *Dalton* involved recommendations to the President rather than to an agency is of no moment. Its logic is that a non-binding advisory input is not itself final agency action, whoever receives it. The CDC Director’s relationship to ACIP recommendations is identical. The Director may adopt or reject them. The CDC Director’s *adoption* of a recommendation, by contrast, is the only action here with any claim to finality, and it is the action the other counts challenge. If anything in this case is final agency action, it is that adoption. Until adoption, no rights or obligations are determined and

no legal consequences flow. The appointments that produce those recommendations are one step further removed.²

Plaintiffs have said the same. To preserve FACA's application to the ACIP after *Braidwood*, they told the district court that the committee is "a primarily advisory body because its functions are deliberative rather than executive"; that its recommendations "are not self-effectuating and only trigger coverage determinations when subsequently adopted by the CDC Director"; that the committee "neither makes nor implements government decisions or policy"; and that the "final agency decisions belong to the Secretary or the CDC Director." Dkt. 276, at 1, 4-5; App. 710, App. 713-14. Plaintiffs made these representations in supplemental briefing the district court ordered on whether FACA applies to the ACIP in light of *Braidwood*.

² Plaintiffs may argue that ACIP recommendations carry greater downstream legal force than the base closure recommendations in *Dalton*. Even if so, that strengthens the government's position. The downstream legal consequences flow from adoption and implementation of the recommendation, not from the appointment of the individuals who produced it. The greater the downstream legal force, the clearer the distinction between the preliminary action and the final action. Nor are ACIP recommendations like the biological opinion in *Bennett*, which itself "alter[ed] the legal regime" and exposed the action agency to penalties. 520 U.S. at 178. By regulation, an ACIP recommendation "is considered in effect" only "after it has been adopted by the Director." 45 C.F.R. § 147.130(a)(1)(ii). Until adoption, it alters nothing.

Dkt. 269; App. 643. Then, at the hearing on that question, their counsel doubled down in the plainest terms: the committee “*is not the final decider.*” Dkt. 283, at 27 (Mar. 4, 2026 Hr’g Tr.) (emphasis added); App. 755. That is a precise description of why neither the recommendations nor the appointments that precede them can be final agency action.

In *Wheeler*, the agency action under review was a formal written directive: a categorical policy of general applicability barring an entire class of scientists from committee service. The directive was published. It was the consummation of a decisionmaking process. And legal consequences flowed immediately. Thousands of scientists became categorically ineligible the moment it issued. No one disputed that the directive was reviewable agency action, and the claims this Court sustained as plausible were claims against the directive; the relief sought ran against the directive.

Nothing in *Wheeler* contemplated vacating individual appointments, enjoining committee meetings, or imposing procedural requirements on future EPA action. Section 704 can function as intended in such a case: the preliminary actions (the composition changes) are reviewed on review of the final action (the directive), and any remedy is directed at the final action. Indeed, *Wheeler* itself drew the line that matters here. The directive was

reviewable because it was “clearly not individual hiring decisions committed to discretion,” but an agency-wide policy. *Wheeler*, 954 F.3d at 18 n.5. What the district court reviewed here—a series of individual selections made at different times—is on the other side of *Wheeler*’s own line.

The reconstitution here has neither feature. It is not a single, dated, published policy but a rolling series of discretionary appointments spread across the better part of a year—terminations on June 9, 2025, eight appointments on June 11, four more on September 11, and further appointments into 2026. There is no governing instrument, no date of consummation, and no settled membership: the charter authorizes up to nineteen voting members, and seats remained open when the court intervened. Dkt. 185-21, at 5; App. 160. That the June 9 terminations were publicly announced changes nothing: an announcement of intent to reconstitute is not an operative directive. It barred no one from service, established no eligibility criteria, and carried no legal consequence of its own. What followed were individual selections made over many months. An action the agency is still making is not final. *Bennett*, 520 U.S. at 178. Defendants said as much below—the unfilled seats left the Secretary “room to add more viewpoints[,]” Dkt. 232, at 32; App. 269—yet the court stayed

individual appointments as not “fairly balanced.” A committee assembled by appointment is the paradigmatic programmatic attack the APA forbids. Defendants objected below on just this ground: this litigation “amounts to a programmatic challenge to HHS’s vaccine policy writ large that is not cognizable under the APA.” Dkt. 272, at 24; App. 667. *See also Norton*, 542 U.S. at 62–64; *Lujan*, 497 U.S. at 890. And the relief here runs against the appointments themselves—the clearest sign the court reviewed what neither the APA nor *Wheeler* reaches.

The district court brushed the distinction aside, calling it immaterial that *Wheeler* “involved a directive precluding a category of people from serving on EPA advisory committees, as opposed to affirmatively favoring a category of people.” MTD Op. at 21; App. 139. That misidentifies the line. The APA does not distinguish excluding from favoring. It distinguishes a reviewable final action from unreviewable personnel decisions. Strip away a *Wheeler*-type directive and no APA vehicle remains, and FACA’s standard can be enforced only through review of the downstream final actions the other counts already challenge.

The proper framework under *Wheeler*: FACA’s fair-balance requirement can be enforced through two channels. First, when an agency

issues a formal policy altering committee composition, that policy is a reviewable final agency action that can be measured against FACA's substantive standard, as *Wheeler* held. Second, when the CDC adopts an ACIP recommendation, the FACA issue folds into analysis of that downstream action; the agency's reliance on a structurally compromised advisory process bears on whether it examined the relevant data and articulated a satisfactory explanation. In both channels, FACA supplies a substantive standard, and the APA supplies the cause of action. What *Wheeler* did not create—and what does not exist—is a third channel: freestanding judicial review of individual appointments with structural remedies, untethered to any reviewable agency action.

Every FACA deficiency Plaintiffs identify—the committee's composition, the meeting process failures, the absence of GRADE review—is cognizable under analysis of the downstream final agency actions challenged in Counts I, III, and IV. Plaintiffs point to no fact or theory cognizable under Count II but not under those counts. Count II should be subsumed, not sustained as a freestanding claim with structural remedies. A FACA claim is an APA claim, and an APA claim gets APA remedies—not judicial staffing of the executive branch.

Plaintiffs argued below that the government waived any objection to finality. Dkt. 237 at 30–31; App. 320. The final-agency-action requirement, however, is an element of the APA claim on which Plaintiffs bear the burden, and whether the appointments satisfy it is a pure question of law that this Court may resolve on the existing record. *See Wulff*, 428 U.S. at 121.³

That conclusion controls the rest of the appeal. Because the appointments are not final agency action, the district court reviewed what the APA does not reach, and the standard-of-review and remedy errors that

³ The statements Plaintiffs invoke – government counsel’s observation at the January 12, 2026 status conference that this case involves multiple final agency actions, Hr’g Tr. at 28–29 (Dkt. 178), and the parties’ Joint Status Report, which reserved finality objections as to the June and December 2025 ACIP votes, Dkt. 181, at 3 – concerned downstream actions, whose finality is not at issue in this appeal. They say nothing about the appointments, which no party then understood to be a target of relief; indeed, the Joint Status Report’s catalogue of finality issues addressed downstream actions only. And the government rejected the waiver assertion below: “Plaintiffs’ quotations of Defendants’ counsel’s comments do not concede anything on finality[,]” Dkt. 232, at 21; App. 258, and objections to final agency action are “a species of failure to state a claim” that “may be raised at any time through trial,” Dkt. 272, at 24 n.6; App. 667 (citing Fed. R. Civ. P. 12(h)(2)). The argument is preserved in substance as well: the government argued below that Count II failed as a matter of law, Dkt. 145, at 23–25; App. 114–16, and the theory that the appointments themselves are reviewable final agency action crystallized only when the court granted relief running against them.

follow are not independent. They are the direct consequences of that threshold mistake.

II. Under *Wheeler*, Correctly Understood, the District Court Applied the Wrong Standard.

The wrong standard is the first consequence of reviewing a non-final action. A court reviewing a final agency action asks, on the record, whether the agency acknowledged the effect on balance and gave a rational reason for it. A court adjudicating appointments directly, with no final action and no record before it, does what the district court did: it reads CVs and credentials the members itself. *Wheeler* authorized only the former.

1. *Wheeler* noted that (in the context of a properly brought APA claim) courts can “enforce at least the outer boundaries” of FACA’s requirements. *Wheeler*, 954 F.3d at 18–19. What the court said, rejecting the EPA’s argument that the fair-balance standard was judicially unmanageable, was that it “disagree[d] with the EPA that courts are not well equipped to enforce at least the outer boundaries of ranges of this type.” *Id.* at 18–19. And the allegations it held sufficient were allegations about the agency’s reasoning: that the EPA “offered no rational reason” for concluding that the policy’s benefits justified the alteration of balance and “did not even acknowledge

that the directive had such an effect.” *Id.* at 20. That is record-based arbitrary-and-capricious review – did the agency consider the relevant factors? It is not de novo assessment of individual qualifications.

“At least” does not license a searching review. *Wheeler* used the phrase to describe the limited review it would undertake of a discrete directive, such as whether the agency acknowledged the directive’s effects and gave a rational reason. *Wheeler*, 954 F.3d at 18–20. Nothing in the *Wheeler* opinion contemplates a court reading individual CVs; the separation-of-powers concerns below confirm that “outer boundaries” marks a ceiling, not a floor. Past it, no principled stopping point remains.

Even where a downstream final action makes fair balance reviewable, that review is deferential. The fair-balance inquiry “falls short of mathematical precision in application,” and “the difficulty of determining what precisely constitutes a ‘fair balance’ may incline courts to be deferential in reviewing the composition of advisory committees,” a difficulty that “may defeat a plaintiff’s claims in a given case[.]” *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). Judge Friedman’s opinion in the same case makes the point on the merits: where a

committee's function "involves highly technical and scientific studies and recommendations," how a fairly balanced membership "is to be achieved" "necessarily lies largely within the discretion of the official who appoints the committee." *Id.* at 423–24 (Friedman, J., concurring in the judgment). Deferential, outer-boundary review of that kind cannot be reconciled with the member-by-member credentialing the district court performed.

The district court went far beyond *Wheeler*. The district court has never articulated a standard of review that would authorize its member-by-member credentialing. At the motion-to-dismiss stage, the court applied Rule 12(b)(6) plausibility and held that Plaintiffs "plausibly alleged" a violation. MTD Op. at 22; App. 140. At the preliminary-injunction stage, the court conducted a member-by-member credentialing review without stating what standard governed. PI Op. at 28–34; App. 843.⁴

⁴The methodology behind the court's member-by-member assessment is not apparent. In a series of footnotes, the court purported to grade each appointee's qualifications without identifying the standard it applied. It discounted Dr. Levi's published research on mRNA-vaccine safety – which it acknowledged was "no doubt relevant to ACIP" – as "only two papers" issued "mere months before his appointment," PI Op. at 30 n.53; App. 845, without explaining how many publications, or of what vintage, would establish "expertise." It dismissed Dr. Hibbeln despite his public-health and maternal- and child-health work, PI Op. at 29 n.49; App. 844. It stayed the appointments of members it never discussed at all. A review that credentials

Wheeler never authorized this. No circuit has. The circuits that entertain fair-balance claims at all have reviewed committee composition deferentially, and none has ever stayed or vacated an appointment or graded an individual member's credentials. See *Cargill, Inc. v. United States*, 173 F.3d 323, 334–41 (5th Cir. 1999); *Ala.-Tombigbee Rivers Coal. v. Dep't of Interior*, 26 F.3d 1103, 1106–07 (11th Cir. 1994) (affirming relief that ran against use of the committee's report, not against its membership); *Colo. Env't Coal. v. Wenker*, 353 F.3d 1221, 1231–34 (10th Cir. 2004); see also *Wheeler*, 954 F.3d at 20 n.6 (collecting these cases). The progression from “outer boundaries” (*Wheeler*) to “read everyone's CV” (district court) is an extension of *Wheeler* that this Court should not ratify and that drives the structural and constitutional problems addressed below. On the other side of an acknowledged disagreement among the circuits, see *Wheeler*, 954 F.3d at 20 & n.6, the Ninth Circuit's holding in *CPATH*—that the statutes there provided “no meaningful standards to apply,” 540 F.3d at 945—shows the danger in the district court's approach: once a court moves past *Wheeler's*

appointees one by one, on no administrative record and by an undisclosed, ad hoc standard, is not the deferential, outer-boundary review *Wheeler* permits—and a stay reaching members the court neither analyzed nor found unqualified confirms that the remedy swept past anything the court decided.

outer-boundary review, there is no principled stopping point. *Wheeler* declined to follow *CPATH*, and the government does not ask this Court to revisit that choice. The point is narrower: the concern that drove *CPATH* materializes the moment review leaves the outer boundary.

The government does not argue these facts can never be relevant to FACA review. Under *Wheeler*'s outer-boundary standard, a court reviewing a downstream final agency action could ask whether the agency acknowledged the reconstitution's effect on the committee's expertise mix and offered a rational reason for the alteration of balance. That inquiry, which is directed at the agency's reasoning, not at individual CVs, is what *Wheeler* authorizes. The district court skipped it entirely and proceeded directly to de novo credentialing.

2. Reviewing a non-final action also led the district court to invert the burden of proof. A party seeking preliminary relief must make a "clear showing" of its entitlement to relief on every element. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). The court did the opposite. It found ACIP unbalanced not from evidence Plaintiffs adduced, but from its own repeated refrain that there was "no evidence in the record" that individual members possessed vaccine-specific expertise. PI Op. at 29–30 & nn.47–52, 55; App.

844–45 (reciting, member by member, that “[t]here is no evidence in the record” of relevant experience). That treats the absence of evidence as proof of a violation and shifts to the Secretary the burden of justifying each appointment—the inverse of the movant’s burden and of the deference fair-balance review demands. The error is compounded because there was no administrative record to review. The court assessed credentials drawn from the ACIP website, acknowledged that “there may be evidence to demonstrate” that the members it discussed “have more relevant experience or expertise than what is before the Court at this juncture[.]” PI Op. at 31 n.56; App. 846, and then resolved that admitted evidentiary gap against the agency. A fair-balance violation cannot be established by an evidentiary vacuum of the movant’s own making. That inversion is especially indefensible given the deference this determination commands: where the movant bears the burden of a clear showing and the agency’s balance is reviewable only at its outer boundary, a gap in the record is a reason to deny relief, not a basis to find a violation.

Below, Plaintiffs invoked the ACIP Membership Balance Plan to argue otherwise. Dkt. 237 at 43–45; App. 333–35. But the MBP is not a statute or regulation. It is an internal agency document, and departure from it is not a

FACA violation. The point is only sharpened by the regulatory history. The requirement that an advisory committee maintain a membership balance plan at all has since been rescinded, 90 Fed. Reg. 58408 (Dec. 16, 2025), and the outreach regulation the court invoked, 41 C.F.R. § 102-3.60(b), has been revised – as the district court itself acknowledged. PI Op. at 31 n.57, 32 n.58; App. 846–47. These are malleable internal and regulatory process choices the Executive controls, not fixed statutory commands whose breach establishes a FACA violation. The substantive question FACA poses is the committee’s composition, not adherence to process the Executive has since withdrawn.

The ACIP charter is no different. The district court measured each member against the charter’s expertise categories, reasoning that the charter reflects HHS’s own account of the expertise the committee requires. PI Op. at 28–29 & n.44; App. 843–44. But the charter, like the MBP, is an Executive-issued and Executive-amendable document: the Secretary writes it, and he amended it in December 2025. Dkt. 185-21, at 5–6; App. 160–61. A charter describes the committee the Secretary intends to assemble. It does not surrender his judgment about which candidates satisfy its categories, and it supplies no warrant for a court to re-grade that judgment résumé by résumé. Treating an instrument of executive supervision as a judicially enforceable

ceiling on the Secretary's appointment discretion inverts its function. And the district court's use of the charter confirms the standard-of-review error rather than curing it: measuring fifteen individuals, one by one, against four expertise categories is *Daubert*-style member-by-member credentialing.

The question is not whether the Secretary made wise appointments. It is whether a federal court has the authority to review those appointments member by member, evaluate each appointee's qualifications, and vacate the ones the court deems insufficiently expert. No statute confers that authority. No precedent supports it. And the Constitution forbids it.

3. The credential review the district court conducted presents a freestanding separation-of-powers problem. Article II vests appointment power in the President and department heads. U.S. Const. art. II, § 2, cl. 2. That power includes the authority to determine what qualifications an appointee should possess and whether a particular individual meets them. When a court reviews individual credentials, counts publications, assesses whether research from the 1980s constitutes current expertise, and concludes member by member that the Secretary's appointees are insufficiently qualified, it is exercising the appointment power under a different name. The Secretary decides what expertise ACIP needs, who has it, and how to weigh

competing qualifications against the committee's mission. A federal judge who substitutes his own assessment of those questions has crossed the line between judicial review and executive staffing. The principle has no limiting point.

III. The Relief Below Is Improper

Everyone agrees the APA supplies the cause of action. That agreement decides the remedy. The APA does not authorize a court to review agency conduct in the abstract. It authorizes a court to “set aside” a final agency action, 5 U.S.C. § 706(2), and to remand for the agency to proceed properly.

A FACA fair-balance objection brought through the APA is therefore an objection to a final action that relied on a compromised committee, reviewed on the record as the committee stood when the agency acted. The proper remedy is ordinary: vacate that action and remand, leaving the agency to cure any imbalance by adjusting the committee's membership. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (“[T]he proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation.”).

The district court never reached that remedy – indeed, it had trouble crafting one – because it never reviewed a final action. At Plaintiffs’ urging,

it adjudicated the appointments themselves (whether viewed as fifteen individual decisions or as one rolling reconstitution) and found them wanting. But the appointments are not final agency action, and having reviewed something the APA does not reach, the court had no final action to vacate and remand. So, it improvised: it stayed the appointments, froze the committee, and dictated terms of its future operation.

The breadth of that remedy is not a separate misstep. It is the consequence of reviewing a non-final action. Tie the FACA inquiry to a final action and the remedy follows automatically, modestly, and naturally. Sever it, as the court below did, and there is nothing to vacate and nothing to remand, which is why the court reached for a structural remedy no statute authorizes. The remedy the court entered is proof the district court adjudicated the wrong thing.

A. The Remedy Exceeds Statutory Authority

FACA provides that advisory committees exist “solely for advisory functions” and that “determinations of action to be taken and policy to be expressed” shall be made “solely by the President or an officer of the Federal Government.” 5 U.S.C. § 1008(b). The district court’s order inverts this. It treats ACIP involvement as a precondition for schedule changes while

ensuring the ACIP cannot act at all because its members' appointments are stayed. The proper remedy for an unbalanced committee, on review of a final agency action, is to vacate that action and remand for the agency to restore balance—not to micromanage the appointment process the Executive controls.

The APA authorizes courts to “hold unlawful and set aside agency action[.]” 5 U.S.C. § 706. It does not authorize courts to restructure the agency’s decisionmaking apparatus, dictate advisory committee composition, or impose preconditions on future agency action that exist in no statute. The ACIP-involvement precondition appears nowhere in any statute. The coverage statutes “say nothing about whether CDC may also follow other processes to make immunization recommendations[.]” Dkt. 272, at 22; App. 665. And HHS “has previously deviated from the ACIP’s recommendations.” *Id.* at 31 (citing Feb. 13, 2026, Hr’g Tr. 46:10–47:17); App. 674.

The stay swept broader than necessary. Plaintiffs sought to enjoin five specific downstream agency actions and to bar future ACIP meetings, but they did not seek a stay of appointments. Dkt. 183-1; App. 141. The government argued that any stay should reach only as many appointments

as necessary to cure the imbalance the court identified. Dkt. 232, at 51; App. 288. The court stayed all thirteen, including members it did not find unqualified, leaving the committee without a quorum. Injunctive 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). A stay of every challenged appointment, when the court faulted only some members and a narrower stay would have cured any imbalance, exceeds that limit.

The defect runs deeper than breadth. Fair balance under FACA is a requirement about a committee’s composition, not about any individual appointment. No single appointment is “unbalanced”; balance is a property of the membership assessed at the time of a final agency action. The remedy for an unbalanced committee is to restore balance, by adding or adjusting members until the composition satisfies the standard. Staying thirteen of fifteen appointments does not produce a balanced committee. It produces no functioning committee at all, one without a quorum and unable to meet. The stay does not cure the violation the court identified. It inflicts a different and greater one. The intrusion is starker because the committee was not even complete: with seats open for the Secretary to add members and improve

balance—as Defendants explained below, Dkt. 232, at 32; App. 269—the court disabled the committee mid-assembly instead of letting the agency finish and cure any imbalance itself.

Nor does the court’s “tainted process” rationale supply the missing fit. Fair balance looks to the composition that results, not to the purity of the process that produced it. Regardless, even a flawed appointment process is corrected by having the agency proceed properly, not by a court order effectively disabling the committee. Restoring balance to an advisory committee is the appointing authority’s task, not the court’s. *Cf. Braidwood*, 606 U.S. at 762 (executive supervision of an advisory body runs through the Secretary’s powers to appoint, remove, and block recommendations). The district court instead stayed the committee out of existence.

Finally, federal courts’ equitable powers do not extend to novel remedies without historical antecedent. *Grupo Mexicano de Desarrollo, S.A. v. All. Bond Fund, Inc.*, 527 U.S. 308, 318–19 (1999). No court has ever vacated individual advisory committee appointments to remedy a FACA fair-balance violation. That is not a gap in the law but further evidence that the remedy exceeds the court’s authority.

B. The Remedy Conflicts With *Braidwood*

In *Braidwood*, the Supreme Court held that the constitutional legitimacy of advisory committees whose recommendations carry downstream legal force depends on two features of executive supervision: the Secretary's at-will removal power over committee members and the Secretary's authority to review and block recommendations before they take effect. *Braidwood*, 606 U.S. at 760–62. Those features make committee members inferior officers whose appointment by the Secretary satisfies the Appointments Clause. *Braidwood* does not supply the rule of decision on this FACA remedy; it confirms, as a structural matter, that supervising an advisory body—through the power to appoint, remove, and block its recommendations—belongs to the Secretary, which is why the order's seizure of that role is improper. *Id.*

The district court's order strips the Secretary of both. Staying individual appointments overrides the Secretary's appointment discretion. Preventing the committee from convening denies the Secretary the advisory input. That inverts the supervisory structure *Braidwood* treated as making the Task Force constitutional. If the same logic governs ACIP, the Secretary's

removal and appointment authority is not merely permissible but may be constitutionally required. The order below strips it away.

Every appointment decision by every executive official reflects policy preferences. That is how democratic accountability works. The Secretary who appointed the prior ACIP members also selected individuals whose views aligned with the then-prevailing approach to vaccine policy. No one suggested those individual appointments were judicially reviewable. The Constitution does not distinguish between a Secretary who appoints experts who agree with him and a Secretary who appoints experts who disagree with his predecessors. *Braidwood* confirms the Secretary's formal authority. Whether he exercises it wisely is a political question subject to political accountability, not judicial credentialing review.

The government does not contend that the Secretary's appointment authority is unconstrained by statute. FACA's fair-balance requirement applies. But again, the remedy for a violation is not judicial management of the committee. It is review of downstream agency actions that rely on a committee's work – and, if warranted, vacatur and remand of those actions. *Braidwood* cannot be squared with the specific unrequested remedy the

district court created and imposed. It does not foreclose all FACA enforcement.

C. *Braidwood* Also Confirms the Final Agency Action Problem

To sustain Count II, Plaintiffs need the ACIP to be consequential enough that its composition constitutes final agency action with legal consequences. But if ACIP recommendations carry effectively binding authority—embedded in the federal coverage statutes described above, *supra* p. 7, and numerous state laws—then *Braidwood*’s Appointments Clause analysis applies with full force. ACIP members would be officers. And if their recommendations carried binding force *despite* the Secretary’s power to block them, the supervisory features that made the *Braidwood* Task Force members *inferior* officers would be absent, pressing ACIP’s members toward principal-officer status and Senate confirmation. No ACIP member has ever been Senate-confirmed.

The district court itself glimpsed the difficulty. Pressing plaintiffs at argument, it observed that “if there’s a FACA violation, then everything that the ACIP did falls away,” but candidly acknowledged it was “struggling

with how to square that with what the Supreme Court said in *Braidwood*.”
Dkt. 283 at 23 (Mar. 4, 2026 Hr’g Tr.); App. 751.

The logical consequence of the district court’s reasoning, if embraced, is that every ACIP recommendation in the committee’s history is constitutionally suspect. That is a result Plaintiffs surely do not seek, one the government does not seek, and one this Court should not invite. Moreover, the framework the district court adopted is not limited to this Secretary or this ACIP. It would subject every future reconstitution of any advisory committee (including one designed to restore the expertise Plaintiffs favor) to the same judicial gauntlet.

The following framing avoids the issue: the ACIP is advisory, the Secretary has plenary appointment authority, and FACA’s fair-balance requirement is not judicially enforceable via a freestanding cause of action.

D. The Practical Consequences and Correct Remedy

If a new pathogen emerges, if safety data warrants removal, or if an outbreak requires emergency modification, the Director cannot act to modify or make new vaccine recommendations. New appointments do not restore a path either: the order articulates no standard a new appointee must satisfy, so every appointment the Secretary makes is exposed to the same scrutiny

and member-by-member credentialing challenge—before the same court—that disabled the committee here. The annual flu vaccine recommendation cycle is already under way, and the committee whose involvement the order requires cannot lawfully convene to do its part. The district court has not just remedied a past violation but has imposed a prospective structural injunction over future Executive Branch action.

The proper relief, if warranted, is to stay the specific actions such as the January 5 Memo and remand to the agency to follow its own established procedures. That is standard APA relief. It does not require individual appointment vacatur, meeting injunctions, or invented procedural preconditions. It lets the Executive Branch fix its own process. See *Fla. Power & Light*, 470 U.S. at 744.

If this Court reverses on Count II, the world looks like this: the stay of the thirteen appointments lifts, the Secretary can rebalance the ACIP, and the ACIP can reconvene. The CDC Director can act on future ACIP recommendations through the established process. The January 5 Memo remains stayed on independent grounds this appeal does not challenge. The stay of the three CDC-adopted votes rested on the Count II holding, but the government does not ask this Court to disturb it in the interim. On remand,

the district court may consider whether equivalent relief is warranted under Counts I, III, and IV, which challenge those adoptions directly. The pre-January 5 immunization schedule remains in effect. Nothing changes for patients or providers in the interim. What changes is that the federal government regains the ability to respond to public health developments through the advisory committee process Congress created – the very process Plaintiffs say is essential.

The APA limits judicial review to final agency action “for which there is no other adequate remedy in a court.” 5 U.S.C. § 704. Counts I, III, and IV are that remedy. Every concrete injury Plaintiffs identify traces back to the CDC-adopted recommendations: the January 5 Memo and the three ACIP votes. Vacate those, remand to the agency, and the harm is gone.

A future ACIP vote, standing alone, determines no rights and works no injury. By regulation, a recommendation has no effect unless and until the Director adopts it. 45 C.F.R. § 147.130(a)(1)(ii). If the Director adopts a future recommendation, that may be subject to immediate challenge, on a record, under the deferential standard the APA supplies. Preliminary relief against the meetings of an advisory body, by contrast, enjoins deliberation itself – something the APA nowhere authorizes.

CONCLUSION

The district court's errors begin in one place. It reviewed a non-final state of an advisory committee that does not injure these Plaintiffs. Correct that, and the standard and the remedy correct themselves. Reversing the relief as to Count II does not erase the FACA evidence or shield the agency from scrutiny. The agency must still address a fair balance issue, to the extent one exists. But the agency should not operate under the district court's structural handcuffs. The order below as to Count II should be reversed, subject to the interim treatment of the stayed votes described above.

Respectfully submitted,

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June 2026

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 11,133 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Word for Microsoft 365 in Book Antiqua 14-point font, a proportionally spaced typeface.

/s/ Matthew C. Zorn

CERTIFICATE OF SERVICE

I hereby certify that on June 17, 2026, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Matthew C. Zorn

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**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,**

Plaintiffs,

v.

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

Defendants.

**Civil Action No.
25-11916-BEM**

**MEMORANDUM AND ORDER ON
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

MURPHY, J.

“Science,” like law, “is far from a perfect instrument of knowledge.” Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 29 (1997). History is littered with once-universal truths that have since come under scrutiny. Nevertheless, science is still “the best we have.” *Id.*¹

“Procedure is to law what scientific method is to science.” *In re Gault*, 387 U.S. 1, 21 (1967) (cleaned up). Although sometimes seemingly tedious, “the procedural rules which have been fashioned from the generality of due process are our best instruments for the distillation and evaluation of essential facts from the conflicting welter of data that life and our adversary methods present.” *Id.*

For our public health, Congress and the Executive have built—over decades—an apparatus that marries the rigors of science with the execution and force of the United States government.

¹ “In this respect, as in many others, it’s like democracy.” Sagan, *supra*, at 29–30.

One extraordinary product of that apparatus has been the eradication and reduction of certain communicable diseases through the development and use of vaccines. In the words of the Centers for Disease Control and Prevention (“CDC”), “[v]accines are one of the greatest achievements of biomedical science and public health.”² Since the rise of vaccine development and usage in the early- to mid-1900s, “[t]he United States of America [has been] one of the pioneering nations to conceptualize and implement a robust immunization system that helped the nation tackle major epidemics.”³

Since its founding in 1964, the Advisory Committee on Immunization Practices (“ACIP”) has aided this endeavor by providing expert guidance on the clinical use of vaccines.⁴ The Department of Health and Human Services (“HHS”), which indirectly oversees ACIP, formalized ACIP’s non-partisan, science-backed nature through ACIP’s governance documents.⁵ And Congress has, in turn, recognized the importance and value of having such independent experts involved in setting our national public health agenda by cementing ACIP’s role in the CDC’s issuance of immunization schedules, which—among other things—determines which vaccines are

² CDC, *Ten Great Public Health Achievements — United States, 1900–1999*, 48 Morb. & Mortal. Wkly. Rep. 241, 247 (1999), <https://www.cdc.gov/mmwr/PDF/wk/mm4812.pdf> [<https://perma.cc/T63J-8AU2>]; *see also* CDC, *Ten Great Public Health Achievements — United States, 2001–2010*, 60 Morb. & Mortal. Wkly. Rep. 605, 619 (2011), <https://www.cdc.gov/mmwr/pdf/wk/mm6019.pdf> [<https://perma.cc/4FW-SNRU>] (describing advances in vaccines and reductions in vaccine-preventable diseases as one of the country’s “[t]en [g]reat [p]ublic [h]ealth [a]chievements” from 2001 to 2010).

³ Sandeep Divate Sathyanarayana et al., *Vaccines in the United States: A Systematic Review on History of Evolution, Regulations, Licensing, and Future Challenges*, 9 Clin. & Exp. Vaccine Rsch. 69, 70 (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC7445324/> [<https://perma.cc/KBN5-5A86>].

⁴ Jean Clare Smith, Alan R. Hinman & Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices — United States, 1964–2014*, 63 Morb. & Mortal. Wkly. Rep. 955, 955 (2014), <https://www.cdc.gov/mmwr/pdf/wk/mm6342.pdf> [<https://perma.cc/4VFQ-V8U8>].

⁵ *See generally*, e.g., Dkt. 185-21 (“ACIP Charter”) (signed by Secretary Kennedy); *see also* *Federal Advisory Committee (FAC) Membership Balance Plan*, ACIP (Jan. 29, 2024), <https://gsa-geo.my.salesforce.com/sfc/p/#t00000000Gyj0/a/3d000002n0y5/SCRGimkNFsTsAtm1GcT4Gu7TM88BO3PwKJZhrdHKkFg> [<https://perma.cc/89RA-KZJE>]; *Advisory Committee on Immunization Practices Policies and Procedures*, ACIP (June 2022), <https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf> [<https://perma.cc/G3D2-VZX4>].

available to patients through insurers and government healthcare programs.⁶ This is all to say that there is a method to how these decisions historically have been made—a method scientific in nature and codified into law through procedural requirements.

Unfortunately, the Government has disregarded those methods and thereby undermined the integrity of its actions. First, the Government bypassed ACIP to change the immunization schedules, which is both a technical, procedural failure itself and a strong indication of something more fundamentally problematic: an abandonment of the technical knowledge and expertise embodied by that committee. Second, the Government removed all duly appointed members of ACIP and summarily replaced them without undertaking any of the rigorous screening that had been the hallmark of ACIP member selection for decades. Again, this procedural failure highlights the very reasons why procedures exist and raises a substantial likelihood that the newly appointed ACIP fails to comport with governing law.

Today, faced with Plaintiffs’ motion for preliminary relief, the Court concludes that Plaintiffs are likely to succeed in showing that the reconstitution of ACIP and the January 2026 changes to the childhood immunization schedule violate the Administrative Procedure Act (“APA”). For the reasons stated below, the Court will grant Plaintiffs’ motion in part.

I. Background

A. Factual Background

This case concerns Defendants’ recent changes to the CDC vaccination schedules and the reconstitution of ACIP, the committee tasked with making recommendations regarding those schedules to the CDC. The Court has previously laid out much of the relevant factual and legal

⁶ See, e.g., 42 U.S.C. § 300gg-13(a)(2); 38 U.S.C. § 1701(1), (9)(G); 42 U.S.C. § 1396a(a)(10)(A), (a)(13)(B).

background.⁷ *See Am. Acad. of Pediatrics v. Kennedy* (“*AAP I*”), — F. Supp. 3d —, 2026 WL 33719, at *1–3 (D. Mass. Jan. 6, 2026).⁸

B. Procedural Background

Plaintiffs filed suit on July 7, 2025. Dkt. 1. The initial complaint challenged only Secretary Kennedy’s May 27, 2025 order that the CDC stop recommending pregnant women and “healthy” children receive the COVID vaccine, *see generally id.*, and was amended to add additional Plaintiffs, *see generally* Dkt. 63. Plaintiffs filed a second amended complaint on September 3, 2025, without objection from Defendants, to add an additional Plaintiff and additional factual allegations. *See generally* Dkt. 99. Plaintiffs filed a third amended complaint on November 5, 2025, again without objection from Defendants, which added challenges to ACIP’s September 2025 vote downgrading the recommendation for the COVID vaccine and the reconstitution of ACIP. *See generally* Dkt. 139. On January 6, 2026, the Court denied Defendants’ motion to dismiss the third amended complaint, holding that Plaintiffs had standing, that the case was not moot, and that Plaintiffs stated a plausible claim for violations of the Federal Advisory Committee Act (“FACA”), 5 U.S.C. § 1001, *et seq.*⁹ *See generally AAP I*, 2026 WL 33719.

On February 13, 2026, the Court granted Plaintiffs’ motion for leave to file a fourth amended complaint.¹⁰ Dkt. 241 (clerk’s notes). Plaintiffs now challenge: (1) Secretary Kennedy’s May 2025 order that the CDC remove its recommendation that pregnant women and “healthy” children receive the COVID vaccine; (2) the reconstitution of ACIP; (3) three votes ACIP took in

⁷ The underlying facts will be discussed in more depth below, when considering the merits of preliminary relief. *See infra* Section III.A.

⁸ Capitalized and collective terms not otherwise defined have the same definitions as used in *AAP I*.

⁹ The parties agree that FACA applies to ACIP.

¹⁰ The fourth amended complaint contains the same allegations as the third amended complaint, which was at issue in the Court’s January 6, 2026 order, and additional allegations, as described below.

2025; and (4) Director O’Neill’s January 2026 memorandum revising the CDC’s childhood immunization schedule (collectively, the “Challenged Actions”). Dkt. 245 (“Complaint” or “Compl.”) ¶¶ 2–5. On January 26, 2026, Plaintiffs moved for preliminary relief, seeking to set aside the Challenged Actions, enjoin further ACIP meetings, and enjoin Defendants from relying on the 2025 ACIP Votes.¹¹ Dkt. 183; *see also* Dkts. 184, 232, 237, 272. The Court held hearings on February 13, 2026, and March 4, 2026, and took the motion under advisement.

II. Standard of Review

Plaintiffs seek a stay of the Challenged Actions under the APA, 5 U.S.C. § 705, and a preliminary injunction barring ACIP from holding additional public meetings until the Court adjudicates the merits of ACIP’s reconstitution.¹² The same standard governs both forms of relief. *See Mass. Fair Hous. Ctr. v. U.S. Dep’t of Hous. & Urb. Dev.*, 496 F. Supp. 3d 600, 609 (D. Mass. 2020); *see also Colorado v. Env’t Prot. Agency*, 989 F.3d 874, 883 (10th Cir. 2021) (“These four [preliminary injunction] factors also determine when a court should grant a stay of agency action under section 705 of the APA.”).

“[T]he issuance of preliminary injunctive relief is ‘an extraordinary and drastic remedy that is never awarded as of right.’” *Howe v. U.S. Bank Nat’l Ass’n as Tr. for RMAC Tr. Series*

¹¹ Though Plaintiffs’ motion is styled as one for a preliminary injunction, Plaintiffs ask the Court to “set aside” various past actions, in addition to enjoining certain future actions. *See, e.g.*, Dkt. 184 at 8 (“[T]he final actions challenged herein violate the Administrative Procedure Act . . . and must be set aside.”). In a preliminary posture, a court stays, rather than sets aside, agency action. *See All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 254 (5th Cir. 2023) (“[A] stay is the temporary form of vacatur.”), *rev’d and remanded on other grounds sub nom., Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367 (2024). Thus, the Court construes Plaintiffs’ motion as seeking both a preliminary injunction and a stay.

¹² In relevant part, 5 U.S.C. § 705 provides:

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.

2016-CTT, 440 F. Supp. 3d 99, 102 (D. Mass. 2020) (quoting *Peoples Fed. Sav. Bank v. People's United Bank*, 672 F.3d 1, 8–9 (1st Cir. 2012)). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Together Emps. v. Mass Gen. Brigham Inc.*, 32 F.4th 82, 85 (1st Cir. 2022) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). “The movant’s likelihood of success on the merits weighs most heavily in the preliminary injunction calculus.” *Ryan v. U.S. Immigr. & Customs Enf’t*, 974 F.3d 9, 18 (1st Cir. 2020). “If the movant ‘cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity.’” *Id.* (quoting *New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002)).

The Court has “broad discretion in deciding what evidence to consider in connection with a motion for preliminary injunction” or other preliminary relief. *Rice v. Wells Fargo Bank, N.A.*, 2 F. Supp. 3d 25, 31 (D. Mass. 2014). The Court may, for example, “rely on otherwise inadmissible evidence, including hearsay.” *Bos. Taxi Owners Ass’n, Inc. v. City of Boston*, 84 F. Supp. 3d 72, 78 (D. Mass. 2015) (citing *Asseo v. Pan Am. Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986)). The Court may also take judicial notice of information on official government websites. *See Gent v. CUNA Mut. Ins. Soc’y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (relying on the contents of the CDC’s website).

III. Preliminary Injunction and Stay

A. Findings

1. May 2025 Directive

On May 27, 2025, Secretary Kennedy ordered the CDC to stop recommending that pregnant women and “healthy” children receive the COVID vaccine (the “May 2025 Directive”

or “Directive”). Dkt. 185-1 at 2; Dkt. 185-2 at 2. The CDC partially implemented this order by removing the COVID vaccine recommendation for pregnant women from the immunization schedule and by redesignating the vaccine recommendation for children as subject to “Shared Clinical Decision Making” (“SCDM”), where the schedule had previously designated the vaccine “routine.”¹³ *See generally* Dkt. 185-3. Defendants do not dispute that ACIP was not consulted before this change was made.¹⁴ *See, e.g.*, Dkt. 272 at 31.

2. ACIP Reconstitution

On June 9, 2025, Secretary Kennedy terminated all 17 members of ACIP.¹⁵ Secretary Kennedy then appointed new members to ACIP on June 11, 2025, September 11, 2025, and

¹³ According to the CDC, “[u]nlike routine . . . recommendations, shared clinical decision-making vaccinations . . . are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. . . . For routine . . . recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated.” *ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html> [<https://perma.cc/3QBY-RXFN>]; *see also* Dkt. 185-25 ¶ 20. The CDC had previously designated only four other vaccines as SCDM. In those instances, the designation was made after application of the Evidence to Recommendation (“EtR”) framework and was limited to specific age groups with certain risk characteristics. *See, e.g.*, Dkt. 146-17 ¶ 10 (“For example, when ACIP considered expanding the HPV (human papillomavirus) vaccine use to adults between 27 and 45 years of age, the EtR framework indicated uncertainties related to the public health problem and acceptability in this age group, variable individual benefits, and high costs associated with use of resources if the recommendation was routine. Accordingly, the HPV vaccine was designated as SCDM for adults between 27 to 45 years of age.”); *see also infra* note 14 (for a discussion of the EtR framework). On those four prior occasions, Plaintiffs allege that the CDC issued an explanation of its underlying rationale and guidance on healthcare providers’ engagement in SCDM with patients, neither of which was issued for the COVID vaccine. Compl. ¶ 88(d).

¹⁴ Plaintiffs allege that this change circumvented the required procedure for changes to vaccine recommendations—including by failing to consult CDC leadership, ACIP, or any public health data, and by failing to use the EtR framework. Compl. ¶¶ 96–102. ACIP adopted the EtR framework to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.” CDC, *ACIP Evidence to Recommendation User’s Guide* 3 (2020), https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf [<https://perma.cc/C7ER-N2A6>].

¹⁵ Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, Wall St. J. (June 9, 2025, at 16:00 ET), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112> (cited at Dkt. 237 at 21 n.37); *see also HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP*, HHS (June 9, 2025), <https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html> [<https://perma.cc/C5YC-Q7ZA>].

January 13, 2026.¹⁶ On February 27, 2026, after the filing of Plaintiffs’ motion, HHS announced the appointment of two new ACIP members.¹⁷ Secretary Kennedy also terminated the participation of members of liaison organizations, including some members of Organizational Plaintiffs, on ACIP workgroups, claiming that liaison organizations constitute “special interest groups.”¹⁸

3. Threatened Legal Liability

After Defendants’ changed the immunization schedules, Plaintiffs began counseling Organizational Plaintiffs’ member-doctors who were directly impacted, *see, e.g.*, Dkt. 185-27 ¶¶ 26–27, and publishing their own immunization schedules, *see, e.g., id.* ¶ 22. The same day that AAP published its own immunization schedules, Secretary Kennedy stated on social media: “AAP today released its own list of corporate-friendly vaccine recommendations. . . . AAP should also

¹⁶ Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, at 16:36 ET), <https://x.com/SecKennedy/status/1932899858920120692> [<https://perma.cc/RRE6-V8Y5>] (cited at Dkt. 237 at 21 n.39); *see also* ACIP Membership Roster, CDC (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html> [<https://perma.cc/ST8M-39AA>]. One of these members, Dr. Kulldorff, is no longer a member of ACIP. Dkt. 272 at 14 n.3; *see also* ACIP Membership Roster, *supra*.

¹⁷ *Secretary Kennedy Appoints Two Physicians to CDC’s Advisory Committee on Immunization Practices*, HHS (Feb. 27, 2026), <https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-physicians-cdc-advisory-committee.html> [<https://perma.cc/AR66-A574>]. According to Plaintiffs, this entire reconstitution was a pretextual effort to replace the prior ACIP members with individuals whose views aligned with Secretary Kennedy’s “anti-vaccine agenda” and circumvented established, rigorous application and vetting procedures. Compl. ¶¶ 75, 78–81.

¹⁸ Brenda Goodman, *HHS Further Constrains Certain Vaccine Advisors to the CDC, Limiting Their Input in Evidence Reviews*, CNN (Aug. 1, 2025), <https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc> [<https://perma.cc/D2GQ-2ZNH>] (cited at Compl. ¶ 82 n.73). Liaison organization members, for example, have previously been responsible for reviewing clinical evidence that may ultimately inform individual members’ votes. *See id.* Workgroups refer to ACIP subcommittees that study scientific research on the safety and effectiveness of vaccines, consider issues of public health importance, and draft the language for recommendations to be voted on by the full committee. *See id.*

be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act.”¹⁹

4. 2025 ACIP Votes

As relevant here, the newly constituted ACIP voted three times to change ACIP's official vaccine recommendations (the “2025 ACIP Votes”).²⁰ At the June 2025 meeting, ACIP voted in favor of “three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults” (the “June Vote”).²¹ See Dkt. 185-6 at 73–74; Dkt. 185-7 at 2–3. At the September 2025 meeting, ACIP voted to change the COVID vaccine recommendation for adults and children from routine to SCDM (the “September Vote”). See Dkt. 185-11 at 89–90. At the December 2025 meeting, ACIP voted “8 to 3 to recommend individual-based 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” (the “December Vote”).²² See Dkt. 185-16 at 2–4.²³ Each of these recommendations was implemented through changes to the CDC immunization schedules. See generally Dkt. 185-8; Dkt. 185-9; Dkt. 185-12; Dkt. 185-13; Dkt. 185-14; Dkt. 185-17.

¹⁹ Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, at 17:17 ET), <https://x.com/SecKennedy/status/1957914911415153107> [<https://perma.cc/RRE6-V8Y5>] (cited at Compl. ¶ 124 n.117).

²⁰ Plaintiffs do not challenge any other votes taken by the newly constituted ACIP.

²¹ Helen Branswell, *HHS Secretary RFK Jr. Accepts Recommendations to Drop Thimerosal From U.S. Flu Vaccines*, Stat (July 23, 2025), <https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/> [<https://perma.cc/7SAA-8D5X>] (cited at Dkt. 237 at 24 n.49).

²² *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CDC (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html> [<https://perma.cc/G2ZG-AD6W>].

²³ Plaintiffs allege that ACIP members and invited speakers made inaccurate or misleading claims at each meeting prior to the voting. Compl. ¶¶ 84–85, 87, 89, 91.

5. January 2026 Memo

On January 5, 2026, HHS issued a memorandum announcing that Director O’Neill had revised the childhood immunization schedule upon recommendations from the Director of the National Institutes of Health, the Administrator of the Centers for Medicare and Medicaid Services, and the Commissioner of the Food and Drug Administration (the “January 2026 Memo”).²⁴ Dkt. 185-18 at 2, 9–10. The January 2026 Memo was the result of a Presidential Memorandum that “direct[ed] . . . [HHS] to ‘FAST TRACK’ a comprehensive evaluation of Vaccine Schedules from other Countries around the World, and better align the U.S. Vaccine Schedule.”²⁵

The January 2026 Memo introduced a new immunization schedule that reduced the number of childhood vaccinations recommended as “routine” from seventeen to eleven, limited the recommendations for RSV, Hepatitis A, Hepatitis B, and Meningococcal ACWY, Meningococcal B, and dengue vaccinations to only high-risk groups, and downgraded the designations for Rotavirus, COVID, Influenza, Hepatitis A, Hepatitis B, and Meningococcal vaccinations to SCDM. Dkt. 185-18 at 2–3, 6–9. In the January 2026 Memo, Director O’Neill stated that he relied on discussions with health officials from Japan, Germany, and Denmark; discussions “with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy”; and a “review of peer nations’ best practices

²⁴ None of these three individuals were affiliated with the CDC or ACIP at the time of the January 2026 Memo. Since then, Jayanta Bhattacharya, who had been serving as the Director of the National Institutes of Health, was appointed acting Director of the CDC. *Acting Director*, CDC (Feb. 18, 2026), <https://www.cdc.gov/about/leadership/director.html> [<https://perma.cc/KK9Y-WJKV>].

²⁵ Presidential Mem., *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (Dec. 5, 2025), <https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/> [<https://perma.cc/P67Y-8UQL>].

and the scientific evidence underlying those practices.” Dkt. 185-18 at 2–3; *see also* Dkt. 185-19 (HHS assessment reviewing peer nations’ vaccination practices). ACIP was not involved in this change. *See generally* Dkt. 185-18; *see also* Dkt. 232 at 22–23 (arguing that the CDC had authority to modify the immunization schedules without consulting ACIP).

B. Likelihood of Success on the Merits

The APA provides that courts must “hold unlawful and set aside agency action” that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right”; “arbitrary” or “capricious”; or “otherwise not in accordance with law.” 5 U.S.C. § 706(2). Plaintiffs contend that they are likely to establish that Defendants violated the APA because the January 2026 Memo, May 2025 Directive, and 2025 ACIP Votes were arbitrary and capricious, and because the reconstituted ACIP does not comport with FACA. In opposition, Defendants argue that Plaintiffs lack standing to assert these claims, that the January 2026 Memo, May 2025 Directive, and 2025 ACIP Votes are not reviewable because they are not final agency action and are committed to agency discretion by law, and that none of the Challenged Actions violated the APA. The Court addresses each in turn.

1. January 2026 Memo

a. Standing

Defendants reassert standing arguments made in their motion to dismiss. Dkt. 232 at 38–42. The Court rejected those arguments in that posture, *see AAP I*, 2026 WL 33719, at *4–8, and does so here again.²⁶

²⁶ The Court notes that its standing determination did not previously, and does not now, turn on every harm Plaintiffs have alleged in their Complaint and various declarations. *See, e.g., All. for Hippocratic Med.*, 602 U.S. at 393–94 (recognizing that a perceived need to engage in issue advocacy does not constitute an injury for standing purposes).

b. Final Agency Action

Defendants argue that the January 2026 Memo is not “final agency action” and thus not reviewable. Dkt. 232 at 20–21 (quoting 5 U.S.C. § 704). In particular, Defendants highlight that the CDC’s immunization schedules are styled as sets of “recommendations” that Defendants assert are “non-binding for States and localities,” characterizing any other consequences as merely “collateral.” Dkt. 232 at 21. However, in so arguing, Defendants fail to acknowledge the legal consequences of the CDC’s immunization schedules and therefore of the January 2026 Memo.

Under the APA, agency action is considered “final” when it is “the ‘consummation’ of the agency’s decisionmaking process,” and an action “by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). Where a decision is so memorialized, an “agency statement . . . designed to implement, interpret, or prescribe law or policy” constitutes the relevant action. *Cf. Biden v. Texas*, 597 U.S. 785, 810 (2022) (quoting 5 U.S.C. § 551(4)). Generally, courts take a “‘pragmatic’ approach” to APA finality. *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016) (quoting *Abbott Lab’ys v. Gardner*, 387 U.S. 136, 149 (1967)).

To begin, the CDC’s vaccine schedule sets the liability regime for healthcare providers. As Secretary Kennedy himself has pointed out, if healthcare providers’ recommendations “diverge from the CDC’s official list[,] [they] are not shielded from liability under the 1986 Vaccine Injury Act.”²⁷ Thus, in changing the content of the CDC’s vaccine ‘recommendations,’ the January 2026

²⁷ Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, at 17:17 ET), <https://x.com/SecKennedy/status/1957914911415153107> [<https://perma.cc/RRE6-V8Y5>] (cited at Compl. ¶ 124 n.117). “The Vaccine Act establishes a no-fault compensation program pursuant to which a person injured by a covered vaccine may file a petition for compensation in the U.S. Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent.” *In re Gardasil Prods. Liab. Litig.*, 619 F. Supp. 3d 1356, 1357 n.4 (U.S. Jud. Pan. Mult. Lit. 2022).

Memo has the coercive effect of “expos[ing] [healthcare providers] to . . . civil liability.”²⁸ *Cf. Parsons*, 878 F.3d at 167; *see also Gen. Elec. Co. v. Env’t Prot. Agency*, 290 F.3d 377, 383 (D.C. Cir. 2002) (“[I]f the language of [a] document is such that private parties can rely on it as a norm or safe harbor by which to shape their actions, it can be binding as a practical matter.” (quoting Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1329 (1992))). Clearly, changing legal liability for vaccine administration is agency action from which “legal consequences will flow.” *See Bennett*, 520 U.S. at 178 (quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)); *Parsons v. U.S. Dep’t of Just.*, 878 F.3d 162, 167 (6th Cir. 2017) (“[A]gency actions that expose an individual to criminal or civil liability cause legal consequences.”).²⁹

The CDC’s immunization schedules moreover determine patients’ entitlement to care. Under federal law, patients are entitled to have their insurers cover, at no cost, vaccines recommended by the CDC. 42 U.S.C. § 300gg-13(a)(2); 45 C.F.R. § 147.130(a)(ii). The immunization schedules likewise determine certain veterans’ benefits, 38 U.S.C. § 1701(9)(G), Medicaid benefits, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B), and benefits under other programs, such as those benefiting low-income children, *id.* § 1396s(a)(2)(A), (d)(1).

²⁸ *See, e.g., Covered Vaccines*, Health Resources & Servs. Admin. (Jan. 2026), <https://www.hrsa.gov/vaccine-compensation/covered-vaccines> [<https://perma.cc/6N5S-3HGM>] (“For a vaccine to be covered, the Centers for Disease Control and Prevention (CDC) must recommend the category of vaccine for routine administration to children or pregnant women, and it must be subject to an excise tax by federal law.”); *Frequently Asked Questions*, Health Resources & Servs. Admin. (Jan. 2026), <https://www.hrsa.gov/vaccine-compensation/faq> [<https://perma.cc/58SZ-Q9YH>] (same).

²⁹ The Court need not resolve the extent to which changing the recommendations from routine to SCDM impacts doctors’ liability under this act. The fact is that CDC changes to its immunization schedules impact liability.

While Defendants downplay the cascading effect of the CDC’s immunization schedules as implemented through local law and policy, *see* Dkt. 232 at 21, that is an overtechnical analysis that ignores “pragmatic” reality, *see Hawkes*, 578 U.S. at 599 (quoting *Abbott*, 387 U.S. at 149). States risk catastrophic losses of funding if they fail to follow the CDC’s ‘recommendations.’ *See, e.g.*, 42 U.S.C. § 1396c. And even where funding is not at issue, states necessarily act against the backdrop of federal law, which establishes nationwide industry standards, *see, e.g.*, 42 U.S.C. § 300gg-13(a), and thus constrains states’ individual power as a matter of administrability, *cf. Appalachian Power Co. v. Env’t Prot. Agency*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (“The short of the matter is that the Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences both for State agencies administering their . . . programs and for [other regulating entities].”); *Texas v. United States*, 809 F.3d 134, 152–53 (5th Cir. 2015) (in standing analysis, recognizing practical consequences of federal action under state law), *aff’d by an equally divided court*, 579 U.S. 547 (2016).³⁰ It is thus unrealistic to talk about more localized consequences as merely the product of states’ choosing to adopt a set of helpful suggestions by the CDC.

c. Contrary to Law

Defendants next argue that, even if the January 2026 Memo is final agency action, it is not reviewable under the APA because it is an action “committed to agency discretion by law.”

³⁰ For further comparison, *see Parsons v. United States Department of Justice*, 878 F.3d 162 (6th Cir. 2017). In *Parsons*, the Sixth Circuit held that the Attorney General’s designation of a group of musical fans as a “loosely-organized hybrid gang” was not final agency action, *id.* at 165, even though it resulted, for example, in one member’s being “detained and questioned numerous times by . . . state and local law-enforcement officers,” *id.* at 166. The court held that these consequences were not attributable to the federal designation because the state officers had only “discretionarily relied on the gang designation.” *Id.* at 170 (concluding that “the government officials’ actions . . . [were] the product of their own independent decisionmaking”). By contrast, as relevant here, individual entities’ compliance with the CDC’s vaccine schedule, under the states’ laws, is not “discretionar[y].” *Cf. id.* And those state laws were themselves enacted against the backdrop of a complex statutory and regulatory regime that, in a number of instances provided in this section, effectively requires states to adopt the vaccine schedule.

Dkt. 232 at 19–20 (quoting 5 U.S.C. § 701(a)(2)). However, Defendants’ argument presupposes that Director O’Neill had authority to issue the order in the first place. “An agency, after all, ‘literally has no power to act’—including under its regulations—unless and until Congress authorizes it to do so by statute.” *Fed. Election Comm’n v. Cruz*, 596 U.S. 289, 301 (2022) (quoting *La. Pub. Serv. Comm’n v. Fed. Commc’ns Comm’n*, 476 U.S. 355, 374 (1986)).

Here, Congress has required ACIP’s involvement in the issuance of the immunization schedules. The CDC must, at least, consider ACIP’s recommendations before adopting an immunization schedule, and following or failing to follow that requirement is reviewable by this Court.³¹ For example, the Affordable Care Act requires insurers to provide, at no cost, “immunizations that have in effect **a recommendation from [ACIP]**.” 42 U.S.C. § 300gg-13(a)(2) (emphasis added). Veterans’ health benefits are likewise tied to the “recommended adult immunization schedule,” 38 U.S.C. § 1701(9)(G), defined as “**the schedule established . . . by [ACIP]**,” *id.* § 1701(10) (emphasis added). Medicaid plans likewise must provide “approved **vaccines recommended by [ACIP]**.” 42 U.S.C. § 1396d(a)(13)(B); *see id.* § 1396a(a)(10)(A). And, similarly, the Vaccines for Children program requires the HHS Secretary to purchase pediatric vaccines for states according to “**the list established . . . by [ACIP]**.” *Id.* § 1396s(d)(1), (e) (emphasis added). As to each instance, Congress’s mention of ACIP would be rendered pure surplusage if the CDC Director were empowered to act entirely apart from it. *But see Fischer v. United States*, 603 U.S. 480, 486 (2024) (“[Courts] must ‘give effect, if possible, to every clause and word of [a] statute.’” (quoting *Williams v. Taylor*, 529 U.S. 362, 404 (2000))).

³¹ Because Director O’Neill acted entirely apart from ACIP, the Court need not decide whether the Director’s role is precisely limited to “adopt[ing]” ACIP’s formal recommendations. *Cf.* Dkt. 237 at 16; *see also* 45 C.F.R. § 147.130(a)(1)(ii) (“[A] recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.”).

Defendants argue that Director O'Neill could unilaterally change the immunization schedules without consulting ACIP pursuant to the HHS Secretary's general authority to "assist" and "advise" states and localities on public health matters.³² Dkt. 232 at 19 (quoting 42 U.S.C. § 243(a)). But that argument ignores the multiple other statutes listed above that directly contemplate ACIP as, at least, a meaningful participant in any change to the CDC's immunization schedules.³³ *See Mellouli v. Lynch*, 575 U.S. 798, 809–10 (2015) ("Statutes should be interpreted 'as a symmetrical and coherent regulatory scheme.'" (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000))). "A well established canon of statutory interpretation succinctly captures the problem: '[I]t is a commonplace of statutory construction that the specific governs the general'":

³² Indeed, Defendants argue that the Secretary's authority under 42 U.S.C. § 243(a) is so broad that he could withdraw all immunization schedules, following no protocol at all. *See* Dkt. 260 at 154:17–19 ("[Defense counsel:] Indeed, the agency has discretion whether to issue immunization schedules at all and even more discretion about what to consider in issuing those schedules."); *see also id.* at 132:12–15 ("THE COURT: So even if what the agency was saying is we like communicable diseases and we think you should get more of them, that's not judicially reviewable. [Defense counsel]: No."); Dkt. 283 at 52:5–9 ("THE COURT: . . . if the secretary said instead of getting a vaccine -- instead of getting a vaccine to prevent measles, I think you should get a shot that gives you measles; is that unreviewable? [Defense counsel]: Yes.").

³³ The CDC's immunization schedules and ACIP's recommendations are necessarily linked. ACIP makes no recommendations apart from the immunization schedules, *see* ACIP Charter at 2–3, and the CDC does not issue any separate immunization schedule, *see, e.g., General Committee-Related Information*, CDC (Aug. 12, 2025), <https://www.cdc.gov/acip/about/index.html> [<https://perma.cc/36Y9-X69B>] ("CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP*." (emphasis added)). It defies logic that the CDC could retain independent discretion as to the creation or revision of the immunization schedules where Congress has explicitly tied obligations to ACIP's exercise of that same authority. That ACIP also takes an additional vote to direct which pediatric vaccines the HHS Secretary purchases for states under the Vaccines for Children program, *see* 42 U.S.C. § 1396s(d)(1), (e), does not change this conclusion.

The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission. . . . But the canon has full application as well to statutes such as the one here, in which a general authorization and a more limited, specific authorization exist side-by-side. There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one.

RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). Thus, Defendants cannot rely on the Secretary’s “general authorization” to override “specific authorization[s]” that overwhelmingly implicate ACIP. *Cf. id.*

The CDC’s own guidance documents and historical practice provide “one more reason yet to question whether [Defendants’] current position represents the best view of the law.” *Bittner v. United States*, 598 U.S. 85, 97 (2023) (“[C]ourts may consider the consistency of an agency’s views when . . . weigh[ing] the persuasiveness of any interpretation it proffers in court.”). By the CDC’s own words, “CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP*.” *General Committee-Related Information*, *supra* note 33 (emphasis added). The CDC immunization schedules themselves cite ACIP’s recommendations. *See, e.g.*, Dkt. 185-3 at 2; Dkt. 185-4 at 2. Moreover, in establishing ACIP’s Policies and Procedures, the agency described a robust process by which the CDC Director was to adopt or reject ACIP recommendations, with required documentation at each step. *See Advisory Committee on Immunization Practices Policies and Procedures* 8, *supra* note 5. By all accounts, this was the consistent practice of the CDC for decades.

In sum, Congress has spoken directly to the CDC’s immunization schedules and has required ACIP’s specific involvement. This rule governs over any more general authorization to “assist” or “advise.” *See* 42 U.S.C. § 243(a); *cf. RadLAX*, 566 U.S. at 645. It is undisputed that Director O’Neill issued the January 2026 Memo without sufficiently consulting ACIP, *see*

generally Dkt. 185-18.³⁴ Therefore, he lacked authority to issue the January 2026 Memo and, in so doing, acted contrary to law.

d. Not Committed to Agency Discretion

Even if one reads the above-cited authorities more loosely, Congress has at least established standards that this Court can apply to evaluate the issuance of the January 2026 Memo such that it was not “committed to agency discretion,” as Defendants argue. Dkt. 232 at 18–20. The APA exempts from judicial review actions that are “committed to agency discretion by law.” 5 U.S.C. § 701. However, the Supreme Court has interpreted this exception “quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency’s exercise of discretion.” *Dep’t of Com. v. New York*, 588 U.S. 752, 772 (2019) (internal quotation marks omitted) (quoting *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 586 U.S. 9, 23 (2018)). The exception is “generally limited . . . to ‘certain categories of administrative decisions that courts traditionally have regarded as “committed to agency discretion.”’” *Id.* (quoting *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993)).

Defendants point the Court to no cases, nor could the Court find any such case, suggesting that the kind of regulatory power at issue in this case has been “traditionally” recognized, *cf id.*, as committed to agency discretion. *See* Dkt. 232 at 18–20. Nevertheless, Defendants argue that the HHS Secretary’s statutory authority to “‘assist States and their political subdivisions in the prevention and suppression of communicable diseases’ and ‘advise the several States on matters

³⁴ The assessment underlying the January 2026 Memo cites in part to the September and December ACIP Votes. Dkt. 185-19 at 21, 25. That does not address the fact that ACIP had no role in any of the *other* changes to vaccine recommendations in the January 2026 Memo.

relating to the preservation and improvement of the public health” provides no judicially manageable standards for this Court to apply. *See* Dkt. 232 at 19 (quoting 42 U.S.C. § 243(a)).

This argument can only be countenanced if one completely abandons the idea of objective fact, a nihilist endeavor this Court does not find appropriately read into Congress’s public health statutes. An exchange during oral argument sums it up well:

THE COURT: . . . let’s say that instead of revising the vaccine schedule, the CDC said, actually, we think measles is good for you; you should go have lunch with someone with measles, and we are sponsoring measles lunches in every city, come have some measles lunch, that would seem to -- that would seem to go right up against the goal of preventing communicable diseases. Would such a policy by the CDC be judicially reviewable?

[DEFENSE COUNSEL:] I think that would still be committed to agency discretion by law.

THE COURT: So even if what the agency was saying is we like communicable diseases and we think you should get more of them, that’s not judicially reviewable.

[DEFENSE COUNSEL:] No.

Dkt. 260 at 132:3–15.³⁵ Suffice it to say that the Court disagrees and would be unlikely to find much difficulty, for example, in assessing whether the Secretary’s theoretical endorsement of getting a communicable disease like measles could reasonably be calculated to advance “the prevention and suppression of communicable diseases.” *See* 42 U.S.C. § 243(a). This common-sense reading is further reinforced by neighboring statutes that, for example, direct the Secretary to fund “a national, evidence-based campaign to *increase awareness and knowledge of the safety and effectiveness of vaccines* for the prevention and control of diseases, combat

³⁵ *See also* Dkt. 283 at 52:5–9 (“THE COURT: . . . if the secretary said instead of getting a vaccine -- instead of getting a vaccine to prevent measles, I think you should get a shot that gives you measles, is that unreviewable? [DEFENSE COUNSEL:] Yes.”). Even though this example is somewhat ridiculous, it is appropriate to note that the Court does not necessarily prejudice even this hypothetical, appreciating that counterintuitive solutions (particularly in the complex realms of health and science) can sometimes be correct (or at least reasonable). Notwithstanding this complexity, the underlying question is nonetheless fully addressable.

misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, *with the goal of increasing rates of vaccination across all ages*, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.” *Id.* § 245(a) (emphases added). It would be quite strange for Congress, in one statute, to authorize the Secretary to “assist” states by encouraging the spread of communicable diseases, *see id.* § 243(a), while, in another statute, requiring the Secretary to work toward “eliminat[ing]” the spread of communicable diseases, *see id.* § 245(a).

Moreover, Defendants’ narrow focus on the Secretary’s “assist” and “advise” authority continues to ignore the broader statutory context within which the CDC issues its immunization schedules. As set forth above, Congress has interwoven and given special effect to the immunization schedules through other statutes, which overwhelmingly implicate ACIP, a recognized body of health experts. *See, e.g.*, 42 U.S.C. § 300gg-13(a)(2). These delegations demonstrate Congress’s intent that decisions be made in accordance with “specialized experience and judgment,” rather than by fiat, untethered to scientific basis or reasoning. *Cf. Tummino v. Hamburg*, 936 F. Supp. 2d 162, 185 (E.D.N.Y. 2013).

The CDC’s consistent past practice with respect to its immunization schedules provides yet another baseline against which this Court might assess the January 2026 Memo’s reasonability. The CDC has consistently treated its role in promulgating the immunization schedules as arising only after ACIP has issued a recommendation. *See supra* p. 17. Put simply, this is not the kind of agency action that is “committed to agency discretion” and not subject to APA review.

e. Arbitrary and Capricious

Having determined that the issuance of the January 2026 Memo is reviewable, the Court concludes that, in addition to being contrary to law, the issuance of the January 2026 Memo was arbitrary and capricious because it abandoned the agency’s longstanding practice of getting

recommendations from ACIP before changing the immunization schedules without sufficient explanation. As discussed above, the CDC cannot simply bypass ACIP in altering the immunization schedules. *See supra* Section III.B.1.c. Even were this not a legal requirement, however, the record contains no explanation for why Defendants circumvented this decades-old practice, other than to comply with a Presidential Memorandum.³⁶

“The APA’s arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.” *Fed. Commc’ns Comm’n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). “A 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.” *Id.* The “reasoned explanation requirement . . . is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public.” *Dep’t of Com.*, 588 U.S. at 785.

Defendants cannot disregard the APA’s requirements simply because they are following the President’s orders. *See, e.g., New York v. Trump*, 2025 WL 3514301, at *9 (D. Mass. Dec. 8, 2025) (“Circuit precedent forecloses” the argument that “an agency is exempt from the requirements of § 706(2)(A) whenever it acts pursuant to a presidential command.”); *Nebraska v. Su*, 121 F.4th 1, 15 (9th Cir. 2024) (“[F]inal agency actions, even if implementing an executive order, are subject to judicial review under the APA.”). As the CDC itself explains, the “CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP.*” *General Committee-Related Information*, *supra* note 33 (emphasis added). “If an agency,” like the CDC, “announces and follows—by rule or by settled course of adjudication—a general policy

³⁶ Presidential Mem., *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries*, *supra* note 25.

by which its exercise of discretion will be governed, an irrational departure from that policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as ‘arbitrary, capricious, [or] an abuse of discretion’ within the meaning of the [APA].” *Thompson v. Barr*, 959 F.3d 476, 484 (1st Cir. 2020) (alteration in original) (quoting *Immigr & Naturalization Serv. v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996)).

While there might be circumstances that could justify bypassing ACIP, the record lacks any explanation, let alone a reasoned one.³⁷ See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“The reviewing court should not attempt itself to make up for such deficiencies: we may not supply a reasoned basis for the agency’s action that the agency itself has not given.”). On the current record, the Court cannot conclude that Defendants “articulate[d] a satisfactory explanation for its action.” *Id.* at 43.

2. May 2025 Directive

Defendants argue that the challenge to the May 2025 Directive is moot because the Directive has been “overtaken” by the January 2026 Memo, Dkt. 272 at 20, and that the Directive is not “final agency action” subject to APA review because it is merely a “recommendation[] without concrete legal effects,” *id.* at 23.

Before turning to the merits of these arguments, it is worth spending a moment considering what the May 2025 Directive purports to do. The Directive “rescind[s]” the June 2022 “HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years” and “the CDC recommendation that pregnant women receive the

³⁷ Additionally, the individuals who advised Director O’Neill on the January 2026 Memo have no affiliation with the CDC and no statutory or regulatory role in the CDC’s vaccine policy development. See Dkt. 185-18 at 2 (noting that the recommendations to change the CDC’s immunization schedules came from the Director of the National Institutes of Health (Jayanta Bhattacharya), the Administrator for the Centers for Medicare and Medicaid Services (Mehmet Oz), and the Commissioner of Food and Drugs (Martin Makary)). Defendants have provided no explanation for relying on their recommendations rather than those of ACIP.

COVID-19 vaccine.” Dkt. 185-1 at 2. In addition, under the May 2025 Directive, “the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunizations Schedule by Age and recommended vaccines during pregnancy.” *Id.* Shortly after Secretary Kennedy issued the May 2025 Directive, the CDC made changes to the vaccine recommendations for pregnant women and “healthy” children. *See generally* Dkt. 185-3.

The relationship between these related agency actions complicates the inquiry as to mootness and finality: the May 2025 Directive is unreviewable if it was *not* a final agency action, but even if it *was* a final agency action, it may have been mooted by subsequent agency actions. To begin, Defendants may be correct that the May 2025 Directive is not final agency action because it does not “mark[] the ‘consummation’ of the agency’s decisionmaking process” and is therefore not an action “by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Bennett*, 520 U.S. at 178 (citations omitted). This characterization is supported by the fact that shortly after the May 2025 Directive was issued, the CDC implemented it by making changes to the COVID vaccine recommendations for pregnant women and “healthy” children. *See* Dkt. 185-3 at 3–6; *see also* Dkt. 185-4 at 5. Notably, the CDC downgraded the recommendation for “healthy” children to SCDM, but did not remove the COVID vaccine from the schedule as instructed by the May 2025 Directive. Dkt. 185-3 at 3, 6. This suggests that the May 2025 Directive was not the “consummation of the agency’s decisionmaking process,” but rather an underlying policy, while the CDC’s implementation thereof and the January 2026 Memo were final agency actions “from which legal consequences [] flow[ed].” *Bennett*, 520 U.S. at 178 (citations and internal quotation marks omitted); *see also supra* Section III.B.1.a. If this is the case, the May 2025 Directive is not final agency action subject to review under the APA. *See* 5 U.S.C. § 704.

If, as Plaintiffs contend, however, the May 2025 Directive *was* a final agency action—also a reasonable proposition, given that the Directive purports to “rescind” prior CDC recommendations and HHS ratifications thereof and to direct agency staff’s actions, Dkt. 185-1 at 2—that action was likely mooted by the CDC’s change to the childhood vaccine schedule made shortly thereafter, which was also, itself, final agency action, as discussed above.³⁸ *See Anderson v. U.S. Dep’t of Hous. & Urb. Dev.*, 731 F. Supp. 3d 19, 31 (D.D.C. 2024) (“[W]hen one agency action supersedes another, prospective challenges to the superseded agency action generally become moot. In those circumstances, vacating the old agency action will not deliver the plaintiff any relief. The new agency action, not the old one, is what injures the plaintiff going forward.” (citations omitted)). Under this reading, it is the CDC’s changed immunization schedules that are the source of Plaintiffs’ alleged harms. Thus, the challenge to the May 2025 Directive would “no longer [be] a ‘Case’ or ‘Controversy’ for purposes of Article III.” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)); *see also id.* (“No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs’ particular legal rights.” (internal quotation marks omitted)). Put simply, if the May 2025 Directive is *not* a final agency action, it is unreviewable, and if it *is* a final agency action, it may have been mooted by subsequent agency actions.

The Court need not determine at this preliminary stage which characterization of the May 2025 Directive is correct. The Court need only determine, as it does here, that Plaintiffs have not met their burden of establishing that their challenge to the May 2025 Directive presents a

³⁸ In light of this conclusion, the Court need not address whether the January 2026 Memo may also have mooted the May 2025 Directive, as argued by Defendants. *See* Dkt. 272 at 20.

justiciable claim that Plaintiffs are likely to win on the merits. Because it is not clear that Plaintiffs’ challenge is viable on threshold questions of mootness and finality, the Court need not evaluate whether Plaintiffs would have standing to bring such a challenge.³⁹

3. ACIP Reconstitution

a. Standing

As with the January 2026 Memo, the Court rejects Defendants’ standing arguments that are based on the same theories articulated in their motion to dismiss. *See supra* Section III.B.1.a. But the parties also raise a new argument: whether Plaintiffs have standing to pursue their FACA claim insofar as standing is based on the termination of Organizational Plaintiffs’ participation in ACIP working groups. Dkt. 232 at 42–43.

Both parties’ argument on this misses the point. FACA’s “‘fairly balanced’ requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee,” and, therefore, when that “requirement is ignored, persons having a direct interest in the committee’s purpose suffer injury-in-fact sufficient to confer standing to sue.” *Am. First Legal Found. v. Cardona*, 630 F. Supp. 3d 170, 180 (D.D.C. 2022) (quoting *Nat’l AntiHunger Coal. v. Exec. Comm. of President’s Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983)); *see also Nat’l Ass’n of Consumer Advocs. v. Uejio*, 521 F. Supp. 3d 130, 144–45 (D. Mass. 2021) (same); *NAACP Legal Def. Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 129 (D.D.C. 2020) (collecting cases). Plaintiffs, comprised of professional medical organizations and individual patients, clearly have “a direct interest in [ACIP’s] purpose,” *Am. First*, 630 F. Supp. 3d at 180, which is the

³⁹ *See, e.g., Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (considering mootness before standing). Similarly, the Court will not analyze the remaining factors for preliminary relief as to the May 2025 Directive, because likelihood of success is the “sine qua non” for preliminary relief. *New Comm*, 287 F.3d at 9.

“effective control of vaccine-preventable diseases in the civilian population of the United States.”⁴⁰ Organizational Plaintiffs’ past participation in ACIP working groups merely demonstrates the obvious—ACIP’s actions “directly affect[]” them in their line of work. *See Am. First*, 630 F. Supp. 3d at 180. In other words, Organizational Plaintiffs’ past participation in ACIP working groups evidences the fact that an unfairly balanced ACIP causes them current injury and Plaintiffs thus have standing to assert that ACIP is not “fairly balanced” under FACA.

b. Contrary to Law

Plaintiffs contend that the reconstitution of ACIP violated FACA, Dkt. 237 at 43–49, which governs the functions and operations of advisory committees that provide expert recommendations to the executive branch, *see* 5 U.S.C. § 1001(2)(A). “FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest.” *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020); *see also* 5 U.S.C. § 1004(b)(2) (requiring “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”). As the First Circuit has noted, “[t]here are certainly many different points of view that [an agency] might take into account in forming its committees and different balances that can be struck in a committee’s membership.” *Union of Concerned Scientists*, 954 F.3d at 19. The Court must assess whether, in light of “the functions assigned to [the] committee[,] . . . its balance is fair.” *Id.* at 20. More specifically:

⁴⁰ ACIP Charter at 2. This version of the ACIP charter was revised on December 3, 2025, and has as a filing date of April 1, 2026. *Id.* at 6. However, prior versions of the charter contained the same or substantially similar language. *See, e.g.,* Kalwant Smagh, *Amendment to the Charter of the Advisory Committee on Immunization Practices*, CDC (April 1, 2024), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/6CNV-L5XR>]. Any differences between the two versions are not material to this motion.

[A]gencies should ensure that they fully consider and understand the potential implications or anticipated impacts of the advisory committee’s potential recommendations. This includes consideration of the groups and entities potentially affected or interested in such recommendations, as appropriate based on the nature and functions of the advisory committee, so that the agency can make informed decisions on the areas of expertise or perspectives that would advance the work of the advisory committee. *Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.*

41 CFR § 102-3.60(b)(1).⁴¹ Furthermore, “[h]aving identified the points of view that would promote a fairly balanced advisory committee membership, agencies should conduct broad outreach.”⁴² *Id.* § 102-3.60(b)(2).

The Court begins with ACIP’s function. ACIP is responsible for “develop[ing] recommendations on the use of vaccines in the civilian population of the United States.”⁴³ These recommendations trigger various obligations in the U.S. health care system. *See supra* Section III.B.1.b; *see also, e.g.*, 42 U.S.C. § 300gg-13(a)(2) (requiring insurers to provide, at no cost, “immunizations that have in effect a recommendation from [ACIP]”). To accomplish this purpose, ACIP considers “disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and

⁴¹ FACA requires that all agency heads “establish uniform administrative guidelines and management controls for [their] advisory committees” and “maintain systematic information on the . . . operations of each advisory committee within its jurisdiction.” 5 U.S.C. § 1007(a). Any advisory committee guidelines and management controls must be “consistent with directives of the [General Services Administration] Administrator,” *id.*, pursuant to their authority to “prescribe administrative guidelines and management controls applicable to advisory committees,” *id.* § 1006(c). Defendants have done so through the ACIP Charter, Membership Balance Plan, and Policies and Procedures. *See generally* ACIP Charter; *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5; *Advisory Committee on Immunization Practices Policies and Procedures*, *supra* note 5.

⁴² The prior version of the regulations, in effect at the time of the majority of Secretary Kennedy’s new ACIP appointments, gave further instruction as to what “broad outreach” should entail, noting that the outreach should “us[e] a variety of means and methods[] to ensure that the call for nominees reaches the interested parties and stakeholder groups likely to possess those points of view.” 89 Fed. Reg. 27673, 27683 (Apr. 18, 2024).

⁴³ *General Committee-Related Information*, *supra* note 33; *see also* ACIP Charter at 2 (“ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States.”).

implementation issues.” Dkt. 185-21 (“ACIP Charter”) at 3. Plaintiffs contend that the current ACIP members lack the qualifications and expertise necessary to achieve ACIP’s function and that the majority shares Secretary Kennedy’s anti-vaccine views. Dkt. 237 at 22, 44–49. Defendants contend that the current ACIP is fairly balanced, made up of members that all have advanced degrees and expertise “from a wide range of clinical and research backgrounds.” Dkt. 232 at 33. While the Court generally defers to an agency’s scientific assessments and recognizes that “[t]here are certainly many different points of view that [an agency] might take into account in forming its committees and different balances that can be struck in a committee’s membership,” *Union of Concerned Scientists*, 954 F.3d at 19, the Court concludes that Plaintiffs are likely to succeed in showing that the reconstitution of ACIP violated FACA and was therefore not in accordance with law under the APA.

The Court acknowledges that many of the ACIP members have extensive expertise in their chosen fields. But “[a]dvisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience *relevant to the functions and tasks to be performed by the committee*.” 41 C.F.R. § 102-3.60(b)(1) (emphasis added). And ACIP’s own charter directs that the members of the committee:

shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.

ACIP Charter at 5.⁴⁴ On this point, there are glaring gaps.⁴⁵

First, of the fifteen members currently on ACIP, even under the most generous reading, only six appear to have any meaningful experience in vaccines—the *very focus of ACIP*.⁴⁶ The Court does not suggest that the other members are not experts in their respective fields, only that the committee as reconstituted is not “fairly balanced in terms of . . . the functions to be performed.” 5 U.S.C. § 1004(b)(2); *see also* ACIP Charter at 5 (directing that members “*shall be*” “knowledgeable in the fields of immunization practices,” “have expertise in the use of vaccines and other immunobiologic agents,” “have expertise with clinical or laboratory vaccine research,” or “have expertise in assessment of vaccine efficacy and safety” (emphasis added)). At least six ACIP members—Dr. Hillary Blackburn,⁴⁷ Dr. Evelyn Griffin,⁴⁸ Dr. Joseph Hibbeln,⁴⁹ Dr. Kirk

⁴⁴ The Court finds the requirements provided in the ACIP Charter instructive for assessing the relevant points of view to be balanced, especially because FACA itself mandates the submission of a charter. *See* 5 U.S.C. § 1008. Pursuant to 5 U.S.C. § 1008(c)(1), advisory committees must maintain a charter that specifies the “expertise or experience required” of its members. 41 C.F.R. § 102-3.75(l).

⁴⁵ The Court respects the technical expertise and specialized judgement of federal agencies and recognizes that agencies are thus entitled to some deference in this determination. Nevertheless, “Congress enacted FACA to constrain executive discretion, suggesting it did not intend to preclude judicial review” of the fair balance requirement. *NAACP Legal Def. Fund*, 496 F. Supp. 3d at 135.

⁴⁶ When Plaintiffs filed their motion, they challenged the appointments of 14 members. One of those members, Dr. Kulldorff, is no longer a member of ACIP, Dkt. 272 at 14 n.3, and so the Court need not consider his appointment. Additionally, on February 27, 2026, Secretary Kennedy announced the appointments of two additional ACIP members. *Secretary Kennedy Appoints Two Physicians to CDC’s Advisory Committee on Immunization Practices*, *supra* note 17. As these most recent appointments post-date the filing of this motion, the Court need not evaluate the two newest members’ qualifications and expertise and will instead assume for purposes of this motion that they are both sufficiently qualified for membership on ACIP.

⁴⁷ Dr. Blackburn is a Doctor of Pharmacy and the Director of Medication Access and Affordability at AscensionRx. *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that she has any relevant vaccine-related experience or expertise.

⁴⁸ Dr. Griffin, the Surgeon General for the State of Louisiana, is “board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that she has any relevant vaccine-related experience or expertise.

⁴⁹ Defendants describe Dr. Hibbeln, a psychiatrist and neuroscientist, as having “experience in clinical research, public health policy, and federal service” and whose “work has informed U.S. public health guidelines, particularly in maternal and child health.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that he has any relevant vaccine-related experience or expertise.

Milhoan,⁵⁰ Dr. James Pagano,⁵¹ Dr. Raymond Pollak,⁵²—appear to lack *any* expertise or professional qualifications *related to vaccines or immunization* as required by ACIP’s Charter.

See *ACIP Membership Roster*, *supra* note 16. An additional three of the current ACIP members—Dr. Retsef Levi,⁵³ Dr. Robert Malone,⁵⁴ and Dr. Catherine Stein⁵⁵—though they have

⁵⁰ Dr. Milhoan “is a pediatric cardiologist and former U.S. Air Force flight surgeon,” who “holds a Ph.D. in the mechanisms of myocardial inflammation.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that Dr. Milhoan has any relevant vaccine-related experience or expertise.

⁵¹ Dr. Pagano “is a board-certified emergency medicine physician with more than 40 years of clinical experience.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that Dr. Pagano has any relevant vaccine-related experience or expertise.

⁵² Dr. Pollak “is a surgeon, transplant immunobiologist, and transplant specialist who has published more than 120 peer-reviewed works and served as principal investigator on NIH transplant biology grants and numerous drug trials.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that Dr. Pollak has any relevant vaccine-related experience or expertise.

⁵³ Defendants describe Dr. Levi, Professor of Operations Management at the MIT Sloan School of Management, as “a leading expert in healthcare analytics, supply chain and manufacturing analytics, risk management, and biologics and vaccine safety” and note that he has “collaborated with industry stakeholders and public health agencies to develop decision-support models to evaluate biologics and vaccine safety” and co-authored studies examining the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes.” *ACIP Membership Roster*, *supra* note 16. However, based on the current record, he has published only two papers discussing vaccines, and both of those were published mere months before his appointment. Retsef Levi, et al., *Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida*, MedRxiv (Apr. 29, 2025), <https://www.medrxiv.org/content/10.1101/2025.04.25.25326460v1> [<https://perma.cc/NGN8-SARX>] (cited at Compl. ¶ 77(g) n.53); Josh Guetzkow, et al., *Observed-to-Expected Fetal Losses Following mRNA COVID-19 Vaccination in Early Pregnancy*, MedRxiv (June 20, 2025), <https://www.medrxiv.org/content/10.1101/2025.06.18.25329352v1.full-text> [<https://perma.cc/EKL3-ELMS>] (cited at Compl. ¶ 77(g) n.53). Publishing two papers on a topic, while no doubt relevant to ACIP, likely does not rise to the level of “expertise” called for under ACIP governing documents. See *Expertise*, Black’s Law Dictionary (12th ed. 2024) (defining “expertise” as “[s]kill or knowledge in a particular subject; specialized experience that gives rise to a facility that comparatively few people possess”).

⁵⁴ Defendants describe Dr. Malone, an adjunct professor at Pennington Biomedical Research Center, Louisiana State University, as “a vaccinologist, scientist, and biochemist known for his early contributions to mRNA vaccine technology” whose “expertise spans molecular biology, immunology, and vaccine development.” *ACIP Membership Roster*, *supra* note 16. The only evidence in the record of his experience related to vaccines is that he was involved in early research on mRNA technology in the 1980s and 1990s. See *id.* Even crediting that experience, the Court cannot conclude that this experience, thirty plus years ago, constitutes the requisite expertise necessary for ACIP today. Further, the scope of his role in that research is disputed, see Davey Alba, *The Latest Covid Misinformation Star Says He Invented the Vaccines*, N.Y. Times (Apr. 3, 2022), <https://www.nytimes.com/2022/04/03/technology/robert-malone-covid.html> (cited at Compl. ¶ 77(h) n.59), which the Court need not resolve at this juncture.

⁵⁵ Dr. Stein is a professor at Case Western Reserve University and “an epidemiologist with more than two decades of research experience on tuberculosis and infectious diseases and 115 peer reviewed publications.” *ACIP Membership Roster*, *supra* note 16. However, there is no evidence in the record that her experience and expertise relate to vaccines, vaccination, vaccine safety, or vaccine policy as to be relevant to ACIP’s function.

some experience arguably relevant to ACIP’s function, appear to lack the qualifications and experience to constitute *expertise in vaccines and immunization*. Compare *id.*, with ACIP Charter at 5.⁵⁶ In short, ACIP is not just a committee of doctors, or even a committee of public health experts; it is a committee specifically dedicated to the “use of vaccines and related agents for effective control of vaccine-preventable diseases.” ACIP Charter at 2. As to that specific function, the newly appointed members appear distinctly unqualified. A committee of non-experts cannot be said to embody “fairly balanced . . . points of view” within the relevant scientific community. See 5 U.S.C. § 1004(b)(2). It is more accurate to say that they do not represent points of view within the relevant expert community.

The deficiencies in ACIP’s membership become more pronounced when considered against ACIP’s own statements on what would constitute a fairly balanced committee. ACIP has a membership balance plan (“MBP”), which identifies specific considerations and requirements that the agency determined would ensure ACIP’s compliance with FACA.⁵⁷ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5. As relevant here, the MBP mandates that individual members have certain expertise: “expertise in the field of immunization practices”; “multi-disciplinary expertise in public health”; “expertise in the use of vaccines and immunologic agents”; or “knowledge of vaccine development, evaluation, safety and delivery.” *Id.* at 2. Further, the MBP directs the Steering Committee that recommends nominees for ACIP to consider

⁵⁶ The Court recognizes that there may be evidence to demonstrate that each of these individuals have more relevant experience or expertise than what is before the Court at this juncture. However, Defendants have provided no basis for the Court to assess how these individual’s experiences and qualifications relate to ACIP’s functions or evidence to contradict that of Plaintiffs, relying only on the ACIP website’s summary of credentials. See Dkt. 232 at 33–34. Thus, on the current record, there is no evidence to demonstrate that these individuals have the *relevant* expertise necessary for membership on ACIP.

⁵⁷ When Secretary Kennedy began reconstituting ACIP, advisory committees were required to have a MBP when establishing or renewing an advisory committee. 41 C.F.R. § 102-3.60(b)(3) (May 20, 2024). This requirement was removed from the regulation, effective on December 16, 2025. 90 Fed. Reg. 58408, 58408 (Dec. 16, 2025). Regardless, ACIP still has a governing MBP.

whether there is a “[b]alance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, academic perspective, public health perspective, etc.).” *Id.* at 3. Through the MBP, Defendants have set forth the requirements and procedures *they* think necessary to achieve a balanced committee that complies with FACA, *see generally id.*, and the MBP has guided appointments for decades, *see, e.g.*, 73 Fed. Reg. 72055 (Nov. 26, 2008) (soliciting nominations for ACIP membership and describing requirements using the MBP phrasing). The Court thus finds the MBP to be instructive as to how a fairly balanced ACIP might be achieved and what it would look like.

The lack of formality and process attending the new ACIP members’ appointment further validates the Court’s finding as to the end product. For example, the FACA regulations direct that, “[h]aving identified the points of view that would promote a fairly balanced advisory committee membership, agencies should conduct broad outreach.” 41 CFR § 102-3.60(b)(2).⁵⁸ Historically, this process took approximately two years, and as directed by ACIP’s MBP, involved a broad e-mail solicitation for potential candidates,⁵⁹ required applicants to submit a current curriculum vitae, letters of recommendation, a cover letter, and various forms related to conflicts and ethics, and included an in-depth review of applicants by the ACIP Steering Committee.⁶⁰ *See, e.g.*,

⁵⁸ *See supra* note 42.

⁵⁹ Including “to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations such as the National Medical Association and the National Hispanic Medical Association, academic centers, and other contacts in the field of vaccinology.” *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5.

⁶⁰ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5. The Court finds the requirements laid out in the ACIP MBP instructive, as they represent the agency’s determination of “the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance.” *Id.*

Dkt. 185-47 ¶¶ 6–8, 18–20; Dkt. 185-48 ¶¶ 8–10; Dkt. 289 ¶¶ 7–19.⁶¹ However, on the current record, the most generous description of the appointment process is that it took a few months and involved some limited outreach to candidates.⁶² Dkt. 240-1 ¶¶ 6–11; Dkt. 185-47 ¶ 24. Defendants also failed to issue a Federal Register notice and ignored the year-round online application process as set forth in ACIP’s MBP and Policies and Procedures.⁶³ This ad hoc outreach fails to comply with the spirit or letter of the FACA regulations governing outreach, all of which seek to promote FACA’s overarching goal of public accountability and transparency.⁶⁴

Even if these regulations are not binding, as Defendants contend, FACA itself directs that “*standards and uniform procedures* should govern the establishment . . . of advisory committees.” 5 U.S.C. § 1002(b)(4) (emphasis added). The Government’s failure to follow both longstanding practice and regulations aimed at ensuring that “the points of view that would promote a fairly balanced advisory committee membership” are represented on the committee is strong evidence

⁶¹ The Court allowed Plaintiffs’ motion for leave to file supplemental declarations. Dkt. 285. The Court did so in light of the nature of the case and motion, and recognizing that because Defendants were given an opportunity to respond, they were not substantially prejudiced. That said, the Court emphasizes that future requests to file last-minute, supplemental materials will not be regarded favorably.

⁶² There were only two days between the termination of the prior ACIP members and the announcement of the first batch of new members. *See, e.g.*, Dkt. 185-47 ¶ 24. However, it is possible that the review process for new applicants began earlier than the date of the terminations. That said, considering Secretary Kennedy was not confirmed to his position until February 13, 2025, Press Release, *Robert F. Kennedy, Jr. Sworn in as 26th Secretary at HHS, President Trump Signs Executive Order to Make America Healthy Again*, HHS (Feb. 13, 2025), <https://www.hhs.gov/press-room/eo-maha.html> [<https://perma.cc/2T54-RMJS>], the evidence suggests that the outreach and appointment process took less than four months, even under the most generous view.

⁶³ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5; *Advisory Committee on Immunization Practices Policies and Procedures*, *supra* note 5. Again, even treating these documents as non-binding, the lack of adherence to these prescribed procedures, designed to ensure compliance with FACA, provides strong evidence that the newly constituted ACIP likely violates FACA.

⁶⁴ FACA was passed out of growing “concerns that the number and membership of advisory committees had proliferated and that the committee operations were not consistent or transparent.” Meghan M. Stuessy & Kathleen E. Marchsteiner, Cong. Rsch. Serv., R47984, *The Federal Advisory Committee Act (FACA): Overview and Considerations for Congress* (2024). Accordingly, “FACA’s principal purpose was to enhance the public accountability of advisory committees established by the Executive Branch and to reduce wasteful expenditures on them.” *Pub. Citizen v. U.S. Dep’t of Just.*, 491 U.S. 440, 459 (1989)

that there is a FACA problem here. The Court reiterates that agencies generally have much discretion in assembling advisory committees. But the constellation of evidence before the Court strongly suggests that little, if any, attention was paid by Secretary Kennedy to the requirements of FACA when appointing the new ACIP members. In light of the evidence before the Court that many of the new members lack relevant experience, the Court concludes that Plaintiffs have demonstrated a strong likelihood of prevailing on the merits of their fairly balanced claim. Having so concluded, the Court need not address Plaintiffs' arguments about undue influence.⁶⁵

Moreover, for all of the reasons described above, the Court concludes that Plaintiffs are likely to succeed in demonstrating that the reconstitution of ACIP was arbitrary and capricious. Defendants have provided no explanation for their disregard of the requirements laid out in ACIP's Charter, MBP, and Policies and Procedures. This failure to articulate *any* reason, let alone a "satisfactory explanation for [the] action," renders the ACIP reconstitution unlawful. *Penobscot*, 164 F.3d at 719; *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016) ("Whatever potential reasons the Department *might have* given, the agency *in fact* gave almost no reasons at all." (emphases added)); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy sub silentio.").

C. Irreparable Harm

Plaintiffs have demonstrated that they are likely to face irreparable harm should the requested preliminary relief not issue. "'Irreparable injury' in the preliminary injunction context means an injury that cannot adequately be compensated for either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy." *Rio*

⁶⁵ Nor will the Court address Plaintiffs' challenges to the 2025 ACIP Votes. *See infra* Section III.E.2 (discussing the scope of remedy).

Grande Cmty. Health Ctr., Inc. v. Rullan, 397 F.3d 56, 76 (1st Cir. 2005). “A finding of 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.” *Baptiste v. Kennealy*, 490 F. Supp. 3d 353, 381 (D. Mass. 2020) (quoting *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004)). “District courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief.” *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 915 (1st Cir. 1989) (quoting *Wagner v. Taylor*, 836 F.2d 566, 575–76 (D.C. Cir. 1987)).

1. January 2026 Memo

Plaintiffs and declarants describe a wide range of harms they contend are likely should the Court decline to issue preliminary relief. The Court focuses on two: the financial harm to Organizational Plaintiffs’ member doctors arising from uncompensated work now required because of the new immunization schedules and the financial harm to Organizational Plaintiffs arising from their work to support their members in complying with the Challenged Actions.⁶⁶

Defendants focus much of their opposition on whether these constitute harm, rather than whether such harms are irreparable. *See* Dkt. 232 at 45–50. Defendants do not dispute that by changing recommendations from routine to SCDM, they require Organizational Plaintiffs’ member doctors to engage in additional work, and instead argue that “creating space for a basic dialogue between physician and patient about whether to receive a vaccine hardly amounts to irreparable harm.” *Id.* at 49. But the issue here is not just lost time, but the lack of compensation.⁶⁷

⁶⁶ The Court is skeptical on the current record that some of the other harms alleged, such as Individual Plaintiffs’ anxiety, constitute irreparable harm. *See Charlesbank*, 370 F.3d at 162.

⁶⁷ Nor is magnitude of harm an issue. *See California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (explaining that the irreparable harm “analysis focuses on irreparability, ‘irrespective of the magnitude of the injury’” (quoting *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999))).

See, e.g., Dkt. 185-25 ¶¶ 27, 31; Dkt. 185-26 ¶ 16; Dkt. 185-27 ¶ 16; Dkt. 185-28 ¶¶ 9, 11, 18–20; Dkt. 185-29 ¶¶ 21–23, 28–29; Dkt. 185-30 ¶¶ 10–11, 13, 16; Dkt. 185-31 ¶¶ 13; Dkt. 185-32 ¶¶ 18, 22–24; Dkt. 185-33 ¶¶ 8, 10–11, 13; Dkt. 185-36 ¶¶ 29, 31–33, 41; Dkt. 185-37 ¶¶ 13–15, 17, 31–33; Dkt. 185-38 ¶¶ 12–13, 19; Dkt. 185-40 ¶ 15; Dkt. 185-41 ¶¶ 22–27; Dkt. 185-42 ¶ 40; Dkt. 185-43 ¶¶ 13–18, 22, 26, 43; Dkt. 185-46 ¶¶ 13, 22–23; Dkt. 185-51 ¶¶ 37, 41–43; Dkt. 185-52 ¶¶ 10–12, 18; Dkt. 240-2 ¶ 11; Dkt. 287 ¶¶ 3–6, 11–12, 15. Plaintiffs’ declarations are clear that the harms they describe from the May 2025 Directive have also arisen from the January 2026 Memo.⁶⁸ *See, e.g.*, Dkt. 185-32 ¶¶ 22, 24. That such work is “part and parcel of a physician’s ordinary clinical responsibility,” Dkt. 232 at 49, merely demonstrates that this is the cost of compliance with the January 2026 Memo.

With regards to Organizational Plaintiffs, the expense of counseling members constitutes harm. Organizational Plaintiffs have detailed how they have been forced to divert resources away from their usual tasks and initiatives in response to the January 2026 Memo, and how that resource diversion has frustrated both specific initiatives and their broader organizational missions, which the Court finds compelling.⁶⁹ *See, e.g.*, Dkt. 185-25 ¶¶ 30–31; Dkt. 185-27 ¶¶ 26–28; Dkt. 185-34 ¶¶ 18–19, 39; Dkt. 185-36 ¶¶ 27, 40–41, 43; Dkt. 185-40 ¶¶ 9–10, 17; Dkt. 185-44 ¶¶ 23, 36, 39; Dkt. 185-46 ¶¶ 17–18; Dkt. 286 ¶¶ 2, 6(c), 6(e), 13; Dkt. 288 ¶¶ 14–15; *see also Mass. Fair Hous. Ctr.*, 496 F. Supp. 3d at 611 (finding irreparable harm where agency action “pose[d] a real and substantial threat of imminent harm to [plaintiff’s] mission by raising the burdens, costs, and effectiveness of disparate impact liability”); *City & County of San Francisco v. U.S. Citizenship & Immigr. Servs.*, 408 F. Supp. 3d 1057, 1126 (N.D. Cal. 2019) (finding irreparable injury where

⁶⁸ Nor is there any reason to believe that this would not be true.

⁶⁹ The Court notes it has previously rejected a similar argument from Defendants in the context of standing. *See AAP I*, 2026 WL 33719 at *7–8; *see also supra* Section III.B.1.a.

the goals of providing healthcare and legal services were frustrated and that plaintiffs' changes to their programs and other diversions of resources constituted irreparable harm), *aff'd sub nom.*, *City & County of San Francisco v. U.S. Citizenship & Immigr. Servs.*, 981 F.3d 742 (9th Cir. 2020).

Although harm is likely to be reparable when it is "almost purely economic," *Longo En-Tech P.R., Inc. v. Env't Prot. Agency*, 2017 WL 878442, at *8 (D.P.R. Mar. 6, 2017), economic harm can be irreparable when it is not compensable by legal remedies, *K-Mart*, 875 F.2d at 914; *see also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (explaining that economic harm can be irreparable where there is no adequate remedy to recover those damages); *Wages & White Lion LLC v. U.S. Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) (holding that "complying with [an agency order] later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs . . . because federal agencies generally enjoy sovereign immunity for any monetary damages" (first alteration and emphasis in original) (citations omitted)). Indeed, "[i]rreparable harm most often exists where a party has no adequate remedy at law." *Charlesbank*, 370 F.3d at 162. Thus, "[w]here a plaintiff stands to suffer a substantial injury that cannot be adequately compensated by an end-of-case award of money damages, irreparable harm exists." *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003).

Plaintiffs could not recover monetary damages in this APA action or in any post-factum recovery action against the Government. As described above, the Court finds compelling Plaintiffs' evidence regarding the financial harm they and their members face because of the January 2026 Memo, independent of their ongoing advocacy work. The cost of complying with the January 2026 Memo is substantial, and there is no real dispute that Plaintiffs will have no avenue to recover those costs even if it is deemed unlawful.

That some of these injuries may be a result of third-party actions (such as insurers making coverage decisions) does not sever the causal connection between the challenged action and harm. “There must be a ‘sufficient causal connection’ between the alleged irreparable harm and the activity to be enjoined, and showing that ‘the requested injunction would forestall’ the irreparable harm qualifies as such a connection.” *Nat’l Wildlife Fed’n v. Nat’l Marine Fisheries Serv.*, 886 F.3d 803, 819 (9th Cir. 2018) (quoting *Perfect 10, Inc. v. Google, Inc.*, 653 F.3d 976, 981–82 (9th Cir. 2011)). “However, a plaintiff ‘need not further show that the action sought to be enjoined is the exclusive cause of the injury.’” *Id.* (quoting *M.R. v. Dreyfus*, 697 F.3d 706, 728 (9th Cir. 2012)). Here, Plaintiffs have demonstrated that but for the January 2026 Memo, they would not suffer these harms. For the reasons described above, *see infra* Section III.B.1.b. it is illogical to claim that the medical community’s response to Defendants’ changes to the immunization schedules is so unrelated to those changes that it breaks the causal connection. That suffices at this stage. For these reasons, the Court concludes Plaintiffs have met their burden of demonstrating irreparable harm as to the January 2026 Memo.

2. ACIP Reconstitution

Plaintiffs have also established that they are likely to suffer irreparable harm should ACIP continue to operate with an unbalanced committee. The current constitution of ACIP thwarts Congress’s intent to “to enhance the public accountability of advisory committees,” *Pub. Citizen v. Dep’t of Just.*, 491 U.S. 440, 459 (1989), by violating Congress’s “command that [advisory] committees be fairly balanced,” *Union of Concerned Scientists*, 954 F.3d at 20–21. Even a procedural violation can give rise to irreparable harm justifying injunctive relief because “the damage done by [the agency’s] violation of the APA cannot be fully cured by later remedial action.” *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 18 (D.D.C. 2009). A final

judgment vacating ACIP appointments would not remedy the harm caused in the immediate future by the committee's action. It would merely guard against further violations post-judgment.

Moreover, Plaintiffs have demonstrated that the harms described above will continue to arise out of further ACIP actions. While Defendants argue that it is merely “speculative” that ACIP will take any votes at a future meeting, Dkt. 254 at 3–4, the Court finds the evidence both credible and compelling that a vote is likely at ACIP's upcoming meeting. When the Court held its first hearing on this motion, ACIP had a meeting scheduled for the end of February, for which the ACIP Vice Chair explicitly stated an intention for ACIP to vote on changes to the Vaccines for Children Program. *See* Dkt. 240-2 ¶ 3.⁷⁰ While this statement does not *guarantee* that ACIP will take a vote or make any recommendation changes, Plaintiffs need not demonstrate that the anticipated harm is certain, merely that it is likely.⁷¹ *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (“Damocles’s sword does not have to actually fall . . . before the court will issue [relief].”). Moreover, since rescheduling the ACIP meeting to March 18–19, ACIP's published statement of “Matters to be Considered” now includes the possibility of

⁷⁰ *See also* Dr. Robert W. Malone, *CDC to Make Announcement on Children's Health Tomorrow*, Malone News (Dec. 18, 2025), <https://www.malone.news/p/hhs-cdc-to-make-announcement-on-childrens> [<https://perma.cc/ACK8-KVKX>] (“ACIP will need to vote during their next meeting to approve language aligning the Congressionally mandated Vaccines for Children program with the new schedule.”) (cited at Dkt. 240-2 ¶ 3 n.1).

⁷¹ It is not unreasonable for the Court to take the ACIP Vice Chair at his word. Indeed, it is merely Defendants' own speculation that ACIP will *not* act in accordance with the ACIP Vice Chair's statements.

additional recommendation votes.⁷² 91 Fed. Reg. 9617 (Feb. 26, 2026). On this record, the Court finds it likely that ACIP will take further action and therefore irreparably harm Plaintiffs.⁷³

D. Balance of the Equities and Public Interest

Finally, the Court must weigh the balance of the equities and determine whether preliminary relief would be in the public interest. “These two inquiries merge in a case like this one, where the Government is the party opposing the preliminary injunction.” *Devitri v. Cronen*, 289 F. Supp. 3d 287, 297 (D. Mass. 2018) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). For the reasons discussed below, these factors favor Plaintiffs.

“To begin with, the Plaintiffs’ likelihood of success on the merits lightens [Defendants’] stated interests.” *Huisha-Huisha v. Mayorkas*, 27 F.4th 718, 734 (D.C. Cir. 2022). The Supreme Court has confirmed that “our system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. Dep’t Health & Hum. Servs.*, 594 U.S. 758, 766 (2021); *see also Nat’l Fed’n Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 120–21 (2022) (staying an unlawful vaccine mandate even though the Government said the mandate would save more than 6,500 lives); *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 582 (1952) (affirming district

⁷² Defendants argued during the March 4, 2026 hearing that this statement was not a final agenda, and thus may change. *See* Dkt. 283 at 63:21–64:1. Regardless of the finality of ACIP’s agenda, it provides compelling evidence that ACIP does plan to take votes at the upcoming meeting. At this time, the Court has no reason to believe that ACIP will not act in accordance with its published plans.

⁷³ The Court takes a moment to acknowledge that this case presents a close call on the issue of irreparable harm. *See Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1262 (10th Cir. 2004) (“Determining whether irreparable harm exists can be a difficult and close question.”); *id.* (“The concept of irreparable harm does not readily lend itself to definition.”). It cannot be that all agency action creates irreparable harm—though nearly every agency action is likely to create some type of compliance cost—as Courts regularly determine that plaintiffs challenging agency action have not met their burden on showing irreparable harm. And Defendants’ arguments about the timing of this case are well taken—the Court itself has consistently offered to expedite this case as much as possible and will continue to do so as the parties brief the merits. But after reviewing the numerous declarations from Plaintiffs’ and their members, the Court is satisfied that Plaintiffs have met their burden in this case. *See Coal. to Protest Democratic Nat’l Convention v. City of Boston*, 327 F. Supp. 2d 61, 69 (D. Mass. 2004) (“The greater the likelihood of success on the merits, the less risk of irreparable harm to the plaintiff must be shown.”), *aff’d sub nom.*, *Bl(a)ck Tea Soc’y v. City of Boston*, 378 F.3d 8 (1st Cir. 2004).

court’s preliminary injunction of an illegal executive order even though a wartime president said his order was “necessary to avert a national catastrophe”).

Plaintiffs and amici have demonstrated that there is a substantial risk to public health absent preliminary relief. *See, e.g.*, Dkt. 218 at 26–35; Dkt. 228 at 24–30; Dkt. 237 at 55–58, 60–61. The Court finds it telling that Defendants make little effort to directly oppose this point, arguing only that Plaintiffs’ requested relief goes against the public interest by restraining Defendants’ speech.⁷⁴ Dkt. 232 at 43–44.⁷⁵ But as discussed above, the Court is not dictating what vaccine-related content Defendants may or may not espouse.⁷⁶ Instead, the Court is regulating the procedure by which Defendants do so. “There is generally no public interest in the perpetuation of unlawful agency action.” *Newby*, 838 F.3d at 12. Thus, the Government “cannot suffer harm from an injunction that merely ends an unlawful practice.” *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013).

Nonetheless, even if Defendants ultimately prevail, a stay, at most, causes Defendants to suffer the minimal harm of continuing their previous approach to promulgating immunization schedules.⁷⁷ Defendants state that their efforts seek to increase vaccination rates in the interest of public health. *See, e.g.* Dkt. 260 at 104:19–22 (“[Defense counsel]: . . . the government’s goal is

⁷⁴ The closest Defendants come on this point is to argue that the purpose of the January 2026 Memo is to promote public trust in vaccines as a general proposition, thereby increasing vaccination rates and improving public health. *See, e.g.*, Dkt. 260 at 108:17–19, 112:18–21; 113:4–13. But that fails to respond to Plaintiffs’ and amici’s evidence on the current risk to public health arising from the reduction in vaccination rates for the *specific* diseases for which the CDC has downgraded the vaccine recommendations.

⁷⁵ Amici Children’s Health Defense raises concerns about the safety of many of the vaccinations at issue. *See generally* Dkt. 281. While the vaccinations may pose some health risk to some individuals, Children’s Health Defense’s proffered evidence does not demonstrate that the risks outweigh the broader benefits of the vaccines. On the record currently before the Court, the Court finds Plaintiffs’ and the other amici’s evidence more compelling on the public health risks.

⁷⁶ As discussed below, the relief the Court will issue is not as broad as that which Plaintiffs request. *See infra* Section III.E.

⁷⁷ *See infra* Section III.E.

to increase vaccine uptake of consensus vaccines such as the measles vaccine. So, again, this is not pro- versus anti-vaccine. Both sides here believe in vaccines.”). Even if Defendants do show after the production of the administrative record that Plaintiffs’ challenges amount only to a difference in opinion as to how best to best achieve these goals, merely returning to Defendants’ prior approach for a short period while the Court adjudicates the merits of Plaintiffs’ claims can hardly be said to impose such a burden that relief would go against the public interest, especially where Plaintiffs have demonstrated a likelihood of success on the merits and irreparable harm.⁷⁸ Thus, the balance of equities and public interest factors weigh in favor of preliminary relief.

E. Remedy

“[I]n drafting equitable relief, courts must consider ‘what is necessary, what is fair, and what is workable.’” *Massachusetts v. Nat’l Insts. of Health*, 770 F. Supp. 3d 277, 328 (D. Mass. 2025) (quoting *North Carolina v. Covington*, 581 U.S. 486, 488 (2017)), *aff’d*, 164 F.4th 1 (1st Cir. 2026). Plaintiffs ask the Court both to stay the Challenged Actions and enjoin Defendants from conducting further public meetings until there has been an adjudication on the merits. *See generally* Dkt. 183-1. Defendants do not dispute that a stay of the January 2026 Memo would be the appropriate remedy should the Court rule for the Plaintiffs but argue that any remedy preventing Defendants from conducting further public meetings is too broad. Dkt. 232 at 50–52.

1. January 2026 Memo

The parties largely agree that, should the Court issue relief as to the January 2026 Memo, a stay is appropriate. Dkt. 232 at 50 (“If the Court finds a defect in the January 2026 action, it should at most enter a stay of that action under the APA.”). In the face of the parties’ agreement,

⁷⁸ Defendants also argue that staying the current immunization schedules would result in “whiplash” that would be exacerbated should Defendants ultimately prevail on the merits. But given the Court’s conclusion that Plaintiffs have demonstrated a likelihood of success on the merits, this “whiplash” is likely a result of Defendants’ own unlawful creation, which does not outweigh the public interests raised by Plaintiffs and amici.

the Court finds that a stay of the January 2026 Memo is an appropriate remedy. *See, e.g., Haitian Evangelical Clergy Ass’n v. Trump*, 789 F. Supp. 3d 255, 274 (E.D.N.Y. 2025) (“[C]ourts ‘routinely stay already-effective agency action under Section 705.’” (quoting *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022) (collecting cases))); *see also West Virginia v. Env’t Prot. Agency*, 577 U.S. 1126 (2016) (staying an Environmental Protection Agency rule pending the outcome of the case). To the extent Plaintiffs seek further relief, *see* Dkt. 183-1 ¶ 2, the Court declines to grant it at this time.

2. ACIP

The parties disagree as to the appropriate remedy for Plaintiffs’ FACA challenge. Plaintiffs ask the Court to enjoin Defendants “from convening, holding, or conducting the ACIP meeting currently scheduled . . . as well as any subsequent ACIP meetings of the current ACIP membership.” Dkt. 183-1 ¶ 3.⁷⁹ Defendants contend that, “[i]f 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.” Dkt. 232 at 51.

The Court lands somewhere in the middle. Plaintiffs are likely to succeed in showing that the reconstituted ACIP does not comport with FACA’s “fairly balanced” requirement. The Court made this determination not on a mathematical formula but based on the unexplained departure from the MBP and the overall composition of the new committee. *See supra* Section III.B.3.b. These findings go beyond “specific appointments,” *cf.* Dkt. 232 at 51, and instead suggest that the

⁷⁹ Since the filing of Plaintiffs’ motion, the ACIP meeting that had been scheduled for February 25–26, 2026, was rescheduled to March 18–19, 2026. 91 Fed. Reg. 9617 (Feb. 26, 2026); *see also* Dkt. 257.

appointment process, in general, and thus the full committee, was tainted. Thus, the remedy should cover the entire challenged committee.⁸⁰

However, it would be inappropriate for the Court either to enjoin ACIP from meeting, as Plaintiffs suggest, or to effectively select-by-veto a different ACIP, as Defendants suggest. There are many “different balances that can be struck in a committee’s membership.” *Union of Concerned Scientists*, 954 F.3d at 19. In the first instance, it is an agency’s job and prerogative to strike that balance, just as it is this Court’s to say when the agency has failed to do so. Identifying specific members of ACIP who should not have been appointed, based on an incomplete record, or assuming that HHS is wholly incapable of assembling a lawful ACIP at this stage and enjoining it from doing so, would impose a far greater intrusion into Defendants’ operation than merely staying the current appointments. A stay will prevent the irreparable injury Plaintiffs have shown is likely: while the appointments of the challenged members of ACIP are stayed, ACIP as currently constituted cannot meet, for how can a committee meet without nearly the entirety of its membership? Moreover, a stay is “less drastic” than, and thus preferable to, an injunction. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010). Thus, the Court concludes that the appropriate remedy at this juncture is to stay the appointments of the thirteen members of ACIP at issue in this motion.⁸¹

However, the Court will also stay all votes taken by the challenged ACIP, as they were taken by a committee that this Court has determined likely violates FACA.⁸² Though courts have recognized that injunctive relief may be appropriate to remedy a FACA violation, *see, e.g., W. Org.*

⁸⁰ *See supra* note 46.

⁸¹ *See supra* note 46.

⁸² Plaintiffs asked the Court to “set aside” the June Vote and the December Vote, either as part of the remedy for violating FACA or as a remedy for their separate challenges to the votes themselves. *See* Dkt. 237 at 22, 48.

of Res. Councils v. Bernhardt, 412 F. Supp. 3d 1227, 1243 (D. Mont. 2019) (concluding that “[a] use injunction” [preventing the agency from relying on an advisory committee’s recommendations or work product] is the only way to achieve FACA’s purpose[] of enhancing public accountability”), in this instance, ACIP’s votes have actual legal weight that can be mitigated directly by a stay.⁸³ Therefore, the Court need not resort to an injunction.

IV. Conclusion

For the foregoing reasons, Plaintiffs’ motion for preliminary relief is GRANTED in part.

(i) The Court STAYS the January 2026 Memo revising the CDC’s childhood immunization schedule pursuant to 5 U.S.C. § 705.

(ii) The Court STAYS the appointments of the thirteen ACIP members appointed on June 11, 2025, September 11, 2025, and January 13, 2026.

(iii) The Court further STAYS all votes taken by the now-stayed ACIP.

So Ordered.

Dated: March 16, 2026

/s/ Brian E. Murphy

Brian E. Murphy

Judge, United States District Court

⁸³ Defendants do not address the propriety of this remedy. *See generally* Dkts. 232, 272.

expenses in the same manner as the payment of final judgments as provided in this Act [probably should be “this title”, see Short Title note above] would be effective only to the extent and in such amounts as are provided in advance in appropriation Acts, was repealed by Pub. L. 99-80, § 4, Aug. 5, 1985, 99 Stat. 186.

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

SHORT TITLE

The provisions of this subchapter and chapter 7 of this title were originally enacted by act June 11, 1946, ch. 324, 60 Stat. 237, popularly known as the “Administrative Procedure Act”. That Act was repealed as part of the general revision of this title by Pub. L. 89-554 and its provisions incorporated into this subchapter and chapter 7 hereof.

§ 551. Definitions

For the purpose of this subchapter—

(1) “agency” means each authority of the Government of the United States, whether or not it is within or subject to review by another agency, but does not include—

- (A) the Congress;
- (B) the courts of the United States;
- (C) the governments of the territories or possessions of the United States;
- (D) the government of the District of Columbia;

or except as to the requirements of section 552 of this title—

(E) agencies composed of representatives of the parties or of representatives of organizations of the parties to the disputes determined by them;

(F) courts martial and military commissions;

(G) military authority exercised in the field in time of war or in occupied territory; or

(H) functions conferred by sections 1738, 1739, 1743, and 1744 of title 12; subchapter II of chapter 471 of title 49; or sections 1884, 1891-1902, and former section 1641(b)(2), of title 50, appendix;

(2) “person” includes an individual, partnership, corporation, association, or public or private organization other than an agency;

(3) “party” includes a person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party, in an agency proceeding, and a person or agency admitted by an agency as a party for limited purposes;

(4) “rule” means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) “rule making” means agency process for formulating, amending, or repealing a rule;

(6) “order” means the whole or a part of a final disposition, whether affirmative, nega-

tive, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) “adjudication” means agency process for the formulation of an order;

(8) “license” includes the whole or a part of an agency permit, certificate, approval, registration, charter, membership, statutory exemption or other form of permission;

(9) “licensing” includes agency process respecting the grant, renewal, denial, revocation, suspension, annulment, withdrawal, limitation, amendment, modification, or conditioning of a license;

(10) “sanction” includes the whole or a part of an agency—

(A) prohibition, requirement, limitation, or other condition affecting the freedom of a person;

(B) withholding of relief;

(C) imposition of penalty or fine;

(D) destruction, taking, seizure, or withholding of property;

(E) assessment of damages, reimbursement, restitution, compensation, costs, charges, or fees;

(F) requirement, revocation, or suspension of a license; or

(G) taking other compulsory or restrictive action;

(11) “relief” includes the whole or a part of an agency—

(A) grant of money, assistance, license, authority, exemption, exception, privilege, or remedy;

(B) recognition of a claim, right, immunity, privilege, exemption, or exception; or

(C) taking of other action on the application or petition of, and beneficial to, a person;

(12) “agency proceeding” means an agency process as defined by paragraphs (5), (7), and (9) of this section;

(13) “agency action” includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act; and

(14) “ex parte communication” means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 381; Pub. L. 94-409, § 4(b), Sept. 13, 1976, 90 Stat. 1247; Pub. L. 103-272, § 5(a), July 5, 1994, 108 Stat. 1373; Pub. L. 111-350, § 5(a)(2), Jan. 4, 2011, 124 Stat. 3841.)

HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
(1)	5 U.S.C. 1001(a).	June 11, 1946, ch. 324, § 2(a), 60 Stat. 237. Aug. 8, 1946, ch. 870, § 302, 60 Stat. 918. Aug. 10, 1946, ch. 951, § 601, 60 Stat. 993. Mar. 31, 1947, ch. 30, § 6(a), 61 Stat. 37. June 30, 1947, ch. 163, § 210, 61 Stat. 201.

HISTORICAL AND REVISION NOTES—CONTINUED

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
(2)–(13)	5 U.S.C. 1001 (less (a)).	Mar. 30, 1948, ch. 161, § 301, 62 Stat. 99. June 11, 1946, ch. 324, § 2 (less (a)), 60 Stat. 237.

In paragraph (1), the sentence “Nothing in this Act shall be construed to repeal delegations of authority as provided by law,” is omitted as surplusage since there is nothing in the Act which could reasonably be so construed.

In paragraph (1)(G), the words “or naval” are omitted as included in “military”.

In paragraph (1)(H), the words “functions which by law expire on the termination of present hostilities, within any fixed period thereafter, or before July 1, 1947” are omitted as executed. Reference to the “Selective Training and Service Act of 1940” is omitted as that Act expired Mar. 31, 1947. Reference to the “Sugar Control Extension Act of 1947” is omitted as that Act expired on Mar. 31, 1948. References to the “Housing and Rent Act of 1947, as amended” and the “Veterans’ Emergency Housing Act of 1946” have been consolidated as they are related. The reference to former section 1641(b)(2) of title 50, appendix, is retained notwithstanding its repeal by § 111(a)(1) of the Act of Sept. 21, 1961, Pub. L. 87–256, 75 Stat. 538, since § 111(c) of the Act provides that a reference in other Acts to a provision of law repealed by § 111(a) shall be considered to be a reference to the appropriate provisions of Pub. L. 87–256.

In paragraph (2), the words “of any character” are omitted as surplusage.

In paragraph (3), the words “and a person or agency admitted by an agency as a party for limited purposes” are substituted for “but nothing herein shall be construed to prevent an agency from admitting any person or agency as a party for limited purposes”.

In paragraph (9), a comma is supplied between the words “limitation” and “amendment” to correct an editorial error of omission.

In paragraph (10)(C), the words “of any form” are omitted as surplusage.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

CODIFICATION

Section 551 of former Title 5, Executive Departments and Government Officers and Employees, was transferred to section 2242 of Title 7, Agriculture.

AMENDMENTS

2011—Par. (1)(H). Pub. L. 111–350 struck out “chapter 2 of title 41;” after “title 12;”.

1994—Par. (1)(H). Pub. L. 103–272 substituted “subchapter II of chapter 471 of title 49; or sections” for “or sections 1622.”

1976—Par. (14). Pub. L. 94–409 added par. (14).

EFFECTIVE DATE OF 1976 AMENDMENT

Amendment by Pub. L. 94–409 effective 180 days after Sept. 13, 1976, see section 6 of Pub. L. 94–409, set out as an Effective Date note under section 552b of this title.

STUDY AND REPORTS ON ADMINISTRATIVE SUBPOENAS

Pub. L. 106–544, § 7, Dec. 19, 2000, 114 Stat. 2719, provided that:

“(a) STUDY ON USE OF ADMINISTRATIVE SUBPOENAS.—Not later than December 31, 2001, the Attorney General, in consultation with the Secretary of the Treasury, shall complete a study on the use of administrative subpoena power by executive branch agencies or entities and shall report the findings to the Committees on the Judiciary of the Senate and the House of Representatives. Such report shall include—

“(1) a description of the sources of administrative subpoena power and the scope of such subpoena power within executive branch agencies;

“(2) a description of applicable subpoena enforcement mechanisms;

“(3) a description of any notification provisions and any other provisions relating to safeguarding privacy interests;

“(4) a description of the standards governing the issuance of administrative subpoenas; and

“(5) recommendations from the Attorney General regarding necessary steps to ensure that administrative subpoena power is used and enforced consistently and fairly by executive branch agencies.

“(b) REPORT ON FREQUENCY OF USE OF ADMINISTRATIVE SUBPOENAS.—

“(1) IN GENERAL.—The Attorney General and the Secretary of the Treasury shall report in January of each year to the Committees on the Judiciary of the Senate and the House of Representatives on the number of administrative subpoenas issued by them under this section and the identity of the agency or component of the Department of Justice or the Department of the Treasury issuing the subpoena and imposing the charges.

“(2) EXPIRATION.—The reporting requirement of this subsection shall terminate in 3 years after the date of the enactment of this section [Dec. 19, 2000].”

§ 552. Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

(1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—

(A) descriptions of its central and field organization and the established places at which, the employees (and in the case of a uniformed service, the members) from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(B) statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(C) rules of procedure, descriptions of forms available or the places at which forms may be obtained, and instructions as to the scope and contents of all papers, reports, or examinations;

(D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and

(E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

(2) Each agency, in accordance with published rules, shall make available for public inspection and copying—

tive Training and Service Act of 1940” is omitted as that Act expired on Mar. 31, 1947. Reference to the “Sugar Control Extension Act of 1947” is omitted as that Act expired on Mar. 31, 1948. References to the “Housing and Rent Act of 1947, as amended” and the “Veterans’ Emergency Housing Act of 1946” have been consolidated as they are related. The reference to former section 1641(b)(2) of title 50, appendix, is retained notwithstanding its repeal by §111(a)(1) of the Act of Sept. 21, 1961, Pub. L. 87–256, 75 Stat. 538, since §111(c) of the Act provides that a reference in other Acts to a provision of law repealed by §111(a) shall be considered to be a reference to the appropriate provisions of Pub. L. 87–256.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

Editorial Notes

REFERENCES IN TEXT

Sections 1884 and 1891–1902 of title 50, appendix, referred to in subsec. (b)(1)(H), were a part of the various Housing and Rent Acts which were classified to section 1881 et seq. of the former Appendix to Title 50, War and National Defense, and had been repealed or omitted from the Code as executed prior to the elimination of the Appendix to Title 50. See Elimination of Title 50, Appendix note preceding section 1 of Title 50. Section 1641 of title 50, appendix, referred to in subsec. (b)(1)(H), was repealed by Pub. L. 87–256, §111(a)(1), Sept. 21, 1961, 75 Stat. 538.

AMENDMENTS

2011—Subsec. (b)(1)(H). Pub. L. 111–350 struck out “chapter 2 of title 41;” after “title 12;”.

1994—Subsec. (b)(1)(H). Pub. L. 103–272 substituted “subchapter II of chapter 471 of title 49; or sections” for “or sections 1622;”.

§ 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof. An action in a court of the United States seeking relief other than money damages and stating a claim that an agency or an officer or employee thereof acted or failed to act in an official capacity or under color of legal authority shall not be dismissed nor relief therein be denied on the ground that it is against the United States or that the United States is an indispensable party. The United States may be named as a defendant in any such action, and a judgment or decree may be entered against the United States: *Provided*, That any mandatory or injunctive decree shall specify the Federal officer or officers (by name or by title), and their successors in office, personally responsible for compliance. Nothing herein (1) affects other limitations on judicial review or the power or duty of the court to dismiss any action or deny relief on any other appropriate legal or equitable ground; or (2) confers authority to grant relief if any other statute that grants consent to suit expressly or impliedly forbids the relief which is sought.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94–574, §1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(a).	June 11, 1946, ch. 324, §10(a), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

Editorial Notes

AMENDMENTS

1976—Pub. L. 94–574 removed the defense of sovereign immunity as a bar to judicial review of Federal administrative action otherwise subject to judicial review.

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. If no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

(Pub. L. 89–554, Sept. 6, 1966, 80 Stat. 392; Pub. L. 94–574, §1, Oct. 21, 1976, 90 Stat. 2721.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(b).	June 11, 1946, ch. 324, §10(b), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

Editorial Notes

AMENDMENTS

1976—Pub. L. 94–574 provided that if no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer as defendant.

§ 704. Actions reviewable

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and pro-

vides that the action meanwhile is inoperative, for an appeal to superior agency authority.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(c).	June 11, 1946, ch. 324, §10(c), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 705. Relief pending review

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a 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.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(d).	June 11, 1946, ch. 324, §10(d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(e).	June 11, 1946, ch. 324, §10(e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

Statutory Notes and Related Subsidiaries

ABBREVIATION OF RECORD

Pub. L. 85-791, Aug. 28, 1958, 72 Stat. 941, which authorized abbreviation of record on review or enforcement of orders of administrative agencies and review on the original papers, provided, in section 35 thereof, that: "This Act [see Tables for classification] shall not be construed to repeal or modify any provision of the Administrative Procedure Act [see Short Title note set out preceding section 551 of this title]."

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

Sec.	
801.	Congressional review.
802.	Congressional disapproval procedure.
803.	Special rule on statutory, regulatory, and judicial deadlines.
804.	Definitions.
805.	Judicial review.
806.	Applicability; severability.
807.	Exemption for monetary policy.
808.	Effective date of certain rules.

§ 801. Congressional review

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency promulgating the rule shall submit to the Comptroller General and make available to each House of Congress—

(i) a complete copy of the cost-benefit analysis of the rule, if any;

(ii) the agency's actions relevant to sections 603, 604, 605, 607, and 609;

(iii) the agency's actions relevant to sections 202, 203, 204, and 205 of the Unfunded Mandates Reform Act of 1995; and

(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(D) For any rule submitted under subparagraph (A), if the Federal agency promulgating

vides that the action meanwhile is inoperative, for an appeal to superior agency authority.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392.)

HISTORICAL AND REVISION NOTES

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(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

<i>Derivation</i>	<i>U.S. Code</i>	<i>Revised Statutes and Statutes at Large</i>
.....	5 U.S.C. 1009(d).	June 11, 1946, ch. 324, §10(d), 60 Stat. 243.

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(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

HISTORICAL AND REVISION NOTES

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- 802. Congressional disapproval procedure.
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- 806. Applicability; severability.
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(iv) any other relevant information or requirements under any other Act and any relevant Executive orders.

(C) Upon receipt of a report submitted under subparagraph (A), each House shall provide copies of the report to the chairman and ranking member of each standing committee with jurisdiction under the rules of the House of Representatives or the Senate to report a bill to amend the provision of law under which the rule is issued.

(D) For any rule submitted under subparagraph (A), if the Federal agency promulgating

Administrator of General Services, shall remain in effect as if issued by the Administrator until amended, modified, or revoked.

SEC. 6. This Order shall be effective November 20, 1977.

JIMMY CARTER.

LOBBYISTS ON AGENCY BOARDS AND COMMISSIONS

Memorandum of President of the United States, June 18, 2010, 75 F.R. 35955, provided:

Memorandum for the Heads of Executive Departments and Agencies

My Administration is committed to reducing the undue influence of special interests that for too long has shaped the national agenda and drowned out the voices of ordinary Americans. Special interests exert this disproportionate influence, in part, by relying on lobbyists who have special access that is not available to all citizens. Although lobbyists can sometimes play a constructive role by communicating information to the government, their service in privileged positions within the executive branch can perpetuate the culture of special-interest access that I am committed to changing.

On the day after my inauguration, I signed Executive Order 13490, which places strict limits on the ability of lobbyists to serve in Government positions related to their prior lobbying activities. Last September, we took another step to close the revolving door through which lobbyists enter and exit Government positions when we announced that my Administration aspires to keep Federal agencies' advisory boards free of federally registered lobbyists. Many departments and agencies are making this aspiration a reality by no longer placing federally registered lobbyists on advisory boards—a practice that I am now establishing as the official policy of my Administration.

Accordingly, I hereby direct the heads of executive departments and agencies not to make any new appointments or reappointments of federally registered lobbyists to advisory committees and other boards and commissions. Within 90 days of the date of this memorandum, the Director of the Office of Management and Budget shall issue proposed guidance designed to implement this policy to the full extent permitted by law. The final guidance shall be issued following public comment on the proposed guidance.

This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

The Director of the Office of Management and Budget is hereby authorized and directed to publish this memorandum in the Federal Register.

BARACK OBAMA.

§ 1003. Applicability

(a) IN GENERAL.—This chapter, and any rule, order, or regulation promulgated under this chapter, shall apply to each advisory committee except to the extent that the Act establishing the advisory committee specifically provides otherwise.

(b) EXEMPTIONS RELATING TO CERTAIN FEDERAL ENTITIES.—Nothing in this chapter shall be construed to apply to an advisory committee established or utilized by—

- (1) the Central Intelligence Agency;
- (2) the Federal Reserve System; or
- (3) the Office of the Director of National Intelligence, if the Director of National Intelligence determines that for reasons of national security the advisory committee cannot comply with the requirements of this chapter.

(c) EXEMPTIONS RELATING TO CERTAIN LOCAL AND STATE ENTITIES.—Nothing in this chapter shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4198.)

HISTORICAL AND REVISION NOTES

Revised Section	Source (U.S. Code)	Source (Statutes at Large)
1003	5 U.S.C. App. (FACA §4)	Pub. L. 92–463, §4, Oct. 6, 1972, 86 Stat. 771; Pub. L. 111–259, title IV, §410(a), Oct. 7, 2010, 124 Stat. 2724.

§ 1004. Responsibilities of congressional committees

(a) REVIEW OF ACTIVITIES.—In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection.

(b) CONSIDERATION OF LEGISLATION.—In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require 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;

(3) contain 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;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 1009 of this chapter to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

(c) ADHERENCE TO GUIDELINES.—To the extent they are applicable, the guidelines set out in subsection (b) shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4198.)

HISTORICAL AND REVISION NOTES

<i>Revised Section</i>	<i>Source (U.S. Code)</i>	<i>Source (Statutes at Large)</i>
1004	5 U.S.C. App. (FACA §5)	Pub. L. 92–463, §5, Oct. 6, 1972, 86 Stat. 771.

§ 1005. Responsibilities of the President

(a) DELEGATION.—The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to the President by Presidential advisory committees.

(b) REPORT ON RESPONSE TO RECOMMENDATIONS.—Within 1 year after a Presidential advisory committee submits a public report to the President, the President or the President's delegate shall submit to Congress a report stating either proposals for action or reasons for inaction, with respect to the recommendations contained in the public report.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4199.)

HISTORICAL AND REVISION NOTES

<i>Revised Section</i>	<i>Source (U.S. Code)</i>	<i>Source (Statutes at Large)</i>
1005	5 U.S.C. App. (FACA §6(a), (b))	Pub. L. 92–463, §6(a), (b), Oct. 6, 1972, 86 Stat. 772.

§ 1006. Responsibilities of the Administrator

(a) COMMITTEE MANAGEMENT SECRETARIAT.—The Administrator shall establish and maintain within the General Services Administration a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) ANNUAL REVIEWS.—

(1) IN GENERAL.—Each year, the Administrator shall conduct a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(A) whether the committee is carrying out its purpose;

(B) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to the committee should be revised;

(C) whether the committee should be merged with other advisory committees; or

(D) whether the committee should be abolished.

(2) OBTAINING INFORMATION.—The Administrator may from time to time request such information as the Administrator deems necessary to carry out functions under this sub-

section. Agency heads shall cooperate with the Administrator in making the reviews required by this subsection.

(3) RECOMMENDATIONS.—Upon completion of the review, the Administrator shall make recommendations to the President and to either the agency head or Congress with respect to action the Administrator believes should be taken.

(c) ADMINISTRATIVE GUIDELINES AND MANAGEMENT CONTROLS.—The Administrator shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out functions under this subsection, the Administrator shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to the agency.

(d) GUIDELINES FOR UNIFORM FAIR PAY RATES.—

(1) IN GENERAL.—The Administrator, after study and consultation with the Director of the Office of Personnel Management, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner that gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. The guidelines shall provide that—

(A) a member of an advisory committee or of the staff of an advisory committee shall not receive compensation at a rate in excess of the maximum rate payable under section 5376 of this title;

(B) members of advisory committees, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of this title for persons employed intermittently in the Government service; and

(C) members of advisory committees may be provided services pursuant to section 3102 of this title while in performance of their advisory committee duties if the members—

(i) are blind or deaf or otherwise qualify as individuals with disabilities (within the meaning of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791)); and

(ii) do not otherwise qualify for assistance under section 3102 of this title by reason of being an employee of an agency (within the meaning of section 3102(a)(1) of this title).

(2) PAY FOR FULL-TIME EMPLOYEES.—Nothing in this subsection shall prevent an individual from receiving compensation at the rate at which the individual would otherwise be compensated (or was compensated) as a full-time employee of the United States if the individual—

(A) is a full-time employee of the United States without regard to service with an advisory committee; or

(B) was a full-time employee of the United States immediately before service with an advisory committee.

(e) BUDGET RECOMMENDATIONS.—The Administrator shall include in budget recommendations a summary of the amounts the Administrator considers necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4199.)

HISTORICAL AND REVISION NOTES

Revised Section	Source (U.S. Code)	Source (Statutes at Large)
1006	5 U.S.C. App. (FACA §7)	Pub. L. 92–463, §7, Oct. 6, 1972, 86 Stat. 772; Pub. L. 96–523, §2, Dec. 12, 1980, 94 Stat. 3040.

In this section, the words “Administrator” and “General Services Administration” are substituted for “Director” and “Office of Management and Budget”, respectively, because of section 5F of Reorganization Plan No. 1 of 1977 (5 U.S.C. App.).

In subsection (b)(1), the words “Each year, the Administrator shall conduct a comprehensive review” are substituted for “The Administrator shall, immediately after the enactment of this Act [October 6, 1972], institute a comprehensive review” and “Thereafter, the Administrator shall carry out a similar review annually” to eliminate obsolete language.

In subsection (d)(1) (matter before subparagraph (A)), the words “Director of the Office of Personnel Management” are substituted for “Civil Service Commission” because of section 102 of Reorganization Plan No. 2 of 1978 (5 U.S.C. App.).

In subsection (d)(1) (matter before subparagraph (A)), the words “The guidelines shall provide” are substituted for “The regulations shall provide” for consistency with the 1st sentence of subsection (d)(1), which provides that the Administrator shall establish “guidelines”, not regulations.

In subsection (d)(1)(A), the words “maximum rate payable under section 5376 of this title” are substituted for “rate specified for GS–18 of the General Schedule under section 5332 of title 5, United States Code” for clarity and because of section 101(c) of the Federal Employees Pay Comparability Act of 1990 (enacted by section 529 of Public Law 101–509 (5 U.S.C. 5376 note)).

In subsection (d)(1)(C)(i), the words “individuals with disabilities” are substituted for “handicapped individuals” for consistency with section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 791).

In subsection (d)(1)(C)(i), the citation to “(29 U.S.C. 791)” is substituted for “(29 U.S.C. 794)” to correct an error in the law.

§ 1007. Responsibilities of agency heads

(a) ADMINISTRATIVE GUIDELINES AND MANAGEMENT CONTROLS.—Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Administrator under sections 1006 and 1009 of this title. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) ADVISORY COMMITTEE MANAGEMENT OFFICER.—The head of each agency that has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplish-

ments of advisory committees established by the agency;

(2) assemble and maintain the reports, records, and other papers of any advisory committee established by the agency during the advisory committee’s existence; and

(3) carry out, on behalf of the agency, the provisions of section 552 of this title with respect to such reports, records, and other papers.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4201.)

HISTORICAL AND REVISION NOTES

Revised Section	Source (U.S. Code)	Source (Statutes at Large)
1007	5 U.S.C. App. (FACA §8)	Pub. L. 92–463, §8, Oct. 6, 1972, 86 Stat. 773.

In subsection (a), the word “Administrator” is substituted for “Director” (meaning the Director of the Office of Management and Budget) because of section 5F of Reorganization Plan No. 1 of 1977 (5 U.S.C. App.).

§ 1008. Establishment and purpose of advisory committees

(a) ESTABLISHMENT.—An advisory committee shall not be established unless establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Administrator, with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) PURPOSE OF ADVISORY COMMITTEES.—Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

(c) ADVISORY COMMITTEE CHARTERS.—

(1) GENERAL REQUIREMENT.—An advisory committee shall not meet or take any action until an advisory committee charter has been filed—

(A) with the Administrator in the case of Presidential advisory committees; or

(B) with—

(i) the head of the agency to whom the advisory committee reports; and

(ii) the standing committees of the Senate and House of Representatives having legislative jurisdiction over the agency to which the advisory committee reports.

(2) CONTENTS OF CHARTER.—The advisory committee charter shall contain—

(A) the committee’s official designation;

(B) the committee’s objectives and the scope of its activity;

(C) the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if the duties are not solely advisory, a specification of the authority for the duties;

(G) the estimated annual operating costs for the committee in dollars and person-years;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than 2 years from the date of the committee's establishment; and

(J) the date the charter is filed.

(3) COPY OF CHARTER TO LIBRARY OF CONGRESS.—A copy of the advisory committee charter shall be furnished to the Library of Congress.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4201.)

HISTORICAL AND REVISION NOTES

<i>Revised Section</i>	<i>Source (U.S. Code)</i>	<i>Source (Statutes at Large)</i>
1008	5 U.S.C. App. (FACA §9)	Pub. L. 92–463, §9, Oct. 6, 1972, 86 Stat. 773.

In subsection (a)(2) and subsection (c)(1)(A), the word “Administrator” is substituted for “Director” (meaning the Director of the Office of Management and Budget) because of section 5F of Reorganization Plan No. 1 of 1977 (5 U.S.C. App.).

§ 1009. Advisory committee procedures

(a) COMMITTEE MEETINGS.—

(1) OPEN TO PUBLIC.—Each advisory committee meeting shall be open to the public.

(2) NOTICE OF MEETINGS.—Except when the President determines otherwise for reasons of national security, timely notice of each meeting shall be published in the Federal Register, and the Administrator shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of each meeting in advance.

(3) PARTICIPATION.—Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

(b) PUBLIC INSPECTION AND COPYING OF RECORDS.—Subject to section 552 of this title, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

(c) MINUTES.—Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified by the chairman of the advisory committee.

(d) CLOSED SESSIONS.—Paragraphs (1) and (3) of subsection (a) shall not apply to any portion of an advisory committee meeting for which the President, or the head of the agency to which the advisory committee reports, determines that such portion of the meeting may be closed to the public in accordance with section 552(b)(3) of this title. Any such determination shall be in writing and shall contain the reasons for the determination. If such a determination is made, the advisory committee shall issue a report, at least annually, setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of this title.

(e) DESIGNATED OFFICER OR EMPLOYEE OF FEDERAL GOVERNMENT.—There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever the officer or employee determines it to be in the public interest, to adjourn any such meeting. An advisory committee shall not conduct any meeting in the absence of that designated officer or employee of the Federal Government.

(f) CALL FOR MEETING OR ADVANCE APPROVAL.—Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal Government, and in the case of advisory committees (other than Presidential advisory committees), with an agenda approved by such officer or employee.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4202.)

HISTORICAL AND REVISION NOTES

<i>Revised Section</i>	<i>Source (U.S. Code)</i>	<i>Source (Statutes at Large)</i>
1009	5 U.S.C. App. (FACA §10)	Pub. L. 92–463, §10, Oct. 6, 1972, 86 Stat. 774; Pub. L. 94–409, §5(c), Sept. 13, 1976, 90 Stat. 1247.

In subsection (a), in paragraphs (2) and (3), the word “Administrator” is substituted for “Director” (meaning the Director of the Office of Management and Budget) because of section 5F of Reorganization Plan No. 1 of 1977 (5 U.S.C. App.).

§ 1010. Availability of transcripts

(a) DEFINITION OF AGENCY PROCEEDING.—In this section, the term “agency proceeding” has the meaning given the term in section 551 of this title.

(b) AVAILABILITY.—Agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of any agency proceeding or advisory committee meeting.

(Pub. L. 117–286, §3(a), Dec. 27, 2022, 136 Stat. 4203.)

HISTORICAL AND REVISION NOTES

<i>Revised Section</i>	<i>Source (U.S. Code)</i>	<i>Source (Statutes at Large)</i>
1010	5 U.S.C. App. (FACA §11)	Pub. L. 92–463, §11, Oct. 6, 1972, 86 Stat. 775.

In subsection (b), the words “Except where prohibited by contractual agreements entered into prior to the ef-

“(1) NONPAYMENT OF PREMIUMS.—The plan sponsor has failed to pay premiums or contributions in accordance with the terms of the health insurance coverage or the issuer has not received timely premium payments.

“(2) FRAUD.—The plan sponsor has performed an act or practice that constitutes fraud or made an intentional misrepresentation of material fact under the terms of the coverage.

“(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RULES.—The plan sponsor has failed to comply with a material plan provision relating to employer contribution or group participation rules, as permitted under section 300gg-11(e) of this title in the case of the small group market or pursuant to applicable State law in the case of the large group market.

“(4) TERMINATION OF COVERAGE.—The issuer is ceasing to offer coverage in such market in accordance with subsection (c) and applicable State law.

“(5) MOVEMENT OUTSIDE SERVICE AREA.—In the case of a health insurance issuer that offers health insurance coverage in the market through a network plan, there is no longer any enrollee in connection with such plan who lives, resides, or works in the service area of the issuer (or in the area for which the issuer is authorized to do business) and, in the case of the small group market, the issuer would deny enrollment with respect to such plan under section 300gg-11(c)(1)(A) of this title.

“(6) ASSOCIATION MEMBERSHIP CEASES.—In the case of health insurance coverage that is made available in the small or large group market (as the case may be) only through one or more bona fide associations, the membership of an employer in the association (on the basis of which the coverage is provided) ceases but only if such coverage is terminated under this paragraph uniformly without regard to any health status-related factor relating to any covered individual.

“(c) REQUIREMENTS FOR UNIFORM TERMINATION OF COVERAGE.—

“(1) PARTICULAR TYPE OF COVERAGE NOT OFFERED.—In any case in which an issuer decides to discontinue offering a particular type of group health insurance coverage offered in the small or large group market, coverage of such type may be discontinued by the issuer in accordance with applicable State law in such market only if—

“(A) the issuer provides notice to each plan sponsor provided coverage of this type in such market (and participants and beneficiaries covered under such coverage) of such discontinuation at least 90 days prior to the date of the discontinuation of such coverage;

“(B) the issuer offers to each plan sponsor provided coverage of this type in such market, the option to purchase all (or, in the case of the large group market, any) other health insurance coverage currently being offered by the issuer to a group health plan in such market; and

“(C) in exercising the option to discontinue coverage of this type and in offering the option of coverage under subparagraph (B), the issuer acts uniformly without regard to the claims experience of those sponsors or any health status-related factor relating to any participants or beneficiaries covered or new participants or beneficiaries who may become eligible for such coverage.

“(2) DISCONTINUANCE OF ALL COVERAGE.—

“(A) IN GENERAL.—In any case in which a health insurance issuer elects to discontinue offering all health insurance coverage in the small group market or the large group market, or both markets, in a State, health insurance coverage may be discontinued by the issuer only in accordance with applicable State law and if—

“(i) the issuer provides notice to the applicable State authority and to each plan sponsor (and participants and beneficiaries covered under such coverage) of such discontinuation at least 180

days prior to the date of the discontinuation of such coverage; and

“(ii) all health insurance issued or delivered for issuance in the State in such market (or markets) are discontinued and coverage under such health insurance coverage in such market (or markets) is not renewed.

“(B) PROHIBITION ON MARKET REENTRY.—In the case of a discontinuation under subparagraph (A) in a market, the issuer may not provide for the issuance of any health insurance coverage in the market and State involved during the 5-year period beginning on the date of the discontinuation of the last health insurance coverage not so renewed.

“(d) EXCEPTION FOR UNIFORM MODIFICATION OF COVERAGE.—At the time of coverage renewal, a health insurance issuer may modify the health insurance coverage for a product offered to a group health plan—

“(1) in the large group market; or

“(2) in the small group market if, for coverage that is available in such market other than only through one or more bona fide associations, such modification is consistent with State law and effective on a uniform basis among group health plans with that product.

“(e) APPLICATION TO COVERAGE OFFERED ONLY THROUGH ASSOCIATIONS.—In applying this section in the case of health insurance coverage that is made available by a health insurance issuer in the small or large group market to employers only through one or more associations, a reference to ‘plan sponsor’ is deemed, with respect to coverage provided to an employer member of the association, to include a reference to such employer.”

Another prior section 2712 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-13. Coverage of preventive health services

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage shall, at a minimum provide coverage for and shall not impose any cost sharing requirements for—

(1) evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force;

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and¹

(3) with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration.²

(4) with respect to women, such additional preventive care and screenings not described in paragraph (1) as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of this paragraph.²

¹ So in original. The word “and” probably should not appear.

² So in original. The period probably should be a semicolon.

(5) for the purposes of this chapter, and for the purposes of any other provision of law, the current recommendations of the United States Preventive Service Task Force regarding breast cancer screening, mammography, and prevention shall be considered the most current other than those issued in or around November 2009.

Nothing in this subsection shall be construed to prohibit a plan or issuer from providing coverage for services in addition to those recommended by United States Preventive Services Task Force or to deny coverage for services that are not recommended by such Task Force.

(b) Interval

(1) In general

The Secretary shall establish a minimum interval between the date on which a recommendation described in subsection (a)(1) or (a)(2) or a guideline under subsection (a)(3) is issued and the plan year with respect to which the requirement described in subsection (a) is effective with respect to the service described in such recommendation or guideline.

(2) Minimum

The interval described in paragraph (1) shall not be less than 1 year.

(c) Value-based insurance design

The Secretary may develop guidelines to permit a group health plan and a health insurance issuer offering group or individual health insurance coverage to utilize value-based insurance designs.

(July 1, 1944, ch. 373, title XXVII, § 2713, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 131.)

PRIOR PROVISIONS

A prior section 300gg-13, act July 1, 1944, ch. 373, title XXVII, § 2713, as added Pub. L. 104-191, title I, § 102(a), Aug. 21, 1996, 110 Stat. 1966, was renumbered section 2709 of act July 1, 1944, and transferred to section 300gg-9 of this title by Pub. L. 111-148, title I, §§ 1001(3), 1563(c)(10)(C), formerly § 1562(c)(10)(C), title X, § 10107(b)(1), Mar. 23, 2010, 124 Stat. 130, 268, 911.

Another prior section 2713 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238f of this title.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-14. Extension of dependent coverage

(a) In general

A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

(b) Regulations

The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

(c) Rule of construction

Nothing in this section shall be construed to modify the definition of “dependent” as used in title 26 with respect to the tax treatment of the cost of coverage.

(July 1, 1944, ch. 373, title XXVII, § 2714, as added Pub. L. 111-148, title I, § 1001(5), Mar. 23, 2010, 124 Stat. 132; amended Pub. L. 111-152, title II, § 2301(b), Mar. 30, 2010, 124 Stat. 1082.)

PRIOR PROVISIONS

A prior section 2714 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

AMENDMENTS

2010—Subsec. (a). Pub. L. 111-152 struck out “(who is not married)” after “adult child”.

EFFECTIVE DATE

Section effective for plan years beginning on or after the date that is 6 months after Mar. 23, 2010, see section 1004 of Pub. L. 111-148, set out as a note under section 300gg-11 of this title.

§ 300gg-15. Development and utilization of uniform explanation of coverage documents and standardized definitions

(a) In general

Not later than 12 months after March 23, 2010, the Secretary shall develop standards for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, in compiling and providing to applicants, enrollees, and policyholders or certificate holders a summary of benefits and coverage explanation that accurately describes the benefits and coverage under the applicable plan or coverage. In developing such standards, the Secretary shall consult with the National Association of Insurance Commissioners (referred to in this section as the “NAIC”), a working group composed of representatives of health insurance-related consumer advocacy organizations, health insurance issuers, health care professionals, patient advocates including those representing individuals with limited English proficiency, and other qualified individuals.

(b) Requirements

The standards for the summary of benefits and coverage developed under subsection (a) shall provide for the following:

(1) Appearance

The standards shall ensure that the summary of benefits and coverage is presented in a uniform format that does not exceed 4 pages in length and does not include print smaller than 12-point font.

(2) Language

The standards shall ensure that the summary is presented in a culturally and linguistically appropriate manner and utilizes terminology understandable by the average plan enrollee.

(3) Contents

The standards shall ensure that the summary of benefits and coverage includes—

(A) uniform definitions of standard insurance terms and medical terms (consistent

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Title 45 — Public Welfare

Subtitle A — Department of Health and Human Services

Subchapter B — Requirements Relating to Health Care Access

Part 147 — Health Insurance Reform Requirements for the Group and Individual Health

Insurance Markets

Authority: 42 U.S.C. 300gg through 300gg-63, 300gg-91, 300gg-92, and 300gg-111 through 300gg-139, as amended, and section 3203, Pub. L. 116-136, 134 Stat. 281.

Source: 75 FR 27138, May 13, 2010, unless otherwise noted.

§ 147.130 Coverage of preventive health services.

(a) **Services —**

- (1) **In general.** Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—
 - (i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);
 - (ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);
 - (iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;
 - (iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133; and
 - (v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—
 - (A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

- (B) An immunization that has in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (regardless of whether the immunization is recommended for routine use). For purposes of this paragraph (a)(1)(v)(B), a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.

(2) **Office visits.**

- (i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.
- (ii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is the delivery of such an item or service, then a plan or issuer may not impose cost-sharing requirements with respect to the office visit.
- (iii) If an item or service described in paragraph (a)(1) of this section is not billed separately (or is not tracked as individual encounter data separately) from an office visit and the primary purpose of the office visit is not the delivery of such an item or service, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.
- (iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.

(ii) *Conclusion.* In this *Example 1*, the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

Example 2. (i) *Facts.* Same facts as *Example 1*. As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.

(ii) *Conclusion.* In this *Example 2*, because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

Example 3. (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider to discuss recurring abdominal pain. During the visit, the individual has a blood pressure screening, which has in effect a rating of A or B in the current

recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 3*, the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.

(ii) *Conclusion.* In this *Example 4*, the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

(3) ***Out-of-network providers.***

- (i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.
- (ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.
- (iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

(4) ***Reasonable medical management.*** Nothing prevents a plan or issuer from using reasonable medical management techniques to determine the frequency, method, treatment, or setting for an item or service described in paragraph (a)(1) of this section to the extent not specified in the relevant

recommendation or guideline. To the extent not specified in a recommendation or guideline, a plan or issuer may rely on the relevant clinical evidence base and established reasonable medical management techniques to determine the frequency, method, treatment, or setting for coverage of a recommended preventive health service.

- (5) **Services not described.** Nothing in this section prohibits a plan or issuer from providing coverage for items and services in addition to those recommended by the United States Preventive Services Task Force or the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, or provided for by guidelines supported by the Health Resources and Services Administration, or from denying coverage for items and services that are not recommended by that task force or that advisory committee, or under those guidelines. A plan or issuer may impose cost-sharing requirements for a treatment not described in paragraph (a)(1) of this section, even if the treatment results from an item or service described in paragraph (a)(1) of this section.

(b) **Timing.**

- (1) A plan or issuer must provide coverage pursuant to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued, except as provided in paragraph (b)(3) of this section.

(2) **Changes in recommendations or guidelines.**

- (i) A plan or issuer that is required to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, must provide coverage through the last day of the plan or policy year, even if the recommendation or guideline changes or is no longer described in paragraph (a)(1) of this section, during the applicable plan or policy year.

- (ii) Notwithstanding paragraph (b)(2)(i) of this section, to the extent a recommendation or guideline described in paragraph (a)(1)(i) of this section that was in effect on the first day of a plan year (in the individual market, policy year), or as otherwise provided in paragraph (b)(3) of this section, is downgraded to a "D" rating, or any item or service associated with any recommendation or guideline specified in paragraph (a)(1) of this section is subject to a safety recall or is otherwise determined to pose a significant safety concern by a Federal agency authorized to regulate the item or service during a plan or policy year, there is no requirement under this section to cover these items and services through the last day of the applicable plan or policy year.

- (3) **Rapid coverage of preventive services for coronavirus.** In the case of a qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, a plan or issuer must provide coverage for such item, service, or immunization in accordance with this section by the date that is 15 business days after the date on which a recommendation specified in paragraph (a)(1)(v)(A) or (B) of this section is made relating to such item, service, or immunization.

- (c) **Recommendations not current.** For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

- (d) **Applicability date.** The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).
- (e) **Sunset date.** The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID-19, including any subsequent renewals of that determination.

[75 FR 41759, July 19, 2010, as amended at 76 FR 46626, Aug. 3, 2011; 78 FR 39896, July 2, 2013; 80 FR 41346, July 14, 2015; 82 FR 47833, 47861, Oct. 13, 2017; 85 FR 71202, Nov. 6, 2020]

APPENDIX

VOLUME I OF III

(App. 1–290)

United States Court of Appeals for the First Circuit

No. 26-1503

American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al.

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APPEAL

**United States District Court
District of Massachusetts (Boston)
CIVIL DOCKET FOR CASE #: 1:25-cv-11916-BEM**

American Academy of Pediatrics et al v. Kennedy et al
Assigned to: Judge Brian E. Murphy
Case in other court: USCA - First Circuit, 25-01907
USCA - First Circuit, 26-01325
26-01503
Cause: 05:551 Administrative Procedure Act

Date Filed: 07/07/2025
Jury Demand: None
Nature of Suit: 899 Other Statutes:
Administrative Procedures Act/Review or
Appeal of Agency Decision
Jurisdiction: U.S. Government Defendant

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Date Filed	#	Docket Text
07/07/2025	<u>1</u>	COMPLAINT (<i>Complaint for Declaratory and Injunctive Relief</i>) against All Defendants Filing fee: \$ 405, receipt number AMADC-11104419 (Fee Status: Filing Fee paid), filed by American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance, Society for Maternal-Fetal Medicine. (Attachments: # <u>1</u> Exhibit A - Civil Cover Sheet, # <u>2</u> Exhibit B - Category Form)(McEvoy, Elizabeth) (Additional attachment(s) added on 7/9/2025: # <u>3</u> SEALED) (MAP). (Entered: 07/07/2025)
07/07/2025	<u>2</u>	NOTICE of Appearance by Elizabeth J. McEvoy on behalf of American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance, Society for Maternal-Fetal Medicine (McEvoy, Elizabeth) (Entered: 07/07/2025)

07/07/2025	3	CORPORATE DISCLOSURE STATEMENT by American Academy of Pediatrics. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	4	CORPORATE DISCLOSURE STATEMENT by American College of Physicians, Inc.. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	5	CORPORATE DISCLOSURE STATEMENT by American Public Health Association. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	6	CORPORATE DISCLOSURE STATEMENT by Infectious Diseases Society of America. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	7	CORPORATE DISCLOSURE STATEMENT by Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	8	CORPORATE DISCLOSURE STATEMENT by Society for Maternal-Fetal Medicine. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	9	MOTION for Protective Order (<i>Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order</i>) by Jane Doe. (Attachments: # 1 Text of Proposed Order (Proposed Order))(McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	10	MEMORANDUM in Support re 9 MOTION for Protective Order (<i>Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order</i>) filed by Jane Doe. (Attachments: # 1 Exhibit A - Declaration of Jane Doe, M.D., # 2 Exhibit B - Declaration of Jane Doe, MD in Support of Her Motion to Proceed Under a Pseudonym and for Protective Order)(McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	11	ELECTRONIC NOTICE of Case Assignment. Judge William G. Young assigned to case. If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge M. Page Kelley. (NMC) (Entered: 07/07/2025)
07/07/2025	12	CERTIFICATE OF CONSULTATION pursuant to LR 7.1 re 9 MOTION for Protective Order (<i>Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order</i>) by Elizabeth J. McEvoy on behalf of Jane Doe. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	13	MOTION for Leave to File Excess Pages by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Text of Proposed Order (Proposed Order))(McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	14	CERTIFICATE OF CONSULTATION pursuant to LR 7.1 re 13 MOTION for Leave to File Excess Pages by Elizabeth J. McEvoy on behalf of All Plaintiffs. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	15	MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health

		Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine.(McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	16	MEMORANDUM in Support re 15 MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (McEvoy, Elizabeth) (Entered: 07/07/2025)
07/07/2025	17	Summons Issued as to All Defendants. Counsel receiving this notice electronically should download this summons, complete one for each defendant and serve it in accordance with Fed.R.Civ.P. 4 and LR 4.1. Summons will be mailed to plaintiff(s) not receiving notice electronically for completion of service. (SEC) (Entered: 07/07/2025)
07/07/2025	18	Judge William G. Young: ELECTRONIC ORDER entered denying 13 Motion for Leave to File Excess Pages (MAP) (Entered: 07/07/2025)
07/07/2025	19	Summons Issued as to Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Does 1-50, inclusive, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. Counsel receiving this notice electronically should download this summons, complete one for each defendant and serve it in accordance with Fed.R.Civ.P. 4 and LR 4.1. Summons will be mailed to plaintiff(s) not receiving notice electronically for completion of service. (MAP) (Entered: 07/07/2025)
07/08/2025	20	~~AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. Jay Bhattacharya served on 7/7/2025, answer due 7/28/2025; Matthew Buzzelli served on 7/7/2025, answer due 7/28/2025; Robert F. Kennedy, Jr served on 7/7/2025, answer due 7/28/2025; Marty Makary served on 7/7/2025, answer due 7/28/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (McEvoy, Elizabeth)~~ Modified on 7/8/2025 to Strike from the Docket as Counsel Filed the Unexecuted Service Under the Wrong Event in CM/ECF. Please see ECF No. 23 for the Return of Service as to the U.S. Attorney for the District of Massachusetts (MAP). (Entered: 07/08/2025)
07/08/2025	21	~~AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America,~~

		~~Massachusetts Public Health Association. Jay Bhattacharya served on 7/8/2025, answer due 7/29/2025; Matthew Buzzelli served on 7/8/2025, answer due 7/29/2025; Robert F. Kennedy, Jr served on 7/8/2025, answer due 7/29/2025; Marty Makary served on 7/8/2025, answer due 7/29/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (McEvoy, Elizabeth)~~ Modified on 7/8/2025 Filed Under the Wrong Event By Counsel. Please see ECF No. 23 for the Properly Filed Return of Service as to the U.S. Attorney for the District of Massachusetts (MAP). (Entered: 07/08/2025)
07/08/2025	22	Judge William G. Young: ORDER entered 9 MOTION for Protective Order (Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order). (MAP) (Entered: 07/08/2025)
07/08/2025	23	SUMMONS Returned Executed as to US Attorney by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association.(MAP) (Entered: 07/08/2025)
07/09/2025	24	Withdrawal of motion: 16 Memorandum in Support of Motion, filed by Infectious Diseases Society of America, Society for Maternal-Fetal Medicine, American College of Physicians, Inc., Massachusetts Public Health Association, American Public Health Association, Jane Doe, American Academy of Pediatrics, 15 MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>) filed by Infectious Diseases Society of America, Society for Maternal-Fetal Medicine, American College of Physicians, Inc., Massachusetts Public Health Association, American Public Health Association, Jane Doe, American Academy of Pediatrics.. (McEvoy, Elizabeth) (Entered: 07/09/2025)
07/10/2025	25	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Richard H. Hughes IV Filing fee: \$ 125, receipt number AMADC-11114533 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Richard H. Hughes IV)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	26	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Stuart M. Gerson Filing fee: \$ 125, receipt number AMADC-11114600 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Stuart M. Gerson)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	27	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Robert E. Wanerman Filing fee: \$ 125, receipt number AMADC-11114635 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of

		Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Robert E. Wanerman)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	28	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of William Walters Filing fee: \$ 125, receipt number AMADC-11114659 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of William Walters)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	29	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Kathleen Barrett Filing fee: \$ 125, receipt number AMADC-11114704 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Kathleen Barrett)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	30	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Carolyn Owens Boucek Filing fee: \$ 125, receipt number AMADC-11114718 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Carolyn Owens Boucek)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	31	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Lydia Pincsak Filing fee: \$ 125, receipt number AMADC-11114734 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Lydia Pincsak)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	32	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Jeremy A. Avila Filing fee: \$ 125, receipt number AMADC-11114757 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Jeremy A. Avila)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	33	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Marguerite McGowan Stringer Filing fee: \$ 125, receipt number AMADC-11114785 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Certificate of Marguerite McGowan Stringer)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/10/2025	34	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of James J. Oh

		Filing fee: \$ 125, receipt number AMADC-11114824 by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine. (Attachments: # <u>1</u> Exhibit A - Certificate of James J. Oh)(McEvoy, Elizabeth) (Entered: 07/10/2025)
07/11/2025	35	Judge William G. Young: ELECTRONIC ORDER entered granting <u>25</u> Motion for Leave to Appear Pro Hac Vice Added Richard H. Hughes IV. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)
07/11/2025	36	Judge William G. Young: ELECTRONIC ORDER entered granting <u>26</u> Motion for Leave to Appear Pro Hac Vice Added Stuart M. Gerson. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 07/11/2025)
07/11/2025	37	Judge William G. Young: ELECTRONIC ORDER entered granting <u>27</u> Motion for Leave to Appear Pro Hac Vice Added Robert E. Wanerman. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm.

		A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)
07/11/2025	38	Judge William G. Young: ELECTRONIC ORDER entered granting <u>28</u> Motion for Leave to Appear Pro Hac Vice Added William Walters. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)
07/11/2025	39	Judge William G. Young: ELECTRONIC ORDER entered granting <u>29</u> Motion for Leave to Appear Pro Hac Vice Added Kathleen Barrett. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 07/11/2025)
07/11/2025	40	Judge William G. Young: ELECTRONIC ORDER entered granting <u>30</u> Motion for Leave to Appear Pro Hac Vice Added Carolyn Owens Boucek. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)

07/11/2025	41	Judge William G. Young: ELECTRONIC ORDER entered granting 31 Motion for Leave to Appear Pro Hac Vice Added Lydia Pincsak. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)
07/11/2025	42	Judge William G. Young: ELECTRONIC ORDER entered granting 32 Motion for Leave to Appear Pro Hac Vice Added Jeremy A. Avila. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MAP) (Entered: 07/11/2025)
07/11/2025	43	Judge William G. Young: ELECTRONIC ORDER entered granting 33 Motion for Leave to Appear Pro Hac Vice Added Marguerite McGowan Stringer. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney.

		(MAP) (Entered: 07/11/2025)
07/11/2025	44	Judge William G. Young: ELECTRONIC ORDER entered granting 34 Motion for Leave to Appear Pro Hac Vice Added James J. Oh. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MAP) (Entered: 07/11/2025)
07/11/2025	45	NOTICE of Appearance by Kathleen Barrett on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Barrett, Kathleen) (Entered: 07/11/2025)
07/14/2025	46	NOTICE of Appearance by Richard Hughes, IV on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Hughes, Richard) (Entered: 07/14/2025)
07/14/2025	47	NOTICE of Appearance by William Walters on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Walters, William) (Entered: 07/14/2025)
07/14/2025	48	NOTICE of Appearance by Lydia Pincsak on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Pincsak, Lydia) (Entered: 07/14/2025)
07/14/2025	49	NOTICE of Appearance by Marguerite McGowan Stringer on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Stringer, Marguerite) (Entered: 07/14/2025)
07/14/2025	50	NOTICE of Appearance by James J. Oh on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Oh, James) (Entered: 07/14/2025)
07/14/2025	51	NOTICE of Appearance by Carolyn Owens Boucek on behalf of Massachusetts Public

		Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Boucek, Carolyn) (Entered: 07/14/2025)
07/14/2025	52	NOTICE of Appearance by Stuart M. Gerson on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Gerson, Stuart) (Entered: 07/14/2025)
07/14/2025	53	NOTICE of Appearance by Robert E Wanerman on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Wanerman, Robert) (Entered: 07/14/2025)
07/15/2025	54	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. United States Department of Health and Human Services served on 7/11/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation)(McEvoy, Elizabeth) (Entered: 07/15/2025)
07/15/2025	55	NOTICE of Appearance by Jeremy A. Avila on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Infectious Diseases Society of America, Society for Maternal-Fetal Medicine (Avila, Jeremy) (Entered: 07/15/2025)
07/16/2025	56	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. Food and Drug Administration served on 7/15/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation) (McEvoy, Elizabeth) (Entered: 07/16/2025)
07/16/2025	57	MOTION to Intervene by Jose A. Perez.(MAP) (Entered: 07/16/2025)
07/16/2025	58	MEMORANDUM in Support re 57 MOTION to Intervene filed by Jose A. Perez. (Attachments: # 1 Exhibit)(MAP) (Entered: 07/16/2025)

07/17/2025	59	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. Centers for Disease Control and Prevention served on 7/17/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation)(McEvoy, Elizabeth) (Entered: 07/17/2025)
07/18/2025	60	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. Robert F. Kennedy, Jr served on 7/18/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation) (McEvoy, Elizabeth) (Entered: 07/18/2025)
07/21/2025	61	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association. Marty Makary served on 7/19/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Infectious Diseases Society of America; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation)(McEvoy, Elizabeth) (Entered: 07/21/2025)
07/23/2025	62	ELECTRONIC NOTICE of Hearing. Case Management Conference set for 7/31/2025 10:00 AM in Courtroom 18 (In person only) before Judge William G. Young. (KB) (Entered: 07/23/2025)
07/23/2025	63	AMENDED COMPLAINT against Robert F. Kennedy, Jr., United States Department of Health and Human Services, Marty Makary, Food and Drug Administration, Jay Bhattacharya, National Institutes of Health, Matthew Buzzelli, Centers for Disease Control and Prevention, Does 1-50 , filed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Infectious Diseases Society of America, Massachusetts Public Health Association, Massachusetts Chapter of the American Academy of Pediatrics, Jane Doe 2.(McEvoy, Elizabeth) Modified on 7/24/2025 (MAP). (Additional attachment(s) added on 7/28/2025: # 1 SEALED) (MAP). (Entered: 07/23/2025)
07/23/2025	64	CORPORATE DISCLOSURE STATEMENT by Massachusetts Chapter of the

		American Academy of Pediatrics. (McEvoy, Elizabeth) (Entered: 07/23/2025)
07/23/2025	65	MOTION for Protective Order <i>Second Individual Plaintiff's Motion to Proceed Under Pseudonym and For Protective Order</i> by Jane Doe 2. (Attachments: # 1 Text of Proposed Order (Proposed Order))(McEvoy, Elizabeth) (Entered: 07/23/2025)
07/23/2025	66	MEMORANDUM in Support re 65 MOTION for Protective Order <i>Second Individual Plaintiff's Motion to Proceed Under Pseudonym and For Protective Order</i> filed by Jane Doe 2. (Attachments: # 1 Exhibit A - Declaration of Jane Doe 2, # 2 Exhibit B - Declaration of Jane Doe 2 in Support of Motion to Proceed Under Pseudonym and For Protective Order)(McEvoy, Elizabeth) (Entered: 07/23/2025)
07/24/2025	67	Judge William G. Young: ELECTRONIC ORDER entered allowed 65 MOTION for Protective Order <i>Second Individual Plaintiff's Motion to Proceed Under Pseudonym and For Protective Order. (MAP)</i> (Entered: 07/24/2025)
07/24/2025	68	AMENDED MEMORANDUM in Support re 57 MOTION to Intervene filed by Jose A. Perez. (MAP) (Entered: 07/24/2025)
07/28/2025	69	MOTION to Seal (<i>Plaintiffs' Motion to File Declarations in Support of Motion for Preliminary Injunction and Declaratory Relief and Request for Expedited Consideration Under Seal</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Text of Proposed Order (Proposed Order)) (McEvoy, Elizabeth) (Entered: 07/28/2025)
07/28/2025	70	MEMORANDUM in Support re 69 MOTION to Seal (<i>Plaintiffs' Motion to File Declarations in Support of Motion for Preliminary Injunction and Declaratory Relief and Request for Expedited Consideration Under Seal</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (McEvoy, Elizabeth) (Entered: 07/28/2025)
07/29/2025	71	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Massachusetts Public Health Association. Jay Bhattacharya served on 7/23/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Jane Doe 2; Infectious Diseases Society of America; Massachusetts Chapter of the American Academy of Pediatrics; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and Return Green Card Confirmation)(McEvoy, Elizabeth) (Entered: 07/29/2025)

07/29/2025	72	AFFIDAVIT OF SERVICE Executed by Jane Doe, American College of Physicians, Inc., American Academy of Pediatrics, Society for Maternal-Fetal Medicine, American Public Health Association, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Massachusetts Public Health Association. Matthew Buzzelli served on 7/23/2025, answer due 9/8/2025. Acknowledgement filed by Jane Doe; American College of Physicians, Inc.; American Academy of Pediatrics; Society for Maternal-Fetal Medicine; American Public Health Association; Jane Doe 2; Infectious Diseases Society of America; Massachusetts Chapter of the American Academy of Pediatrics; Massachusetts Public Health Association. (Attachments: # 1 Exhibit A - U.S.P.S. Certified Mail Receipt and U.S.P.S. Electronic Delivery Confirmation)(McEvoy, Elizabeth) (Entered: 07/29/2025)
07/29/2025	73	MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Text of Proposed Order (Proposed Order))(Oh, James) (Entered: 07/29/2025)
07/29/2025	74	MEMORANDUM in Support re 73 MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 07/29/2025)
07/29/2025	75	APPENDIX/EXHIBIT re 74 Memorandum in Support of Motion, (<i>Appendix of Evidence in Support of Plaintiffs' Motion for Preliminary Injunction and Declaratory Relief and Request for Expedited Consideration</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit 1 - The Vaccine Life Cycle: Safety at Every Phase, CDC (infographic, 2020), # 2 Exhibit 2 - Plaintiffs Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations), # 3 Exhibit 3 - Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States, CDC (December 30, 2020), # 4 Exhibit 4 - Declaration of Jamie Loehr, MD, FAAFP, dated July 5, 2025, # 5 Exhibit 5 - Declaration of Jane Doe, MD, dated July 6, 2025, # 6 Exhibit 6 - Robert F. Kennedy, Jr., Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women (May 19, 2025), # 7 Exhibit 7 - Adult Immunization Schedule by Medical Condition and Other Indication, CDC (May 29, 2025), # 8 Exhibit 8 - Vaccine Recommendations Before, During, and After Pregnancy, CDC (June 24, 2024), # 9 Exhibit 9 - Child and Adolescent Immunization Schedule by Age, CDC (May 29, 2025), # 10 Exhibit 10 -

		Child and Adolescent Immunization Schedule by Age, CDC (July 2, 2025), # 11 Exhibit 11 - Declaration of Mary Doherty-OShea Gallucci, MD, dated July 3, 2025, # 12 Exhibit 12 - Declaration of Jane Doe 2, dated July 25, 2025, # 13 Exhibit 13 - Declaration of Susan J. Kressly, MD, FAAP, dated July 3, 2025, # 14 Exhibit 14 - Declaration of Ravi Jhaveri, MD, dated July 5, 2025, # 15 Exhibit 15 - Declaration of Shannon Scott-Vernaglia, MD, dated July 7, 2025, # 16 Exhibit 16 - Declaration of Regina LaRocque, MD, MPH, FIDSA, dated July 5, 2025, # 17 Exhibit 17 - Declaration of Caroline E. Rouse, MD, dated July 4, 2025, # 18 Exhibit 18 - Declaration of Jason M. Goldman, MD, MACP, dated July 28, 2025, # 19 Exhibit 19 - Declaration of Georges C. Benjamin, MD, dated July 3, 2025, # 20 Exhibit 20 - Declaration of Andrew T. Pavia, MD, FAAP, FACP, FIDSA, dated July 4, 2025, # 21 Exhibit 21 - Declaration of Carlene Pavlos, dated July 6, 2025, # 22 Exhibit 22 - Declaration of James D. Campbell, MD, MS, dated July 10, 2025, # 23 Exhibit 23 - Declaration of Aaron Bornstein, MD, dated July 26, 2025, # 24 Exhibit 24 - Declaration of Brenda Anders Pring, MD, dated July 26, 2025, # 25 Exhibit 25 - Declaration of Patrick S. Ramsey, MD, MSPH, dated July 29, 2025, # 26 Exhibit 26 - Declaration of Robert H. Hopkins, Jr., MD, MACP, dated July 10, 2025, # 27 Exhibit 27 - Declaration of J. Edward Johnson, dated July 7, 2025, # 28 Exhibit 28 - Declaration of Jenifer Leaf Jaeger, MD, MPH, FAAP, dated July 15, 2025, # 29 Exhibit 29 - Declaration of Charlotte Moser, MS, dated July 6, 2025, # 30 Exhibit 30 - Declaration of Sindhu K. Srinivas, MD, MSCE, dated July 6, 2025, # 31 Exhibit 31 - Declaration of Shetal Shah, MD, dated July 28, 2025)(Oh, James) (Entered: 07/29/2025)
07/30/2025	76	ELECTRONIC NOTICE issued requesting SINGLE SIDED PAPER courtesy copy for 74 Memorandum in Support of Motion, 75 Appendix/Exhibit, 73 MOTION for Preliminary Injunction (<i>and Declaratory Relief and Request for Expedited Consideration</i>). Counsel who filed this document are requested to submit a courtesy copy of this document (or documents) to the Clerk's Office by Attention Matthew Paine - Docket Clerk - Judge Young. These documents must be clearly marked as a Courtesy Copy and reflect the document number assigned by CM/ECF. (MAP) (Entered: 07/30/2025)
07/30/2025	77	NOTICE of Appearance by Isaac Belfer on behalf of Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services (Belfer, Isaac) (Entered: 07/30/2025)
07/30/2025	78	NOTICE of Appearance by Michael Fitzgerald on behalf of Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services (Fitzgerald, Michael) (Entered: 07/30/2025)
07/30/2025	79	Opposition re 57 MOTION to Intervene filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 07/30/2025)

07/30/2025	80	JOINT STATEMENT re scheduling conference . (Oh, James) (Entered: 07/30/2025)
07/31/2025	81	Judge William G. Young: ELECTRONIC ORDER entered denying 57 MOTION to Intervene by Jose A. Perez. Motion denied. The proposed intervenor is welcome to file a brief amicus curiae. (KB) (Entered: 07/31/2025)
07/31/2025	82	Copy re 81 Order on Motion to Intervene mailed to Jose Perez on 7/31/2025. (KB) (Entered: 07/31/2025)
07/31/2025	83	Electronic Clerk's Notes for proceedings held before Judge William G. Young: Case Management Conference held on 7/31/2025.The Court enters order re # 73 Motion for Preliminary Injunction; the motion is collapsed with trial on the merits in accordance with Rule 65(a).Court sets a Motion hearing on any Motion to Dismiss for Wednesday September 3, 2025 at 2:30pm. If the Motion to Dismiss is denied in whole or in part the Court will hold a bench trial with oral argument on Tuesday, October 14th at 9:00am. The administrative record is to be produced by September 26, 2025 at noon and disclosed to the Court and plaintiffs. Parties may file briefs on the merits between September 26th and October 14th. Plaintiffs' withdraw # 69 Motion to Seal. Court withdraws the motion. Court discusses amicus briefs. Court denies # 57 Motion to Intervene. (Court Reporter: Richard Romanow at rhr3tubas@aol.com.)(Attorneys present: James Oh, Kathleen Barrett, Richard Hughes for the plaintiffs and Isaac Belfer and Michael Fitzgerald for the defendants) (KB) (Entered: 07/31/2025)
08/06/2025	84	REPLY to Response to 57 MOTION to Intervene and Second Amended Motion to Intervene filed by Jose A. Perez. (Attachments: # 1 Exhibits, # 2 Envelope)(MAP) Modified on 8/19/2025 (KB). (Entered: 08/06/2025)
08/06/2025	85	Joint MOTION to Reschedule Motion Hearing on Defendants Motion to Dismiss and Set a Briefing Schedule re 83 Order on Motion to Seal,,,,, Order on Motion for Preliminary Injunction,,,,, Case Management Conference,,,,, Terminate Hearings,,,,, Set Hearings,,,, by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Text of Proposed Order)(Belfer, Isaac) (Entered: 08/06/2025)
08/11/2025	86	Transcript of Case Management Conference held on July 31, 2025, before Judge William G. Young. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Richard Romanow at rhr3tubas@aol.com. Redaction Request due 9/2/2025. Redacted Transcript Deadline set for 9/11/2025. Release of Transcript Restriction set for 11/10/2025. (DRK) (Entered: 08/11/2025)
08/11/2025	87	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 08/11/2025)
08/12/2025	88	MOTION to Vacate the July 31, 2025 Order Denying the Motion to Intervene by Jose

		A. Perez.(MAP) (Entered: 08/13/2025)
08/14/2025	89	Judge William G. Young: ORDER entered granting 85 Joint MOTION to Reschedule Motion Hearing on Defendants' Motion to Dismiss and Set a Briefing Schedule. (KB) (Entered: 08/14/2025)
08/14/2025	90	NOTICE Resetting a Hearing. Motion hearing on any Motion to Dismiss filed is reset to 9/11/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. (KB) (Entered: 08/14/2025)
08/14/2025	91	Opposition re 88 MOTION to Vacate the July 31, 2025 Order Denying the Motion to Intervene (<i>Plaintiffs' Response in Opposition to Jose Perez's Rule 59(e) Motion to Vacate the July 31, 2025 Order Denying the Motion to Intervene</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 08/14/2025)
08/19/2025	92	Opposition re 84 Second Amended MOTION to Intervene filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (KB) (Entered: 08/19/2025)
08/19/2025	93	REPLY to Response to 88 MOTION to Vacate the July 31, 2025 Order Denying the Motion to Intervene filed by Jose A. Perez. (KB) (Main Document 93 replaced on 8/20/2025) (KB). (Entered: 08/20/2025)
08/20/2025	94	MOTION for Leave to File A <i>Second Amended Complaint And Joint Motion to Modify Case Schedule (Unopposed)</i> by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit 1 - Proposed Second Amended Complaint for Declaratory and Injunctive Relief, # 2 Text of Proposed Order Granting Unopposed Motion for Leave to File a Second Amended Complaint)(Oh, James) (Additional attachment(s) added on 9/2/2025: # 3 SEALED) (MAP). (Entered: 08/20/2025)
08/22/2025	95	REPLY to Response to 84 Second Amended MOTION to Intervene filed by Jose A. Perez. (KB) (Entered: 08/22/2025)
09/03/2025	96	Judge William G. Young: ELECTRONIC ORDER entered allowed 94 MOTION for Leave to File A Second Amended Complaint And Joint Motion to Modify Case Schedule (Unopposed) ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MAP) (Entered: 09/03/2025)

09/03/2025	97	Reset Deadlines: Motion to Dismiss Due by September 3, 2025 Opposition Due by September 17, 2025 Reply Due by September 23, 2025 Administrative Record To Be Produced By October 10, 2025 (MAP) (Entered: 09/03/2025)
09/03/2025	98	ELECTRONIC NOTICE OF RESCHEDULING: The Motion Hearing originally scheduled for 9/11/2025 is reset for 10/1/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html. For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here. (KB) (Entered: 09/03/2025)
09/03/2025	99	AMENDED COMPLAINT (<i>Second Amended Complaint for Declaratory and Injunctive Relief</i>) against All Defendants, filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine, Jane Doe 3.(Oh, James) (Additional attachment(s) added on 9/9/2025: # 1 SEALED - Second Amended Complaint) (MAP). (Entered: 09/03/2025)
09/03/2025	100	MOTION for Protective Order (<i>Third Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order</i>) by Jane Doe 3. (Attachments: # 1 Text of Proposed Order (Proposed Order))(Oh, James) (Entered: 09/03/2025)
09/03/2025	101	MEMORANDUM in Support re 100 MOTION for Protective Order (<i>Third Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order</i>) filed by Jane Doe 3. (Attachments: # 1 Exhibit A - Declaration of Third Individual Plaintiff in Support of Her Memorandum of Law in Support of Motion to Proceed Under Pseudonym and for Protective Order))(Oh, James) (Entered: 09/03/2025)
09/03/2025	102	MOTION to Dismiss for Lack of Jurisdiction by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 2 Text of Proposed Order)(Belfer, Isaac)

		Modified on 9/4/2025 (MAP). (Entered: 09/03/2025)
09/03/2025	103	DECLARATION re 102 MOTION to Dismiss for Lack of Jurisdiction by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C)(Belfer, Isaac) (Entered: 09/03/2025)
09/04/2025	104	MEMORANDUM in Support re 102 MOTION to Dismiss for Lack of Jurisdiction filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (MAP) (Entered: 09/04/2025)
09/05/2025	105	Judge William G. Young: ELECTRONIC ORDER entered allowed 100 Third Individual Plaintiff's Motion to Proceed Under Pseudonym and for Protective Order) (MAP) (Entered: 09/05/2025)
09/09/2025	106	MOTION for the Court to Grant or Deny the Rule 59(e) Motion or in the Alternative a Certification Pursuant to 28 U.S.C. 1292(b) by Jose A. Perez.(MAP) (Entered: 09/09/2025)
09/10/2025	107	Judge William G. Young: ELECTRONIC ORDER entered denying 106 MOTION for the Court to Grant or Deny the Rule 59(e) Motion or in the Alternative a Certification Pursuant to 28 U.S.C. 1292(b) by Jose A. Perez. (KB) (Entered: 09/10/2025)
09/10/2025	108	Copy re 107 Order on Motion mailed to Jose Perez on 9/10/2025. (KB) (Entered: 09/10/2025)
09/11/2025	109	Judge William G. Young: ELECTRONIC ORDER entered denying 88 MOTION to Vacate the July 31, 2025 Order Denying the Motion to Intervene by Jose A. Perez. (KB) (Entered: 09/11/2025)
09/11/2025	110	Copy re 109 Order mailed to Jose A. Perez on 9/11/2025. (KB) (Entered: 09/11/2025)
09/11/2025	111	Joint MOTION to Modify Schedule by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Text of Proposed Order (Proposed Order))(Oh, James) (Entered: 09/11/2025)
09/15/2025	112	Judge William G. Young: ELECTRONIC ORDER entered re 111 Joint MOTION to Modify Schedule by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. Motion allowed. The Court will set a hearing date for the motion to dismiss. The Court will, if necessary, set a date for the production of the administrative record at that time. (KB) (Entered: 09/15/2025)

09/15/2025	113	ELECTRONIC NOTICE Resetting Hearing on Motion 102 MOTION to Dismiss for Lack of Jurisdiction : Motion Hearing reset for 10/8/2025 02:00 PM in Courtroom 18 (In person with remote access provided) before Judge William G. Young. Audio access to the hearing may be available to the media and public. Please check the Court schedule. In order to gain access to the hearing, you must sign up at the following address: https://forms.mad.uscourts.gov/courtlist.html. For questions regarding access to hearings, you may refer to the general orders and public notices of the Court available on www.mad.uscourts.gov or contact the session here. (KB) (Entered: 09/15/2025)
09/15/2025	114	Reset Deadlines as to 102 MOTION to Dismiss for Lack of Jurisdiction . Responses due by 9/24/2025. Replies due by 10/3/2025. (KB) (Entered: 09/15/2025)
09/23/2025	115	NOTICE OF APPEAL as to 81 ELECTRONIC ORDER, 109 ELECTRONIC ORDER by Jose A. Perez. NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the First Circuit Court of Appeals web site at http://www.ca1.uscourts.gov MUST be completed and submitted to the Court of Appeals. Counsel shall register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf. Counsel shall also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at http://www.ca1.uscourts.gov/cmecf. US District Court Clerk to deliver official record to Court of Appeals by 10/14/2025. (MAP) (Entered: 09/23/2025)
09/23/2025	116	Certified and Transmitted Abbreviated Electronic Record on Appeal to US Court of Appeals re 115 Notice of Appeal. (MAP) (Entered: 09/23/2025)
09/24/2025	117	USCA Case Number 25-1907 for 115 Notice of Appeal, filed by Jose A. Perez. (MAP) (Entered: 09/24/2025)
09/24/2025	118	Opposition re 102 MOTION to Dismiss for Lack of Jurisdiction filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10)(Oh, James) Modified on 9/25/2025 (MAP). (Entered: 09/24/2025)
09/30/2025	119	ELELECTRONIC NOTICE Cancelling Hearings. The Motion Hearing set for 10/8/2025 and the Bench Trial set for 10/14/2025 are cancelled and will be rescheduled for dates to be determined. (KB) (Entered: 09/30/2025)
10/01/2025	120	Filing fee/payment: \$ 605.00, receipt number 100013154 for 115 Notice of Appeal,,,

		(NVB) (Entered: 10/01/2025)
10/01/2025	121	Consent MOTION to Stay re 114 Set/Reset Motion and R&R Deadlines/Hearings by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services.(Belfer, Isaac) (Entered: 10/01/2025)
10/02/2025	122	Judge William G. Young: ELECTRONIC ORDER entered granting 121 Defendants' Unopposed Motion for a Stay of Their Reply Deadline in Light of Lapse of Appropriations filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (KB) (Entered: 10/02/2025)
10/09/2025	123	Amicus Curiae APPEARANCE entered by Thanithia R. Billings on behalf of American College of Obstetricians & Gynecologists, American Academy of Family Physicians, American Academy of Nursing, American College of Chest Physicians, American College of Medical Genetics and Genomics, American College of Nurse-Midwives, American Gynecological and Obstetrical Society, American Medical Association, American Medical Womens Association, American Society for Reproductive Medicine, Council of Chairs of Obstetrics and Gynecology, Massachusetts Medical Society, National Association of Nurse Practitioners in Womens Health, National Association of Pediatric Nurse Practitioners, North American Society for Pediatric and Adolescent Gynecology, Society for Adolescent Health and Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists. (Billings, Thanithia) (Entered: 10/09/2025)
10/09/2025	124	MOTION for Leave to Appear Pro Hac Vice for admission of Kimberly A. Parker, Mark L. Hanin, Molly A. Meegan, Francisco M. Negron, Jr., Meaghan H. Davant Filing fee: \$ 625, receipt number AMADC-11291470 by American Academy of Family Physicians, American Academy of Nursing, American College of Chest Physicians, American College of Medical Genetics and Genomics, American College of Nurse-Midwives, American College of Obstetricians & Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Medical Womens Association, American Society for Reproductive Medicine, Council of Chairs of Obstetrics and Gynecology, Massachusetts Medical Society, National Association of Nurse Practitioners in Womens Health, National Association of Pediatric Nurse Practitioners, North American Society for Pediatric and Adolescent Gynecology, Society for Adolescent Health and Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists. (Attachments: # 1 Exhibit A - Declaration of Kimberly A. Parker in Support, # 2 Exhibit B - Declaration of Mark L. Hanin in Support, # 3 Exhibit C - Declaration of Molly A. Meegan in Support, # 4 Exhibit D - Declaration of Francisco M. Negron, Jr. in Support, # 5 Exhibit E - Declaration of Meaghan H. Davant in Support)(Billings, Thanithia) Modified on 10/14/2025 (MAP). Modified on 10/14/2025 (MAP). (Entered: 10/09/2025)

10/09/2025	125	MOTION for Leave to File <i>Amicus Brief in Support of Plaintiffs (Unopposed)</i> by American Academy of Family Physicians, American Academy of Nursing, American College of Chest Physicians, American College of Medical Genetics and Genomics, American College of Nurse-Midwives, American College of Obstetricians & Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Medical Womens Association, American Society for Reproductive Medicine, Council of Chairs of Obstetrics and Gynecology, Massachusetts Medical Society, National Association of Nurse Practitioners in Womens Health, National Association of Pediatric Nurse Practitioners, North American Society for Pediatric and Adolescent Gynecology, Society for Adolescent Health and Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists. (Attachments: # 1 Exhibit A - Proposed Amicus Brief)(Billings, Thanithia) (Entered: 10/09/2025)
10/09/2025	126	CORPORATE DISCLOSURE STATEMENT by American Academy of Family Physicians, American Academy of Nursing, American College of Chest Physicians, American College of Medical Genetics and Genomics, American College of Nurse-Midwives, American College of Obstetricians & Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Medical Womens Association, American Society for Reproductive Medicine, Council of Chairs of Obstetrics and Gynecology, Massachusetts Medical Society, National Association of Nurse Practitioners in Womens Health, National Association of Pediatric Nurse Practitioners, North American Society for Pediatric and Adolescent Gynecology, Society for Adolescent Health and Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists. (Billings, Thanithia) (Entered: 10/09/2025)
10/20/2025	127	MOTION to Continue This Case on Schedule During the Federal Government Shutdown (<i>Plaintiffs' Motion to Lift Stay and Continue This Case on Schedule During the Federal Government Shutdown</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Oh, James) Motion terminated 10/30/2025 (BIB). (Entered: 10/20/2025)
10/22/2025	128	Judge William G. Young: ELECTRONIC ORDER entered. ORDER REASSIGNING CASE. With the approval of the Chief Judge, pursuant to Local Rule 40.1 (j) (1), it is hereby ORDERED that this case is RETURNED to the Clerk to be randomly reassigned.(KB) (Entered: 10/22/2025)
10/22/2025	129	ELECTRONIC NOTICE of Case Reassignment. Judge Brian E. Murphy assigned to case. If the trial Judge issues an Order of Reference of any matter in this case to a Magistrate Judge, the matter will be transmitted to Magistrate Judge M. Page Kelley. (LBO) (Entered: 10/22/2025)
10/23/2025	130	NOTICE by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary,

		National Institutes of Health, United States Department of Health and Human Services re 127 MOTION to Continue This Case on Schedule During the Federal Government Shutdown (<i>Plaintiffs' Motion to Lift Stay and Continue This Case on Schedule During the Federal Government Shutdown</i>) Notice of Intent to File an Opposition (Belfer, Isaac) (Entered: 10/23/2025)
10/23/2025	131	NOTICE OF MOTION HEARING: Hearing on 127 Plaintiffs' Motion to Continue This Case on Schedule During the Federal Government Shutdown is SCHEDULED for 10/30/2025 at 11:00 a.m. in Courtroom 12 (In person only) before Judge Brian E. Murphy. In addition, Defendants' counsel shall file any opposition no later than 3:00 p.m. on 10/29/2025. (BIB) (Entered: 10/23/2025)
10/27/2025	132	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 124 Motion for Leave to Appear Pro Hac Vice Added Kimberly A. Parker, Mark L. Hanin, Molly A. Meegan, Francisco M. Negron, Jr. and Meaghan H. Davant. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm . A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 10/27/2025)
10/29/2025	133	Opposition re 127 MOTION to Continue This Case on Schedule During the Federal Government Shutdown (<i>Plaintiffs' Motion to Lift Stay and Continue This Case on Schedule During the Federal Government Shutdown</i>) filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 10/29/2025)
10/30/2025	134	CLERK'S NOTES for Motion Hearing held in-person before Judge Brian E. Murphy: Argument heard on 127 Motion to Lift Stay and Continue this Case on Schedule During the Federal Government Shutdown. Court LIFTS the Stay for the reasons stated on the record. Court takes a brief recess to allow counsel to consult and propose a briefing schedule. Schedule set by the Court. Cross motions for summary judgment to be addressed after motion to dismiss practice. Defendants to file a status report by 11/12/2025 re the compilation time line for disclosing the administrative record to the plaintiffs.

		SCHEDULE: Amended complaint to be filed by 11/5/2025. Defendants' Motion to Dismiss to be filed by 11/19/2025. Opposition to Motion to Dismiss to be filed by 12/3/2025. Reply Brief in further support of Motion to Dismiss to be filed by 12/12/2025. NOTICE OF HEARINGS: Hearing on Motion to Dismiss set for 12/17/2025 at 10:00 a.m. in Courtroom 12 (In person only) before Judge Brian E. Murphy. Status Conference set for 1/12/2026 at 2:30 p.m. remotely by Zoom before Judge Brian E. Murphy. (Court Reporter: Jessica Bisailon at jsteno99@gmail.com.)(Attorneys present: Oh, Hughes, Wanerman, Belfer, AUSA Fitzgerald) (BIB) (Entered: 10/30/2025)
10/30/2025	135	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 125 Motion for Leave to File Document ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 10/30/2025)
10/31/2025	136	AMICUS BRIEF filed by American Academy of Family Physicians, American Academy of Nursing, American College of Chest Physicians, American College of Medical Genetics and Genomics, American College of Nurse-Midwives, American College of Obstetricians & Gynecologists, American Gynecological and Obstetrical Society, American Medical Association, American Medical Womens Association, American Society for Reproductive Medicine, Council of Chairs of Obstetrics and Gynecology, Massachusetts Medical Society, National Association of Nurse Practitioners in Womens Health, National Association of Pediatric Nurse Practitioners, North American Society for Pediatric and Adolescent Gynecology, Society for Adolescent Health and Medicine, Society of General Internal Medicine, Society of Gynecologic Oncology, Society of Gynecologic Surgeons, Society of OB/GYN Hospitalists <i>in Support of Plaintiffs</i> . (Billings, Thanithia) (Entered: 10/31/2025)
10/31/2025	137	Transcript of Motion Hearing held on October 30, 2025, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Jessica Bisailon at jsteno99@gmail.com. Redaction Request due 11/21/2025. Redacted Transcript Deadline set for 12/1/2025. Release of Transcript Restriction set for 1/29/2026. (DRK) (Entered: 11/03/2025)
10/31/2025	138	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 11/03/2025)
11/05/2025	139	AMENDED COMPLAINT [<i>THIRD AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF</i>] against All Defendants, filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe

		3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine.(Oh, James) (Entered: 11/05/2025)
11/12/2025	140	STATUS REPORT <i>Regarding the Administrative Record</i> by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 11/12/2025)
11/13/2025	141	NOTICE by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine re 140 Status Report, (<i>Plaintiffs' Notice of Intent to File a Response to Defendants' Status Report Regarding the Administrative Record</i>) (Oh, James) (Entered: 11/13/2025)
11/18/2025	142	STATUS REPORT (<i>Plaintiffs' Reply to Defendants' November 12 Status Report</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 11/18/2025)
11/18/2025	143	DECLARATION re 142 Status Report, by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit 1, # 2 Exhibit Exhibit 2, # 3 Exhibit Exhibit 3, # 4 Exhibit Exhibit 4, # 5 Exhibit Exhibit 5)(Oh, James) (Entered: 11/18/2025)
11/19/2025	144	MOTION to Dismiss for Lack of Jurisdiction , MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM (Responses due by 12/3/2025) by Centers for Disease Control and Prevention, Robert F. Kennedy, Jr, United States Department of Health and Human Services. (Attachments: # 1 Text of Proposed Order)(Belfer, Isaac) (Entered: 11/19/2025)
11/19/2025	145	MEMORANDUM in Support re 144 MOTION to Dismiss for Lack of Jurisdiction MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by Centers for Disease Control and Prevention, Robert F. Kennedy, Jr, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 11/19/2025)
12/03/2025	146	MEMORANDUM in Opposition re 144 MOTION to Dismiss for Lack of Jurisdiction MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM (<i>Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss the Third Amended Complaint</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of

		America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit 1, # 2 Exhibit Exhibit 2, # 3 Exhibit Exhibit 3, # 4 Exhibit Exhibit 4, # 5 Exhibit Exhibit 5, # 6 Exhibit Exhibit 6, # 7 Exhibit Exhibit 7, # 8 Exhibit Exhibit 8, # 9 Exhibit Exhibit 9, # 10 Exhibit Exhibit 10, # 11 Exhibit Exhibit 11, # 12 Exhibit Exhibit 12, # 13 Exhibit Exhibit 13, # 14 Exhibit Exhibit 14, # 15 Exhibit Exhibit 15, # 16 Exhibit Exhibit 16, # 17 Exhibit Exhibit 17, # 18 Exhibit Exhibit 18, # 19 Exhibit Exhibit 19, # 20 Exhibit Exhibit 20, # 21 Exhibit Exhibit 21, # 22 Exhibit Exhibit 22, # 23 Exhibit Exhibit 23, # 24 Exhibit Exhibit 24, # 25 Exhibit Exhibit 25, # 26 Exhibit Exhibit 26, # 27 Exhibit Exhibit 27, # 28 Exhibit Exhibit 28, # 29 Exhibit Exhibit 29, # 30 Exhibit Exhibit 30, # 31 Exhibit Exhibit 31, # 32 Exhibit Exhibit 32, # 33 Exhibit Exhibit 33, # 34 Exhibit Exhibit 34, # 35 Exhibit Exhibit 35, # 36 Exhibit Exhibit 36, # 37 Exhibit Exhibit 37, # 38 Exhibit Exhibit 38, # 39 Exhibit Exhibit 39)(Oh, James) (Entered: 12/03/2025)
12/09/2025	147	MOTION for Leave to File <i>Supplemental Declaration of Dr. Jason Goldman in Support of Plaintiffs' Opposition to Defendants' Motion to Dismiss</i> by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit A, # 2 Exhibit Exhibit B)(Oh, James) (Entered: 12/09/2025)
12/11/2025	148	NOTICE of Appearance by James W Harlow on behalf of Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Does 1-50, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services (Harlow, James) (Entered: 12/11/2025)
12/12/2025	149	NOTICE of Appearance by Ashley H. Wisneski on behalf of Pediatric Infectious Diseases Society, Inc. (Wisneski, Ashley) (Entered: 12/12/2025)
12/12/2025	150	MOTION for Leave to Appear Pro Hac Vice for admission of Holly E. Peterson Filing fee: \$ 125, receipt number AMADC-11416071 by Pediatric Infectious Diseases Society, Inc..(Wisneski, Ashley) (Attachments: # 1 Certificate of Holly E. Peterson) (MBM). (Entered: 12/12/2025)
12/12/2025	151	MOTION for Leave to Appear Pro Hac Vice for admission of Kevin M. Serafino Filing fee: \$ 125, receipt number AMADC-11416106 by Pediatric Infectious Diseases Society, Inc..(Wisneski, Ashley) (Attachments: # 1 Certificate of Kevin M. Serafino) (MBM). (Entered: 12/12/2025)
12/12/2025	152	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 150 Motion for Leave to Appear Pro Hac Vice Added Holly E. Peterson. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or

		it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 12/12/2025)
12/12/2025	153	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 151 Motion for Leave to Appear Pro Hac Vice Added Kevin M. Serafino. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 12/12/2025)
12/12/2025	154	REPLY to Response to 144 MOTION to Dismiss for Lack of Jurisdiction MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 12/12/2025)
12/12/2025	155	MOTION for Leave to File <i>Amicus Brief in Support of Plaintiffs (Unopposed)</i> by Defend Public Health. (Attachments: # 1 Exhibit Exhibit A: Proposed Amicus Brief) (Schumacher, David) (Entered: 12/12/2025)
12/15/2025	156	NOTICE of Appearance by Holly Peterson on behalf of Pediatric Infectious Diseases Society, Inc. (Peterson, Holly) (Entered: 12/15/2025)
12/15/2025	157	NOTICE of Appearance by Kevin Serafino on behalf of Pediatric Infectious Diseases Society, Inc. (Serafino, Kevin) (Entered: 12/15/2025)
12/15/2025	158	Assented to MOTION for Leave to File <i>Amicus Brief</i> by Pediatric Infectious Diseases Society, Inc..(Peterson, Holly) (Entered: 12/15/2025)
12/16/2025	159	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 147 , 155 , 158 Motion for Leave to File Document ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 12/16/2025)

		12/16/2025)
12/16/2025	160	AMICUS BRIEF filed by Pediatric Infectious Diseases Society, Inc. <i>Leave to File Granted on 12/16/25</i> . (Peterson, Holly) (Entered: 12/16/2025)
12/16/2025	161	NOTICE by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services re 159 Order on Motion for Leave to File,,,,, (Belfer, Isaac) (Entered: 12/16/2025)
12/16/2025	162	DECLARATION re 159 Order on Motion for Leave to File,,,,, [SUPPLEMENTAL DECLARATION OF DR. JASON GOLDMAN IN SUPPORT OF PLAINTIFFS OPPOSITION TO DEFENDANTS MOTION TO DISMISS] by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 12/16/2025)
12/16/2025	163	AMICUS BRIEF filed by Defend Public Health <i>in Support of Plaintiffs</i> . (Schumacher, David) (Entered: 12/16/2025)
12/17/2025	164	CLERK'S NOTES for Motion Hearing held in-person before Judge Brian E. Murphy: Discussion regarding the applicability of the Court's allowance of 147 Motion for Leave to File Supplemental Declaration. Argument heard on pending Motions to Dismiss 102 144 . Motions taken under advisement.(Court Reporter: Jessica Bisailon at jsteno99@gmail.com.)(Attorneys present: Oh, Hughes, Wanerman, Belfer, Harlow) (BIB) (Entered: 12/17/2025)
12/22/2025	165	Transcript of Motion Hearing held on December 17, 2025, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Jessica Bisailon at jsteno99@gmail.com. Redaction Request due 1/12/2026. Redacted Transcript Deadline set for 1/22/2026. Release of Transcript Restriction set for 3/23/2026. (DRK) (Entered: 12/22/2025)
12/22/2025	166	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 12/22/2025)
12/23/2025	167	NOTICE of Appearance by Heather Romero on behalf of Defend Public Health (Romero, Heather) (Entered: 12/23/2025)
01/06/2026	168	Judge Brian E. Murphy: ORDER entered. MEMORANDUM AND ORDER on Defendants' Motion to Dismiss. Defendants' motion to dismiss, Dkt. 144 , is DENIED. (MBM) (Entered: 01/06/2026)
01/06/2026	169	Judge Brian E. Murphy: ELECTRONIC ORDER entered. By 5:00 p.m. on 1/9/2026,

		the parties shall file a Joint Status Report with a case management plan, including: 1) a proposed deadline for filing the administrative record; 2) a proposed briefing schedule for any contemplated motions; and 3) any other matters which should be addressed at the conference. (MBM) (Entered: 01/06/2026)
01/06/2026	170	MOTION to Withdraw as Attorney by Carolyn Owens Boucek (<i>unopposed</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine.(Boucek, Carolyn) (Entered: 01/06/2026)
01/07/2026	171	NOTICE of Appearance by Gianna Monet Costello on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine (Costello, Gianna) (Entered: 01/07/2026)
01/08/2026	172	NOTICE RE HEARING: The Status Conference scheduled for 1/12/2026 at 2:30 p.m. will now be held in-person in Courtroom 12 before Judge Brian E. Murphy. (BIB) (Entered: 01/08/2026)
01/08/2026	173	MOTION to Withdraw as Attorney by Lydia Pincsak (<i>UNOPPOSED</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine.(Pincsak, Lydia) (Entered: 01/08/2026)
01/08/2026	174	MOTION to Withdraw as Attorney by Marguerite Stringer (<i>UNOPPOSED</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine.(Stringer, Marguerite) (Entered: 01/08/2026)
01/09/2026	175	STATUS REPORT (<i>JOINT Status Report Filed Per the Court's January 6, 2026 Order - Dkt. No. 169</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 01/09/2026)
01/12/2026	176	Electronic Clerk's Notes for proceedings held before Judge Brian E. Murphy: Status Conference held on 1/12/2026. Scheduling and procedure addressed; status report re the collection of the administrative record due 1/21/2026; plttfs' motion for leave to file 4th amended complaint due 1/19/2026; plttfs' motion for preliminary injunction due 1/26/2026; defts' response due 2/9/2026; status report re prospective evidence and length of hearinbg due 2/9/2026; hearing on Preliminary Injunction set for 2/13/2026 09:00 AM in Courtroom 12 (In person only) before Judge Brian E. Murphy. (Court

		Reporter: Jamie Halpin at jkhhalpin@gmail.com.)(Attorneys present: Ho for the plttfs; Belfer for the defts) (JL) (Entered: 01/12/2026)
01/13/2026	177	NOTICE of Withdrawal of Appearance by Carolyn Owens Boucek (Boucek, Carolyn) (Entered: 01/13/2026)
01/14/2026	178	Transcript of Status Conference held on January 12, 2026, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Jamie Halpin at jkhhalpin@gmail.com. Redaction Request due 2/4/2026. Redacted Transcript Deadline set for 2/17/2026. Release of Transcript Restriction set for 4/14/2026. (DRK) (Entered: 01/14/2026)
01/14/2026	179	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 01/14/2026)
01/19/2026	180	MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File a Fourth Amended Complaint</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit (Exhibit 1), # 2 Text of Proposed Order (Proposed Order))(Oh, James) (Entered: 01/19/2026)
01/21/2026	181	STATUS REPORT (<i>Joint Status Report Regarding the Administrative Record</i>) by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 01/21/2026)
01/22/2026	182	Judge Brian E. Murphy: ELECTRONIC ORDER entered. Having reviewed the parties' Joint Status Report, the Court ORDERS the following schedule for Defendants' production of the administrative record: Records related to the May 2025 Directive by March 12, 2026. Records related to the October 2025 changes to the COVID vaccine recommendation by March 23, 2026. Records related to the reconstitution of ACIP by March 23, 2026. Should the Court grant Plaintiffs' motion for leave to amend the complaint, records related to actions challenged in the proposed 4th Amended Complaint will be due within 60 days of the Court's order on said motion. The Court will grant extensions only upon a showing of good cause. Any requests to amend the schedule should detail the efforts already made with specific dates of action, the status of those efforts, what work remains, and why more time is

		necessary. (MBM) (Entered: 01/22/2026)
01/26/2026	183	MOTION for Preliminary Injunction by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit A - Proposed Order) (Oh, James) (Entered: 01/26/2026)
01/26/2026	184	MEMORANDUM in Support re 183 MOTION for Preliminary Injunction filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 01/26/2026)
01/26/2026	185	APPENDIX/EXHIBIT re 183 MOTION for Preliminary Injunction by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit 1, # 2 Exhibit Exhibit 2, # 3 Exhibit Exhibit 3, # 4 Exhibit Exhibit 4, # 5 Exhibit Exhibit 5, # 6 Exhibit Exhibit 6, # 7 Exhibit Exhibit 7, # 8 Exhibit Exhibit 8, # 9 Exhibit Exhibit 9, # 10 Exhibit Exhibit 10, # 11 Exhibit Exhibit 11, # 12 Exhibit Exhibit 12, # 13 Exhibit Exhibit 13, # 14 Exhibit Exhibit 14, # 15 Exhibit Exhibit 15, # 16 Exhibit Exhibit 16, # 17 Exhibit Exhibit 17, # 18 Exhibit Exhibit 18, # 19 Exhibit Exhibit 19, # 20 Exhibit Exhibit 20, # 21 Exhibit Exhibit 21, # 22 Exhibit Exhibit 22, # 23 Exhibit Exhibit 23, # 24 Exhibit Exhibit 24, # 25 Exhibit Exhibit 25, # 26 Exhibit Exhibit 26, # 27 Exhibit Exhibit 27, # 28 Exhibit Exhibit 28, # 29 Exhibit Exhibit 29, # 30 Exhibit Exhibit 30, # 31 Exhibit Exhibit 31, # 32 Exhibit Exhibit 32, # 33 Exhibit Exhibit 33, # 34 Exhibit Exhibit 34, # 35 Exhibit Exhibit 35, # 36 Exhibit Exhibit 36, # 37 Exhibit Exhibit 37, # 38 Exhibit Exhibit 38, # 39 Exhibit Exhibit 39, # 40 Exhibit Exhibit 40, # 41 Exhibit Exhibit 41, # 42 Exhibit Exhibit 42, # 43 Exhibit Exhibit 43, # 44 Exhibit Exhibit 44, # 45 Exhibit Exhibit 45, # 46 Exhibit Exhibit 46, # 47 Exhibit Exhibit 47, # 48 Exhibit Exhibit 48, # 49 Exhibit Exhibit 49, # 50 Exhibit Exhibit 50, # 51 Exhibit Exhibit 51, # 52 Exhibit Exhibit 52, # 53 Exhibit Exhibit 53)(Oh, James) (Entered: 01/26/2026)
01/29/2026	186	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 170 Motion to Withdraw as Attorney. (MBM) (Entered: 01/29/2026)
01/29/2026	187	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 173 Motion to Withdraw as Attorney. Attorney Lydia Pincsak terminated. (MBM) (Entered: 01/29/2026)
01/29/2026	188	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 174 Motion to Withdraw as Attorney. Attorney Marguerite McGowan Stringer terminated. (MBM)

		(Entered: 01/29/2026)
01/29/2026	189	NOTICE OF HEARING: At the request of counsel, a Status Conference is SCHEDULED for 1/30/2026 at 12:00 p.m. remotely by Zoom before Judge Brian E. Murphy. (BIB) (Entered: 01/29/2026)
01/30/2026	190	CLERK'S NOTES for Status Conference held remotely by Zoom before Judge Brian E. Murphy: Parties discuss the arbitrary and capricious issues raised in the scope of the 183 Motion for Preliminary Injunction. Court discusses bifurcating the issues for hearing. The hearing presently scheduled for 2/13/2026 will be limited to the January 5th vaccine guidance and the February 25-26 ACIP hearing. Defendants' to brief the remaining issues no later than 2/27/2026. Secondary hearing scheduled. Parties to file status report no later than 3/2/2026 re prospective evidence and length of the second hearing. NOTICE OF HEARING: Secondary Hearing on Motion for Preliminary Injunction is SCHEDULED for 3/4/2026 at 9:00 a.m. in Courtroom 12 (In person only) before Judge Brian E. Murphy. (Court Reporter: Rachel Lopez at raeufp@gmail.com.)(Attorneys present: Oh, McEvoy, Gerson, Hughes, Walters, Belfer) (BIB) (Entered: 01/30/2026)
02/02/2026	191	NOTICE of Appearance by Allison Aviki on behalf of Lynn R. Goldman, Nicole L. Huberfeld, Timothy Stoltzfus Jost, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens (Aviki, Allison) (Entered: 02/02/2026)
02/02/2026	192	MOTION for Leave to Appear Pro Hac Vice for admission of Andrew J. Pincus Filing fee: \$ 125, receipt number AMADC-11519747 by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost. (Attachments: # 1 Exhibit A - Certificate of Andrew J. Pincus)(Aviki, Allison) (Entered: 02/02/2026)
02/02/2026	193	MOTION for Leave to Appear Pro Hac Vice for admission of Natasha Harnwell-Davis Filing fee: \$ 125, receipt number AMADC-11519757 by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost. (Attachments: # 1 Exhibit A - Certificate of Natasha Harnwell-Davis)(Aviki, Allison) (Entered: 02/02/2026)
02/02/2026	194	MOTION for Leave to Appear Pro Hac Vice for admission of Crystal Paulino Filing fee: \$ 125, receipt number AMADC-11519759 by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost. (Attachments: # 1 Exhibit A - Certificate of Crystal Paulino)(Aviki, Allison) (Entered: 02/02/2026)
02/02/2026	195	MOTION for Leave to Appear Pro Hac Vice for admission of Graham White Filing fee: \$ 125, receipt number AMADC-11519763 by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara

		Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost. (Attachments: # 1 Exhibit A - Certificate of Graham White)(Aviki, Allison) (Entered: 02/02/2026)
02/02/2026	196	MOTION for Leave to File <i>Amici Curiae Public Health and Administrative Law Scholars to File a Brief in Support of Plaintiffs</i> by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost. (Attachments: # 1 Exhibit A)(Aviki, Allison) (Attachments: # 2 Appendix) (MBM). (Entered: 02/02/2026)
02/03/2026	197	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 192 Motion for Leave to Appear Pro Hac Vice Added Andrew J. Pincus. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account . (MBM) (Entered: 02/03/2026)
02/03/2026	198	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 193 Motion for Leave to Appear Pro Hac Vice Added Natasha Harnwell-Davis. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm . A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/03/2026)
02/03/2026	199	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 194 Motion for Leave to Appear Pro Hac Vice Added Crystal Paulino. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or

		it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/03/2026)
02/03/2026	200	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting <u>195</u> Motion for Leave to Appear Pro Hac Vice Added Graham White. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/03/2026)
02/03/2026	<u>201</u>	NOTICE of Appearance by Natasha Harnwell-Davis on behalf of Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost (Harnwell-Davis, Natasha) (Entered: 02/03/2026)
02/03/2026	<u>202</u>	NOTICE of Appearance by Crystal Paulino on behalf of Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost (Paulino, Crystal) (Entered: 02/03/2026)
02/03/2026	<u>203</u>	NOTICE of Appearance by Andrew J. Pincus on behalf of Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost (Pincus, Andrew) (Entered: 02/03/2026)
02/03/2026	<u>204</u>	NOTICE of Appearance by Graham White on behalf of Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost (White, Graham) (Entered: 02/03/2026)
02/03/2026	<u>205</u>	NOTICE of Appearance by Megan Barbero on behalf of American Association of Immunologists, America's Physician Groups (Barbero, Megan) (Entered: 02/03/2026)
02/03/2026	<u>206</u>	MOTION for Leave to Appear Pro Hac Vice for admission of Justin A. Coen Filing

		fee: \$ 125, receipt number AMADC-11522986 by America's Physician Groups, American Association of Immunologists. (Attachments: # 1 Certification of Justin A. Coen)(Barbero, Megan) (Entered: 02/03/2026)
02/03/2026	207	MOTION for Leave to Appear Pro Hac Vice for admission of Kyle H. Keraga Filing fee: \$ 125, receipt number AMADC-11522987 by America's Physician Groups, American Association of Immunologists. (Attachments: # 1 Certification of Kyle H. Keraga)(Barbero, Megan) (Entered: 02/03/2026)
02/03/2026	208	MOTION for Leave to Appear Pro Hac Vice for admission of Sarah M. Allen Filing fee: \$ 125, receipt number AMADC-11522988 by America's Physician Groups, American Association of Immunologists. (Attachments: # 1 Certification of Sarah M. Allen)(Barbero, Megan) (Entered: 02/03/2026)
02/03/2026	209	MOTION for Leave to File <i>Amicus Brief in Support of Plaintiffs' Motion for a Preliminary Injunction (Unopposed)</i> by America's Physician Groups, American Association of Immunologists. (Attachments: # 1 Proposed Amicus Brief)(Barbero, Megan) (Entered: 02/03/2026)
02/04/2026	210	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 206 Motion for Leave to Appear Pro Hac Vice Added Justin A. Coen. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/04/2026)
02/04/2026	211	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 207 Motion for Leave to Appear Pro Hac Vice Added Kyle H. Keraga. Attorneys admitted Pro Hac Vice must have an individual upgraded PACER account, not a shared firm account, to electronically file in the District of Massachusetts. Counsel may need to link their CM/ECF account to their upgraded individual pacer account. Instructions on how to link CM/ECF accounts to upgraded pacer account can be found at https://www.mad.uscourts.gov/caseinfo/nextgen-current-pacer-accounts.htm#link-account. (MBM) (Entered: 02/04/2026)
02/04/2026	212	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 208 Motion for

		Leave to Appear Pro Hac Vice Added Sarah M. Allen. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/04/2026)
02/05/2026	213	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 196 Motion for Leave to File Document ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 02/05/2026)
02/05/2026	214	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 209 Motion for Leave to File Document ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 02/05/2026)
02/05/2026	215	Assented to MOTION for Leave to Appear Pro Hac Vice for admission of Daniella R. Lee by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit A)(McEvoy, Elizabeth) (Entered: 02/05/2026)
02/05/2026	216	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 215 Motion for Leave to Appear Pro Hac Vice Added Daniella R. Lee. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney.

		(MBM) (Entered: 02/05/2026)
02/05/2026	217	AMICUS BRIEF filed by Lynn R. Goldman, Nicole L. Huberfeld, Paula Lantz, Jeffrey Levi, Frances Miller, Christopher Robertson, Sara Rosenbaum, William M. Sage, Joshua M. Sharfstein, Laura Stephens, Timothy Stoltzfus Jost . (Aviki, Allison) (Entered: 02/05/2026)
02/05/2026	218	AMICUS BRIEF filed by America's Physician Groups, American Association of Immunologists <i>in Support of Plaintiffs' Motion for a Preliminary Injunction</i> . (Barbero, Megan) (Entered: 02/05/2026)
02/05/2026	219	NOTICE of Appearance by Julia Caldwell on behalf of Defend Public Health (Caldwell, Julia) (Entered: 02/05/2026)
02/05/2026	220	NOTICE of Appearance by Justin Coen on behalf of America's Physician Groups, American Association of Immunologists (Coen, Justin) (Entered: 02/05/2026)
02/05/2026	221	NOTICE of Appearance by Kyle Keraga on behalf of America's Physician Groups, American Association of Immunologists (Keraga, Kyle) (Entered: 02/05/2026)
02/05/2026	222	NOTICE of Appearance by Sarah Allen on behalf of America's Physician Groups, American Association of Immunologists (Allen, Sarah) (Entered: 02/05/2026)
02/06/2026	223	Amicus Curiae APPEARANCE entered by Andrew M. London on behalf of American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, Robert Wood Johnson Foundation, American Academy of Allergy, Asthma, & Immunology, 119 Deans, Chairs, and Public Health and Health Policy Scholars. (London, Andrew) (Entered: 02/06/2026)
02/06/2026	224	MOTION for Leave to Appear Pro Hac Vice for admission of Caroline Farrell Filing fee: \$ 125, receipt number AMADC-11532051 by 119 Deans, Chairs, and Public Health and Health Policy Scholars, American Academy of Allergy, Asthma, & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, Robert Wood Johnson Foundation. (Attachments: # 1 Exhibit A - Certificate of Caroline Farrell, Esq., # 2 Exhibit B - List of Amici Curiae) (London, Andrew) (Entered: 02/06/2026)
02/06/2026	225	MOTION for Leave to File <i>Brief of Amici Curiae in Support of Plaintiffs' Motion for Preliminary Injunction (Unopposed)</i> by 119 Deans, Chairs, and Public Health and Health Policy Scholars, American Academy of Allergy, Asthma, & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, Robert Wood Johnson Foundation. (Attachments: # 1 Exhibit A) (London, Andrew) (Entered: 02/06/2026)
02/09/2026	226	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 224 Motion for Leave to Appear Pro Hac Vice Added Caroline Farrell. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number

		under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/09/2026)
02/09/2026	227	Judge Brian E. Murphy: ELECTRONIC ORDER granting 225 Unopposed Motion for Leave to File Brief of Amici Curiae; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (BIB) (Entered: 02/09/2026)
02/09/2026	228	AMICUS BRIEF filed by 119 Deans, Chairs, and Public Health and Health Policy Scholars, American Academy of Allergy, Asthma, & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, Robert Wood Johnson Foundation <i>in Support of Plaintiffs' Motion for a Preliminary Injunction</i> . (London, Andrew) (Entered: 02/09/2026)
02/09/2026	229	Assented to MOTION for Leave to File <i>a Corrected Memorandum of Law in Support of Their Motion for Preliminary Injunction</i> by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit Exhibit A, # 2 Exhibit Exhibit B, # 3 Text of Proposed Order [Proposed] Order)(Oh, James) (Entered: 02/09/2026)
02/09/2026	230	STATUS REPORT <i>Joint Status Report Regarding February 13, 2026 Hearing</i> by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/09/2026)
02/09/2026	231	Second MOTION for Leave to File <i>Amicus Brief in Support of Plaintiffs' Motion for Preliminary Injunction (Unopposed)</i> by Defend Public Health. (Attachments: # 1 Exhibit A: Proposed Amicus Brief)(Schumacher, David) (Entered: 02/09/2026)
02/09/2026	232	Opposition re 183 MOTION for Preliminary Injunction filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 02/09/2026)

02/09/2026	233	Opposition re 180 MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File a Fourth Amended Complaint</i>) filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 02/09/2026)
02/10/2026	234	Judge Brian E. Murphy: ELECTRONIC ORDER granting 231 Unopposed Motion for Leave to File Amicus Curiae Brief. Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (BIB) (Entered: 02/10/2026)
02/10/2026	235	Judge Brian E. Murphy: ELECTRONIC ORDER granting 229 Assented to Motion for Leave to File a Corrected Memorandum of Law in Support of Their Motion for Preliminary Injunction. Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (BIB) (Entered: 02/10/2026)
02/10/2026	236	Amicus Curiae APPEARANCE entered by Caroline Lindsay Farrell on behalf of 119 Deans, Chairs, and Public Health and Health Policy Scholars, American Academy of Allergy, Asthma, & Immunology, American College of Chest Physicians, American Thoracic Society, Network for Public Health Law, Robert Wood Johnson Foundation. (Farrell, Caroline) (Entered: 02/10/2026)
02/10/2026	237	MEMORANDUM in Support re 183 MOTION for Preliminary Injunction (<i>Plaintiffs' CORRECTED Memorandum of Law in Support of Their Motion for Preliminary Injunction</i>) (<i>Leave to File Granted on February 10, 2026</i>) filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/10/2026)
02/10/2026	238	AMICUS BRIEF filed by Defend Public Health <i>in Support of Plaintiffs</i> . (Schumacher, David) (Entered: 02/10/2026)
02/12/2026	239	NOTICE of Appearance by Daniella Lee on behalf of Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine (Lee, Daniella) (Entered: 02/12/2026)
02/12/2026	240	MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1

		Exhibit (Exhibit A), # 2 Exhibit (Exhibit B), # 3 Exhibit (Exhibit C), # 4 Text of Proposed Order (Proposed Order))(Oh, James) (Entered: 02/12/2026)
02/13/2026	241	CLERK'S NOTES: for Motion Hearing held in-person before Judge Brian E. Murphy: Court hears argument on 240 Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction. Motion preliminarily GRANTED, the defendants to file supplemental opposition by 5:00 p.m. on 2/18/2026. Court addresses 180 Plaintiffs' Motion for Leave to File a Fourth Amended Complaint and GRANTS the Motion. Counsel to file additional briefing regarding the legal consequence of the January guidance no later than 2/18/2026. Court hears argument on 183 Motion for Preliminary Injunction and takes the motion under advisement. (Court Reporter: Jennifer Vaillancourt at jenn.m.vaillancourt@gmail.com.)(Attorneys present: Oh, Belfer, McEvoy, Barrett, Lee, Hughes, Wanerman, Harlow) (BIB) (Entered: 02/17/2026)
02/17/2026	242	DECLARATION re 241 Order on Motion for Leave to File,,, Order on Motion for Preliminary Injunction,,,,,,, Motion Hearing,,, (<i>Declaration of Diana Zuckerman, Ph.D. in Support of Their Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/17/2026)
02/17/2026	243	DECLARATION re 241 Order on Motion for Leave to File,,, Order on Motion for Preliminary Injunction,,,,,,, Motion Hearing,,, (<i>Second Supplemental Declaration of Susan J. Kressly, M.D., FAAP in Support of Their Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/17/2026)
02/17/2026	244	DECLARATION re 241 Order on Motion for Leave to File,,, Order on Motion for Preliminary Injunction,,,,,,, Motion Hearing,,, (<i>Second Supplemental Declaration of Suzanne Berman, M.D. in Support of Their Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/17/2026)
02/17/2026	245	AMENDED COMPLAINT (<i>Fourth Amended Complaint for Declaratory and Injunctive Relief - Leave to File Granted on February 17, 2026</i>) against Does 1-50, United States Department of Health and Human Services, Centers for Disease Control and Prevention, Robert F. Kennedy, Jr, filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious

		Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine.(Oh, James) (Entered: 02/17/2026)
02/18/2026	246	NOTICE of Appearance by Robert N. Meltzer on behalf of Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	247	MOTION for Leave to Appear Pro Hac Vice for admission of Richard Jaffe Filing fee: \$ 125, receipt number AMADC-11556971 by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. (Attachments: # 1 Affidavit, # 2 Text of Proposed Order)(Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	248	Emergency MOTION to Intervene by Children's Health Defense , Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. (Attachments: # 1 Supplement Proposed Answer and Counterclaim, # 2 Text of Proposed Order Proposed Order)(Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	249	MEMORANDUM in Support re 248 Emergency MOTION to Intervene filed by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. (Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	250	AFFIDAVIT in Support re 248 Emergency MOTION to Intervene filed by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. (Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	251	ADDENDUM re 248 Emergency MOTION to Intervene <i>re Opposition to Preliminary Injunction</i> filed by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. (Attachments: # 1 Text of Proposed Order Proposed Order of PI Opposition)(Meltzer, Robert) (Entered: 02/18/2026)
02/18/2026	252	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 247 Motion for Leave to Appear Pro Hac Vice Added Richard Jaffe. Attorneys admitted Pro Hac Vice must have an individual PACER account, not a shared firm account, to electronically file in the District of Massachusetts. To register for a PACER account, go the Pacer website at https://pacer.uscourts.gov/register-account. You must put the docket number under ADDITIONAL FILER INFORMATION on your form when registering or it will be rejected. Pro Hac Vice Admission Request Instructions https://www.mad.uscourts.gov/caseinfo/nextgen-pro-hac-vice.htm. A Notice of Appearance must be entered on the docket by the newly admitted attorney. (MBM) (Entered: 02/18/2026)
02/18/2026	253	Supplemental DECLARATION in Support of Pro Hac Vic Motion by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (Meltzer, Robert) (Entered: 02/18/2026)

02/18/2026	254	RESPONSE to Motion re 240 MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction</i>) filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 02/18/2026)
02/18/2026	255	BRIEF by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine (<i>PLAINTIFFS SUPPLEMENTAL BRIEF ON THE LEGAL CONSEQUENCES OF THE JANUARY 5, 2026, ACTION CHANGING THE CDCs CHILDHOOD IMMUNIZATION SCHEDULE</i>). (Oh, James) (Entered: 02/18/2026)
02/19/2026	256	NOTICE of Appearance by Richard Jaffe on behalf of Children's Health Defense (Jaffe, Richard) (Entered: 02/19/2026)
02/19/2026	257	NOTICE by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services (Belfer, Isaac) (Entered: 02/19/2026)
02/19/2026	258	NOTICE by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine re 248 Emergency MOTION to Intervene (<i>Plaintiffs' Notice of Intent to File Opposition to Emergency Motion to Intervene as Defendants and Counterclaim Plaintiffs</i>) (Oh, James) (Entered: 02/19/2026)
02/19/2026	259	STATEMENT OF COUNSEL of All Plaintiffs on Record re 257 Notice (Other), (<i>Plaintiffs' Statement Regarding Postponement of Next ACIP Meeting</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 02/19/2026)
02/20/2026	260	Transcript of Motion Hearing held on February 13, 2026, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Jennifer Vaillancourt at jenn.m.vaillancourt@gmail.com. Redaction Request due 3/13/2026. Redacted Transcript Deadline set for 3/23/2026. Release of Transcript Restriction set for 5/21/2026. (DRK) (Entered: 02/20/2026)
02/20/2026	261	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at

		https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 02/20/2026)
02/20/2026	262	Judge Brian E. Murphy: ELECTRONIC ORDER entered. The parties are ORDERED to respond to 248 Emergency MOTION to Intervene filed by Children's Health Defense by 6 p.m. on Thursday, February 26, 2026. (MBM) (Entered: 02/20/2026)
02/23/2026	263	First ADDENDUM re 248 Emergency MOTION to Intervene <i>Supplemental Memo for March 4th hearing</i> filed by Children's Health Defense. (Jaffe, Richard) (Entered: 02/23/2026)
02/23/2026	264	Second AFFIDAVIT of Children's Health Defense in Support re 248 Emergency MOTION to Intervene filed by Children's Health Defense. (Jaffe, Richard) (Entered: 02/23/2026)
02/24/2026	265	NOTICE by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine (<i>Plaintiffs' Notice of Rescheduling of ACIP Meeting to March 18-19, 2026</i>) (Attachments: # 1 Exhibit (Exhibit A))(Oh, James) (Entered: 02/24/2026)
02/24/2026	266	NOTICE by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services (Belfer, Isaac) (Entered: 02/24/2026)
02/26/2026	267	MEMORANDUM in Opposition re 248 Emergency MOTION to Intervene filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Harlow, James) (Entered: 02/26/2026)
02/26/2026	268	Opposition re 248 Emergency MOTION to Intervene filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit (Exhibit A), # 2 Exhibit (Exhibit B), # 3 Exhibit (Exhibit C))(Oh, James) (Entered: 02/26/2026)
02/27/2026	269	Judge Brian E. Murphy: ELECTRONIC ORDER entered. The parties are directed to submit supplemental briefing of no more than ten pages on the applicability of the Federal Advisory Committee Act (FACA) to the Advisory Committee on Immunization Practices (ACIP) by Thursday, March 5, 2026. In <i>Kennedy v. Braidwood Mgmt., Inc.</i> , 606 U.S. 748 (2025), the Supreme Court stated that the U.S. Preventive Services Task Force (PSTF), a comparable “entity within the Department of Health and Human Services, [which] issues public recommendations about preventive healthcare services,” <i>id.</i> at 753, “ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act [“ACA”] and empowered the Task Force to issue binding recommendations,” <i>id.</i> at 766 n.3 (internal quotation

		marks omitted). The ACA provisions granting authority to PSTF and ACIP are similar, <i>see</i> 42 U.S.C. s. 300gg-13(a)(1)-(2), and the <i>Braidwood</i> Court appeared to discount ACIP's subsequently issued regulation, requiring adoption of its recommendations, <i>see</i> 45 C.F.R. s. 147.130(a)(1)(ii), as a relevant distinction, <i>see</i> 606 U.S. at 767 & n.4 (concluding that the ACA did not violate the Appointments Clause, in part, because "the Secretary can use his rulemaking authority... to establish a formal review process," like the one applicable to ACIP, even though the Secretary had not done so). Given the Supreme Court's characterization of PSTF's authority (and, by extension, ACIP's authority) as the power "to issue binding regulations," <i>Braidwood</i> , 606 U.S. at 766 n.3, the Court is uncertain as to whether ACIP continues to "perform primarily... advisory [as opposed to 'operational'] functions" for purposes of FACA. <i>See Nat. Res. Def. Council v. EPA</i> , 806 F. Supp. 275, 276 (D.D.C. 1992) (quoting 42 C.F.R. s. 101-6.1004(g) [sic] (1992), current version at 41 C.F.R. s. 102-3.40(j) (2025)). (MBM) (Entered: 02/27/2026)
02/27/2026	270	First MOTION for Leave to File <i>Reply Memorandum of Law</i> by Children's Health Defense. (Attachments: # 1 Text of Proposed Order, # 2 Exhibit Reply Memorandum) (Jaffe, Richard) (Entered: 02/27/2026)
02/27/2026	271	Judge Brian E. Murphy: ELECTRONIC ORDER entered DENYING 248 Motion to Intervene by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller. Motion denied. The proposed intervenors are welcome to file a brief as amici curiae. (MBM) (Entered: 02/27/2026)
02/27/2026	272	Opposition re 183 MOTION for Preliminary Injunction filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 02/27/2026)
02/27/2026	273	DECLARATION re 272 Opposition to Motion, by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Belfer, Isaac) (Entered: 02/27/2026)
03/02/2026	274	MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit (Exhibit A), # 2 Exhibit (Exhibit B), # 3 Exhibit (Exhibit C), # 4 Exhibit (Exhibit D), # 5 Exhibit (Exhibit E), # 6 Text of Proposed Order (Proposed Order)) (Oh, James) (Entered: 03/02/2026)
03/02/2026	275	STATUS REPORT (<i>JOINT</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of

		America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/02/2026)
03/04/2026	276	BRIEF by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine to 269 Order,,,,,, (Plaintiffs' Supplemental Brief Regarding the Applicability of the Federal Advisory Committee Act to the Advisory Committee on Immunization Practices). (Hughes, Richard) (Entered: 03/04/2026)
03/04/2026	277	CLERK'S NOTES for Motion Hearing held in-person before Judge Brian E. Murphy: Argument heard on the bifurcated portion of the 183 Motion for Preliminary Injunction. Motion taken under advisement. Plaintiffs' offer a PDF version of powerpoint presentation to the Court. Defendants to review and notify the Court by the end of the day if they object. Defendants to file their opposition to the 274 Plaintiffs' Motion to File Supplemental Declaration by the close of business Monday, 3/9/2026. Attorney Jaffe, who previously filed a Motion to Intervene, will file an Amici Brief on 3/9/2026. (Court Reporter: Jennifer Vaillancourt at jenn.m.vaillancourt@gmail.com.)(Attorneys present: Oh, McEvoy, Hughes, Lee, Costello, Walters, Belfer, Harlow) (BIB) (Entered: 03/05/2026)
03/04/2026	280	Plaintiffs' PowerPoint Presentation from Motion Hearing held on 3/4/2026. (BIB) (Entered: 03/06/2026)
03/05/2026	278	Judge Brian E. Murphy: ELECTRONIC ORDER finding as moot 270 Motion for Leave to File Reply Memorandum of Law. (BIB) (Entered: 03/05/2026)
03/05/2026	279	BRIEF by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services to 269 Order,,,,,,. (Belfer, Isaac) (Entered: 03/05/2026)
03/09/2026	281	AMICUS BRIEF filed by Andrea Shaw <i>Shanticia Nelson, Dr. Paul Thomas, Dr. Kenneth Stoller and Children's Health Defense</i> . (Attachments: # 1 Appendix Counsel's Declaration with Appendices)(Jaffe, Richard) (Entered: 03/09/2026)
03/09/2026	282	Opposition re 274 MOTION for Leave to File (<i>Plaintiffs' Motion for Leave to File Supplemental Declarations in Support of Their Motion for Preliminary Injunction</i>) filed by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 03/09/2026)
03/12/2026	283	Transcript of Motion Hearing held on March 4, 2026, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Jennifer Vaillancourt at jenn.m.vaillancourt@gmail.com. Redaction Request due 4/2/2026. Redacted Transcript Deadline set for 4/13/2026.

		Release of Transcript Restriction set for 6/10/2026. (DRK) (Entered: 03/12/2026)
03/12/2026	284	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 03/12/2026)
03/13/2026	285	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 274 Motion for Leave to File Document ; Counsel using the Electronic Case Filing System should now file the document for which leave to file has been granted in accordance with the CM/ECF Administrative Procedures. Counsel must include - Leave to file granted on (date of order)- in the caption of the document. (MBM) (Entered: 03/13/2026)
03/13/2026	286	DECLARATION re 285 Order on Motion for Leave to File, (<i>Second Supplemental Declaration of Georges C. Benjamin, MD, in Support of Plaintiffs' Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/13/2026)
03/13/2026	287	DECLARATION re 285 Order on Motion for Leave to File, (<i>Second Supplemental Declaration of Suzanne Berman, MD, in Support of Plaintiffs' Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/13/2026)
03/13/2026	288	DECLARATION re 285 Order on Motion for Leave to File, (<i>Declaration of Jason M. Goldman, MD, MACP, in Support of Plaintiffs' Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/13/2026)
03/13/2026	289	DECLARATION re 285 Order on Motion for Leave to File, (<i>Declaration of Jose R. Romero in Support of Plaintiffs' Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/13/2026)
03/13/2026	290	DECLARATION re 285 Order on Motion for Leave to File, (<i>Declaration of Fiona P. Havers in Support of Plaintiffs' Motion for Preliminary Injunction</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American

		Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 03/13/2026)
03/16/2026	291	Judge Brian E. Murphy: ORDER entered. MEMORANDUM AND ORDER on Plaintiffs' Motion for Preliminary Injunction. Plaintiffs' motion for preliminary relief is GRANTED in part. (i) The Court STAYS the January 2026 Memo revising the CDC's childhood immunization schedule pursuant to 5 U.S.C. § 705. (ii) The Court STAYS the appointments of the thirteen ACIP members appointed on June 11, 2025, September 11, 2025, and January 13, 2026. (iii) The Court further STAYS all votes taken by the now-stayed ACIP. (MBM) (Entered: 03/16/2026)
03/20/2026	292	Transcript of Status Conference held on January 30, 2026, before Judge Brian E. Murphy. The Transcript may be purchased through the Court Reporter, viewed at the public terminal, or viewed through PACER after it is released. Court Reporter Name and Contact Information: Rachel Lopez at raeufp@gmail.com. Redaction Request due 4/10/2026. Redacted Transcript Deadline set for 4/20/2026. Release of Transcript Restriction set for 6/18/2026. (DRK) (Entered: 03/20/2026)
03/20/2026	293	NOTICE is hereby given that an official transcript of a proceeding has been filed by the court reporter in the above-captioned matter. Counsel are referred to the Court's Transcript Redaction Policy, available on the court website at https://www.mad.uscourts.gov/caseinfo/transcripts.htm (DRK) (Entered: 03/20/2026)
03/23/2026	294	Letter from a group of licensed physicians. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H)(MBM) (Entered: 03/23/2026)
03/23/2026	295	Assented to MOTION for Extension of Time to <i>Produce the Remaining Administrative Records</i> by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Text of Proposed Order)(Belfer, Isaac) (Entered: 03/23/2026)
03/24/2026	296	Judge Brian E. Murphy: ORDER granting 295 Assented to Motion for Extension of Time to Produce the Remaining Administrative Records. The second Administrative Record (AR) is due April 13, 2026; the third AR is due April 17, 2026; the fourth AR is due May 1, 2026; the fifth AR is due May 5, 2026; and the sixth AR is due May 12, 2026. (BIB) (Entered: 03/24/2026)
03/25/2026	297	NOTICE OF APPEAL as to 291 Memorandum & ORDER,, 271 Order on Motion to Intervene, by Andrea Shaw. Filing fee: \$ 605, receipt number AMADC-11633791 Fee Status: Not Exempt. NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the First Circuit Court of Appeals web site at http://www.ca1.uscourts.gov

		MUST be completed and submitted to the Court of Appeals. Counsel shall register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf. Counsel shall also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at http://www.ca1.uscourts.gov/cmecf. US District Court Clerk to deliver official record to Court of Appeals by 4/14/2026. (Jaffe, Richard) (Entered: 03/25/2026)
03/29/2026	298	Certified and Transmitted Abbreviated Electronic Record on Appeal to US Court of Appeals re 297 Notice of Appeal. (MAP) (Entered: 03/29/2026)
03/30/2026	299	USCA Case Number 26-1325 for 297 Notice of Appeal, filed by Andrea Shaw. (MAP) (Entered: 03/30/2026)
03/31/2026	300	MOTION to Withdraw as Attorney by <i>Justin Coen</i> by America's Physician Groups, American Association of Immunologists.(Coen, Justin) (Entered: 03/31/2026)
04/01/2026	301	Judge Brian E. Murphy: ELECTRONIC ORDER entered granting 300 Motion to Withdraw as Attorney. Attorney Justin Coen terminated. (MBM) (Entered: 04/01/2026)
04/08/2026	302	TRANSCRIPT ORDER FORM by Children's Health Defense for proceedings held on 2/13 and 3/4/2026 Judge Judge Brian E. Murphy.. (Jaffe, Richard) (Entered: 04/08/2026)
04/20/2026	303	MOTION to Stay <i>Preliminary Injunction Order</i> by Andrea Shaw. (Attachments: # 1 Affidavit Declaration of Richard Jaffe, # 2 Text of Proposed Order)(Jaffe, Richard) (Entered: 04/20/2026)
04/23/2026	304	MOTION to Stay <i>Proceedings Pending the Resolution of Any Appeal of the March 16, 2026, Order of Preliminary Relief (Expedited Ruling Requested)</i> by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Text of Proposed Order)(Belfer, Isaac) (Entered: 04/23/2026)
04/24/2026	305	Judge Brian E. Murphy: ELECTRONIC PROCEDURAL ORDER entered. Plaintiffs shall file a response to 304 Defendants' Motion to Stay Proceedings no later than 12:00 pm on Friday, May 1. (MBM) (Entered: 04/24/2026)
04/29/2026	306	NOTICE OF APPEAL as to 291 Memorandum & ORDER,, by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. Fee Status: US Government. NOTICE TO COUNSEL: A Transcript Report/Order Form, which can be downloaded from the First Circuit Court of Appeals web site at http://www.ca1.uscourts.gov MUST be completed and submitted to the Court of Appeals. Counsel shall register for a First Circuit CM/ECF Appellate Filer Account at http://pacer.psc.uscourts.gov/cmecf. Counsel shall also review the First Circuit requirements for electronic filing by visiting the CM/ECF Information section at http://www.ca1.uscourts.gov/cmecf. US District Court Clerk to deliver official

		record to Court of Appeals by 5/19/2026. (Belfer, Isaac) (Entered: 04/29/2026)
04/30/2026	307	Certified and Transmitted Abbreviated Electronic Record on Appeal to US Court of Appeals re 306 Notice of Appeal. (MBM) (Entered: 04/30/2026)
04/30/2026	308	USCA Case Number 26-1503 for 306 Notice of Appeal filed by National Institutes of Health, Marty Makary, Robert F. Kennedy, Jr., Centers for Disease Control and Prevention, Matthew Buzzelli, Food and Drug Administration, United States Department of Health and Human Services, Jay Bhattacharya. (MBM) (Entered: 04/30/2026)
05/01/2026	309	Opposition re 304 MOTION to Stay <i>Proceedings Pending the Resolution of Any Appeal of the March 16, 2026, Order of Preliminary Relief (Expedited Ruling Requested)</i> filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 05/01/2026)
05/01/2026	310	DECLARATION re 309 Opposition to Motion,, (<i>Declaration of James J. Oh</i>) by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 05/01/2026)
05/01/2026	311	Judge Brian E. Murphy: ELECTRONIC ORDER entered DENYING 304 Defendants' Motion to Stay Proceedings Pending the Resolution of Any Appeal. Defendants have not established good cause that a stay is warranted, as opposed to continuing in the usual course of litigation. <i>See Marquis v. F.D.I.C.</i> , 965 F.2d 1148, 1155 (1st Cir. 1992) (“[S]tays cannot be cavalierly dispensed: there must be good cause for their issuance; they must be reasonable in duration; and the court must ensure that competing equities are weighed and balanced.”); <i>see also Contour Design, Inc. v. Chance Mold Steel Co.</i> , 649 F.3d 31, 34 (1st Cir. 2011) (“An appeal from the grant or denial of a preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending.... The only restriction on the trial court’s power occurs if the appellate court enters an order staying the lower court until the appeal has been completed.’... the district court is free to carry forward and order permanent relief after the merits are resolved.” (quoting 11A Wright & Miller, Federal Practice and Procedure § 2962, at 438–39 (2d ed. 1995))). The Court also notes that the present motion was filed on April 23, 2026, while Defendants filed an appeal of the preliminary injunction order on April 30, 2026. (MBM) (Entered: 05/01/2026)
05/04/2026	312	Opposition re 303 MOTION to Stay <i>Preliminary Injunction Order</i> filed by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Oh, James) (Entered: 05/04/2026)

05/04/2026	313	DECLARATION re 312 Opposition to Motion, by Massachusetts Public Health Association, American Academy of Pediatrics, American College of Physicians, Inc., American Public Health Association, Jane Doe, Jane Doe 2, Jane Doe 3, Infectious Diseases Society of America, Massachusetts Chapter of the American Academy of Pediatrics, Society for Maternal-Fetal Medicine. (Attachments: # 1 Exhibit (Exhibit 1), # 2 Exhibit (Exhibit 2))(Oh, James) (Entered: 05/04/2026)
05/06/2026	314	Judge Brian E. Murphy: ELECTRONIC ORDER entered DENYING 303 Motion to Stay Preliminary Injunction Order. Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, Dr. Kenneth Stoller, and Children’s Health Defense (together, “Movants”) have moved to stay this Court’s preliminary injunction order “in light of the intervening charter renewal” pending appeal, under Federal Rule of Civil Procedure 62(d). Dkt. 303 at 2. A district court may stay injunctive relief while an appeal is pending. Fed. R. Civ. P. 62(d). “Deciding a motion for a stay pending appeal requires an exercise of the court’s equitable discretion.” <i>Ark. Tchr. Ret. Sys. v. State St. Bank & Tr. Co.</i>, 527 F. Supp. 3d 40, 58 (D. Mass. 2021) (citing <i>Common Cause R.I. v. Gorbea</i>, 970 F.3d 11, 15–16 (1st Cir. 2020)). The Court can resolve this motion without reaching the merits. Movants’ motion fails because they provide no authority that Movants—acting in this case solely as amici curiae after this Court denied their motion to intervene, <i>see</i> Dkt. 271 —have standing to seek a stay of this Court’s prior order. “[A]n amicus curiae is merely a ‘friend of the court,’ not a party to the action, and to that end, an amicus may not assume the functions of a party, nor may it initiate, create, extend, or enlarge the issues.” <i>League of Women Voters of N.H. v. Kramer</i>, 2024 WL 4604323, at *1 (D.N.H. Oct. 29, 2024) (quoting <i>Famulus Health, LLC v. GoodRX, Inc.</i>, 2024 WL 4151090, at *5 (D.S.C. Sept. 11, 2024)). As such, First Circuit precedent directs that a court should ignore arguments advanced only “by amici and not by parties,” apart from those related to jurisdiction. <i>In re Sony BMG Music Ent.</i>, 564 F.3d 1, 3 (1st Cir. 2009); <i>see also United States v. Chiaradio</i>, 684 F.3d 265, 284 n.7 (1st Cir. 2012) (“[W]e adhere to the established principle that an amicus may not ‘interject into a case issues which the litigants, whatever their reasons might be, have chosen to ignore.’” (quoting <i>Lane v. First Nat’l Bank of Bos.</i>, 871 F.2d 166, 175 (1st Cir. 1989))), <i>cert. denied</i>, 568 U.S. 1004 (2012). Further, the Court has found no authority for the proposition that a non-party may move for relief that a party has not themselves sought, <i>cf. Disability L. Ctr. v. Mass. Dep’t of Corr.</i>, 2017 WL 1042068, at *2 (D. Mass. Mar. 17, 2017) (“Aldrich lacks standing to seek to reopen the case [under Federal Rule of Civil Procedure 60] because he was not a party to it.”); <i>Murphy v. Franklin Reg’l Hosp.</i>, 2008 WL 5054688, at *1 (D.N.H. Nov. 20, 2008) (“Because NH HHS is not a party, it lacks standing to file a motion to reconsider an order issued in this case.”), and it is Movants’ responsibility to identify legal authority in support of their position, <i>see Lovern v. Astrue</i>, 2011 WL 4621455, at *6 (D. Mass. Sept. 29, 2011) (noting that “it is the parties[’] burden, not the court[’s], to develop arguments in support of their claims/positions, with citation to relevant legal authority” (citing <i>Shaner v. Chase Bank USA</i>, 587 F.3d 488, 494 (1st Cir. 2009))); <i>see also United States v. Zannino</i>, 895

		F.2d 1, 17 (1st Cir. 1990) (“It is not enough merely to mention a possible argument in the most skeletal way, leaving the court to do counsel’s work, create the ossature for the argument, and put flesh on its bones.”). Accordingly, Movants’ motion is DENIED. (MBM) (Entered: 05/06/2026)
05/20/2026	315	NOTICE OF HEARING: Status Conference is scheduled for 6/2/2026 at 10:30 a.m. remotely by Zoom before Judge Brian E. Murphy. A review of the docket indicates that production of the administrative record should have been completed but has not been filed. Defendants shall file the administrative record on the docket no later than May 22, 2026. By noon on May 29, 2026, the parties shall file a Joint Status Report indicating the current status of the case, including: (1) a summary of any disputes regarding the administrative record; (2) if there are disputes over the scope of the record, a proposed briefing schedule to resolve such disputes; (3) a proposed briefing schedule for summary judgment motions; and (4) any other matters which should be addressed at the conference. (BIB) (Entered: 05/20/2026)
05/22/2026	316	Assented to MOTION Relief from the May 22, 2026 Deadline to File the Administrative Records on the Docket re 315 Notice of Hearing,,, by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Does 1-50, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 Text of Proposed Order)(Harlow, James) (Entered: 05/22/2026)
05/22/2026	317	Judge Brian E. Murphy: ORDER entered granting 316 Assented to MOTION Relief from the May 22, 2026 Deadline to File the Administrative Records on the Docket re 315 Notice of Hearing. (MBM) (Entered: 05/22/2026)
05/29/2026	318	Joint MOTION for Protective Order by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Attachments: # 1 [Proposed] Stipulated Protective Order, # 2 Exhibit 1: Confidentiality Agreement)(Belfer, Isaac) (Entered: 05/29/2026)
05/29/2026	319	STATUS REPORT <i>Joint Status Report</i> by Jay Bhattacharya, Matthew Buzzelli, Centers for Disease Control and Prevention, Food and Drug Administration, Robert F. Kennedy, Jr, Marty Makary, National Institutes of Health, United States Department of Health and Human Services. (Belfer, Isaac) (Entered: 05/29/2026)
06/01/2026	320	Judge Brian E. Murphy: STIPULATED PROTECTIVE ORDER granting 318 Joint Motion for Entry of Protective Order. (BIB) (Entered: 06/01/2026)
06/01/2026	321	NOTICE CANCELING HEARING: Upon review of the 319 Joint Status Report filed on May 29, 2026, the Status Conference scheduled for 6/2/2026, is CANCELED. The parties are ORDERED to file a further Status Report no later than 6/24/2026. (BIB) (Entered: 06/01/2026)

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**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

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

Defendants Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services; United States Department of Health and Human Services; Jim O’Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention (“CDC”); and CDC move this Court under Federal Rules of Civil Procedure 12(b)(1) and (6) to dismiss this action for lack of subject-matter jurisdiction and failure to state a claim for relief. The grounds for this motion are fully set forth in an accompanying memorandum.

November 19, 2025

Respectfully submitted,

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LOCAL RULE 7.1 CERTIFICATE

Per Local Rule 7.1, counsel for Defendants state that they conferred with counsel for Plaintiffs by email on November 19, 2025, and counsel for Plaintiffs stated that they oppose Defendants' Motion to Dismiss the Third Amended Complaint for Lack of Subject-Matter Jurisdiction and Failure to State a Claim for Relief.

/s/ Isaac C. Belfer
Isaac C. Belfer

CERTIFICATE OF SERVICE

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

November 19, 2025

/s/ Isaac C. Belfer
Isaac C. Belfer

**UNITED STATES DISTRICT COURT
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**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

**[Proposed] Order Granting Defendants' Motion to Dismiss the Third Amended
Complaint for Lack of Subject-Matter Jurisdiction and Failure to State a
Claim for Relief**

Before the Court is Defendants' Motion to Dismiss the Third Amended Complaint for Lack of Subject-Matter Jurisdiction and Failure to State a Claim for Relief. Having considered the parties' arguments in light of the governing standards, it is hereby ORDERED that Defendants' Motion is GRANTED, and this case is DISMISSED for lack of subject-matter jurisdiction and failure to state a claim for relief. The Clerk shall close the case.

SO ORDERED.

Dated: _____

HON. BRIAN E. MURPHY
U.S. DISTRICT JUDGE

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

AMERICAN ACADEMY OF PEDIATRICS,
et al.,

Plaintiffs,

V.

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

Defendants.

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

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

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Regulations

INTRODUCTION

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

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

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

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

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

BACKGROUND

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

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

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

preventable diseases.” ACIP Charter, <https://perma.cc/6CNV-L5XR>, at 1.¹ Its recommendations “are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in [CDC’s] *Morbidity and Mortality Weekly Report*.” *Id.*

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

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

II. The Directive and Its Implementation by CDC

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

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

groups.² On May 27, 2025, Secretary Kennedy issued the Directive. ECF No. 103-1³; *see* 42 U.S.C. §§ 242c(b), 243. Based on recommendations from FDA and the National Institutes of Health (“NIH”), the Secretary rescinded two prior directives that had “ratif[ied] CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years” and rescinded CDC’s “recommendation that pregnant women receive” the vaccine. ECF No. 103-1.

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

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

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

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

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

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

On September 19, 2025, ACIP voted in favor of new recommendations for the COVID-19 vaccine, which the Acting Director of CDC then adopted. *See* HHS, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-making*, <https://perma.cc/BP2T-97ZS> (September 19, 2025). On October 6, 2025, CDC’s immunization schedules were updated to reflect the new ACIP recommendations. *See* CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making⁴ for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, <https://perma.cc/SD3P-G2V7> (Oct. 6, 2025) (“CDC Announcement”).

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

⁴ “Individual-based decision-making” is also known as “shared clinical decision-making.” <https://perma.cc/SD3P-G2V7>.

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

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

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

IV. Procedural History

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

LEGAL STANDARD

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

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

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

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

ARGUMENT

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

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

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

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

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

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

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

II. Plaintiffs Lack Standing to Assert Any of Their Claims

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

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

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

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

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

A. The Individual Plaintiffs Do Not Have Standing

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Alleged Interference with the Standard of Care

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

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

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

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

2. Alleged Harm to Medical Practices

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

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

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

According to Plaintiffs, their members are “not able to bill for the additional time” spent counseling their patients, calling around “to determine [vaccine] availability,” or “counseling fellow practitioners” about the vaccine and so must “perform uncompensated work.” *Id.* ¶¶ 90, 102–07. However, any financial injury is not fairly traceable to the challenged CDC immunization recommendations or ACIP membership. Rather, the “chain of causation is simply too attenuated,” involving speculation about the decisions of numerous “independent actors.” *All. for Hippocratic Med.*, 602 U.S. at 383, 391 (quotation omitted). Plaintiffs have conceded that healthcare providers are reimbursed for counseling patients about the vaccine “if the vaccine is actually administered to the patient” but not if the patient declines the vaccine. ECF No. 118-4, ¶¶ 13, 18.⁹ Thus, the alleged injury to healthcare providers rests on “speculation” about how “independent” patients will exercise their “unfettered choice[]” whether to get vaccinated. *All. for Hippocratic Med.*, 602 U.S. at 383 (quotation omitted). Plaintiffs’ alleged injuries also rest on speculation about insurers’ reimbursement decisions. And if, despite knowing he will not be compensated, a healthcare provider chooses to do additional work, such as helping other providers care for their patients, TAC ¶ 107, any harm is “self-inflicted” and not fairly traceable to the challenged actions. *Pennsylvania v. New Jersey*, 426 U.S. 660, 664 (1976) (per curiam).

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

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

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

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

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

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

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

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

Finally, Plaintiffs cannot show standing based on their members’ “ideological[] or policy objection” to the challenged actions. *All. for Hippocratic Med.*, 602 U.S. at 381. For example, Massachusetts Public Health Association members assert a “generalized grievance” based on their “abstract” interest in “maternal and child health, vaccine delivery, and pandemic response in Massachusetts.” TAC ¶ 97; *All. for Hippocratic Med.*, 602 U.S. at 381.¹² Columbus Public Health asserts a similar generalized grievance, TAC ¶ 93, and, in any event, it is not an independent legal entity that can confer standing on the American Public Health Association

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

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

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

3. Alleged Injuries to Members’ Patients

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

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

III. Count II Fails to State a Claim for Relief

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

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

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

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

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

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

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

CONCLUSION

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

November 19, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

November 19, 2025

/s/ Isaac C. Belfer
Isaac C. Belfer

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action No.
25-11916-BEM

**MEMORANDUM AND ORDER ON
DEFENDANTS' MOTION TO DISMISS**

MURPHY, J.

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

I. Background

A. Factual Background

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

54, 59 (1st Cir. 2017). Additionally, on a Rule 12(b) motion, the Court may consider “facts subject to judicial notice,” *Cangrejeros De Santurce Baseball Club, LLC v. Liga De Beisbol Profesional De P.R.*, 146 F.4th 1, 11 (1st Cir. 2025), including information on official government websites, *Gent v. CUNA Mut. Ins. Soc’y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010).

1. The Parties

Plaintiffs are seven professional medical organizations (collectively, “Organizational Plaintiffs”),¹ and three individuals (collectively, “Individual Plaintiffs,” and with Organizational Plaintiffs, “Plaintiffs”).²

Defendants are the U.S. Department of Health and Human Services (“HHS”); the Secretary of HHS, Robert F. Kennedy, Jr. (“Secretary Kennedy”); the Centers for Disease Control and Prevention (the “CDC”); the Acting Director of the CDC, Jim O’Neill (“Director O’Neill”); and Does 1 through 50.³

2. Statutory Framework

Congress requires the Secretary of HHS to conduct an “evidence-based campaign” aimed at combating misinformation and increasing rates of vaccination. 42 U.S.C. § 245(a). To assist in this public health mission, the CDC relies on the Advisory Committee on Immunization Practices (“ACIP”). Dkt. 139 (“Compl.” or “Complaint”) ¶¶ 29–32.⁴ ACIP, a federal advisory committee

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

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

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

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

constituted under the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et seq.* (“FACA”), is responsible for developing and issuing evidence-based recommendations for the use of vaccines in the United States. Compl. ¶¶ 29–34.⁵ In 2018, ACIP adopted the Evidence to Recommendation (“EtR”) framework “to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.”⁶ *Id.* ¶ 60. These recommendations for whether and how vaccines are listed on the CDC’s immunization schedules are provided to the CDC Director to decide whether to adopt and publish them in the official immunization schedules, which guide healthcare providers and state public health authorities. *Id.* ¶¶ 29–34.

3. May 2025 Directive

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

⁵ See also *supra* note 4.

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

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

4. ACIP Reconstitution

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

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

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

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

5. Threatened Legal Liability

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

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

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

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

6. ACIP September 2025 Vote

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

B. Procedural Background

Plaintiffs filed suit on July 7, 2025. Dkt. 1. In the Complaint, Plaintiffs allege that Defendants’ changes to the vaccine recommendations and reconstitution of ACIP (collectively, the “Challenged Actions”) violate section 706(2)(A) of the Administrative Procedure Act (“APA”) because they were arbitrary and capricious (Count I), and that the reconstitution of ACIP violates section 706(2)(A) of the APA because it was contrary to law (Count II). Compl. ¶¶ 108–126.¹¹ On September 3, 2025, Defendants moved to dismiss the Complaint under Rules 12(b)(1) and 12(b)(6). Dkt. 144; *see also* Dkt. 145 (“Mem.”); Dkt. 146 (“Opp.”); Dkt. 146 (“Reply”). The Court held a hearing on December 17, 2025, and took the matter under advisement.

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

II. Standard of Review

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

III. Jurisdiction

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

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

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

A. Standing

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

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

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

1. Organizational Plaintiffs

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

a. Organizational Standing

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

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

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

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

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

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

Defendants argue that AAP’s “educational and advocacy work” to respond to the Challenged Actions is merely “a continuation of [its] ‘ongoing activities.’” Mem. at 17. But AAP has alleged more than that. Similarly to *Havens*, AAP alleges that its ability to provide its regular programming and resources to both its members and others has been impaired by the need to specifically address the Challenged Actions and to divert resources in response to Defendants’ actions. *Havens*, 455 U.S. at 379. AAP—and additional Organizational Plaintiffs¹⁴—has alleged that it needed to divert resources away from its usual business activities because of the Challenged Actions, including by counseling member-doctors who have been directly impacted (such as through direct counseling and webinars). Compl. ¶ 86; Dkt. 118-9 ¶¶ 4–6; *cf. Friends of the Earth v. Sanderson Farms, Inc.*, 992 F.3d 939, 943 (9th Cir. 2021) (“Once [the defendant’s] misleading advertisements were brought to the attention of the [plaintiff organizations], they simply continued doing what they were already doing—publishing reports on and informing the public of various companies’ antibiotic practices.”). Furthermore, Defendants mischaracterize AAP’s immunization schedules by calling them mere “educational and advocacy work.” Mem. at 17. AAP “[maintains] and publi[shes] . . . the AAP Red Book [containing] . . . AAP’s immunization recommendations” as part of its efforts “to support the professional needs of its members.” Dkt. 146-5 ¶ 8. AAP’s recommendations to physicians on vaccine use predate the creation of

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

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

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

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

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

b. Associational Standing

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

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

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

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

i. Financial Injury

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

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

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

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

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

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

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

ii. Threat of Legal Action

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

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

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

2. Individual Plaintiffs

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

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

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

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

B. Mootness

“A case becomes moot—and therefore no longer a ‘Case’ or ‘Controversy’ for purposes of Article III—when the issues presented are no longer ‘live’ or the parties lack a legally cognizable interest in the outcome.” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)). “The Supreme Court has placed the ‘heavy burden of persuasion’ with respect to mootness on the party advocating for it.” *Town of Barnstable v. O’Connor*, 786 F.3d 130, 142 (1st Cir. 2015) (quoting *United States v. Concentrated Phosphate Exp. Ass’n*, 393 U.S. 199, 203 (1968)). “[T]he key question ‘is whether the relief sought would, if granted, make a difference to the legal interests of the parties (as distinct from their psyches, which might remain deeply engaged with the merits of the litigation).’” *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 8 (1st Cir. 2021) (quoting *Air Line Pilots Ass’n, Int’l v. UAL Corp.*, 897 F.2d 1394, 1396 (7th Cir. 1990)).

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

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

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

IV. Merits

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

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

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

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

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

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

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

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

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

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

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

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

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

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

V. Conclusion

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

So Ordered.

Dated: January 6, 2026

/s/ Brian E. Murphy

Brian E. Murphy

Judge, United States District Court

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

EXHIBIT A

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

AMERICAN ACADEMY OF PEDIATRICS,
AMERICAN COLLEGE OF PHYSICIANS,
INC., AMERICAN PUBLIC HEALTH
ASSOCIATION, INFECTIOUS DISEASES
SOCIETY OF AMERICA, MASSACHUSETTS
PUBLIC HEALTH ASSOCIATION D/B/A
MASSACHUSETTS PUBLIC HEALTH
ALLIANCE, SOCIETY FOR MATERNAL-
FETAL MEDICINE, THE MASSACHUSETTS
CHAPTER OF THE AMERICAN ACADEMY
OF PEDIATRICS, JANE DOE 1, JANE DOE 2,
and JANE DOE 3,

Plaintiffs,

VS.

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

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive,

Defendants.

[PROPOSED] PRELIMINARY INJUNCTION ORDER

This matter comes before the Court on the motion of Plaintiffs for a preliminary injunction. Having reviewed Plaintiffs' Fourth Amended Complaint, the memorandum of law, declarations, and other evidence in support of the motion, as well as any papers filed in opposition to this motion and the presentations by each party at the February 13, 2026 hearing, and in accordance with FED. R. CIV. P. 65, and for good cause shown, the Court finds that Plaintiffs have satisfied the

requirements for the issuance of a preliminary injunction. Plaintiffs have established: a substantial likelihood of success on the merits of their claims, that Plaintiffs will be irreparably harmed absent a preliminary injunction, and that the public interest and balance of the equities strongly favor entry of a preliminary injunction.

It is hereby ORDERED that Plaintiffs' Motion for Preliminary Injunction is GRANTED and a PRELIMINARY INJUNCTION is entered in this case.

It is further ORDERED that:

1. Defendants are ENJOINED from implementing, enforcing, or giving effect to the following actions pending final judgment in this case or further order of this Court:

- a. The Secretarial Directive, announced in a video posted on X on May 27, 2025, instructing the Centers for Disease Control and Prevention ("CDC") to remove the recommendations from CDC immunization schedules that pregnant women and children receive the Covid vaccine;
- b. The June 26, 2025 Advisory Committee on Immunization Practices ("ACIP") vote to remove thimerosal from all influenza vaccines distributed in the United States, and the adoption by the Secretary of Health and Human Services (Robert F. Kennedy, Jr.) of that vote on July 23, 2025;
- c. The September 19, 2025 ACIP vote downgrading the COVID-19 vaccine recommendation for individuals under age 65 from routinely recommended to shared clinical decision-making ("SCDM"), and the CDC's adoption of that vote on October 6, 2025;
- d. The December 5, 2025 vote of the ACIP to downgrade the Hepatitis B ("HepB") vaccine recommendation from a routinely recommended three-dose series starting at birth for all children to SCDM for all doses for children born to HepB negative mothers, and the CDC's adoption of that vote on December 16, 2025.
- e. The Decision Memo signed by Acting CDC Director Jim O'Neill on January 5, 2026 revising the CDC Recommended Immunization Schedule for Children and Adolescents by downgrading: Hepatitis A, HepB, MenACWY, and RSV vaccines to risk-based recommendations; downgrading Hepatitis A, Influenza, MenACWY, and Rotavirus vaccines to shared clinical decision-making; removing the second dose of the HPV vaccine; removing the HepB birth dose for infants in the shared clinical decision-making category; and limiting the age range of the MenB shared clinical decision-making recommendation.

2. Defendants are FURTHER ENJOINED 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.

3. Defendants are ENJOINED 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. This injunction shall remain in effect until final adjudication on the merits of Plaintiffs' claims challenging the lawfulness of the current ACIP membership and appointments, or further order of the Court.

4. Defendants shall file a status report with the Court within 24 hours of entry of this Order of preliminary injunction confirming their compliance with this Order.

5. Defendants shall provide notice of this Order within 24 hours of entry of this Order to all Defendants, their employees, agents, and anyone acting in concert with them.

6. The Court, in its discretion, waives the requirement that Plaintiffs post bond under FED. R. CIV. P. 65(c).

The preliminary injunction shall remain in effect pending final judgment or further order of this Court.

SO ORDERED.

Dated: _____

HON. BRIAN E. MURPHY
U.S. DISTRICT JUDGE

EXHIBIT 18

**Decision Memo**

DATE: January 5, 2026

TO: Jim O'Neill, Acting Director, Centers for Disease Control and Prevention (CDC)

FROM: Jay Bhattacharya, MD, PhD, Director, National Institutes of Health
Mehmet Oz, MD, MBA, Administrator, Centers for Medicare and Medicaid Services
Marty Makary, MD, MPH, Commissioner of Food and Drugs

SUBJECT: DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

PURPOSE

This memorandum proposes a revised childhood and adolescent immunization schedule for your review and approval.

RECOMMENDATION AND ACTION REQUESTED

After considering the data and recommendations contained in TAB 1, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," and your discussions with relevant health officials, you should approve the revised immunization schedule.

BACKGROUND AND SUMMARY OF RECOMMENDED ACTION

On December 5, 2025, the President directed the Department of Health and Human Services (HHS) and the Centers for Disease Prevention and Control (CDC) to review best practices from peer, developed nations regarding core childhood vaccination recommendations and the scientific evidence underlying those practices. The President further instructed that, "if [HHS and CDC] determine that those best practices are superior to current domestic recommendations, 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."

As part of this review, you discussed childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark. You also discussed immunizations with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy, respectively.

TAB 1 is the review of peer nations' best practices and the scientific evidence underlying those practices. Dr. Tracy Beth Høeg, Acting Director of the FDA Center for Drug Evaluation and Research (CDER), and Dr. Martin Kullendorff, Chief Science and Data Officer, HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), authored TAB 1 in consultation with subject matter

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officials at CDC, FDA, the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS). After a careful review of the current U.S. childhood and adolescent immunization schedule, peer nations' schedules and best practices, and the underlying evidence and data, TAB 1 recommends adopting a revised childhood and adolescent immunization schedule that is based on those vaccines for which there is broad-based international consensus. The consensus vaccines are recommended for all children.

The recommended schedule includes consensus vaccines for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella. This vaccine schedule reflects the Danish schedule except that this revised schedule adds the varicella vaccine, which is not currently on the Danish schedule. TAB 1 proposes that the CDC recommend these vaccines for all children.

In addition to the consensus vaccines, the schedule recommended in TAB 1 includes immunizations for high-risk groups and immunizations based on shared clinical decision making. Unlike the consensus vaccines, these are immunizations for which there is not broad-based consensus and TAB 1 discusses the scientific evidence regarding why they should not be recommended for all children.

TAB 1 does not assess and propose any changes to recommendations for high-risk populations. Those immunizations include: Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue.

TAB 1 also proposes that CDC's recommended childhood and adolescent immunization schedule list vaccines for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 be based on shared clinical decision making. The CDC applies shared clinical decision-making recommendations when evidence indicates that individuals may benefit from vaccination based on an analysis of the individual's characteristics, values, and preferences, the provider's medical judgment, and the characteristics of the vaccine being considered.

The recommendation to realign the CDC's immunization schedule under a framework built on 11 consensus vaccines is not a significant departure from the current recommended immunization construct. The current CDC schedule (TAB 2) categorizes routine immunization recommendations into three general categories: (1) population-based (i.e., age-based, including catch-up), (2) risk-based (i.e., immunosuppression, other underlying medical conditions, work-related, or other special circumstances that increase risk of illness), and (3) shared clinical decision-making-based.

Under the new framework, measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella constitute category 1, the population-based category of routine immunizations, and are recommended for all children. Immunizations currently recommended for high-risk groups continue to be recommended for high-risk groups under category 2 in the preceding paragraph. Hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 remain on the schedule based on shared clinical decision-making, category 3 above.

Finally, consistent with the President's direction to "preserv[e] access to vaccines currently available to Americans," all the immunizations listed in the preceding paragraphs are (i) on the current schedule, (ii) will remain on the revised schedule, and, therefore, (iii) continue to be covered without cost sharing by

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private insurance and covered by Medicaid, Children’s Health Insurance Program (CHIP), and the Vaccines for Children Program.

*** Figure 1 on pages 2-3 of TAB 1 illustrates the proposed schedule with recommended doses and ages.**

DISCUSSION

Before reviewing and assessing the current childhood and adolescent immunization schedule relative to those of peer nations, it is important to first understand what, if any, problems currently exist with childhood immunization in the United States.

Current Problem: Decreased Vaccine Uptake and Trust

Childhood vaccination rates in America have fallen over the past five years. From the 2019/20 to 2023/24 school year, there was a decline in childhood measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%. In the 2024-2025 academic year, 16 states had MMR vaccination rates below 90%, which is below the critical threshold for herd immunity for measles. Consequently, in 2025 there were nearly 50 measles outbreaks and over 1,800 measles cases attributed to those outbreaks. Finally, although the CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.

Robust immunization programs are an essential public health tool, but those tools are only effective when there is public trust. Unscientific belief that vaccine-acquired immunity was superior to infection-acquired immunity combined with inaccurate CDC claims that the COVID-19 vaccine would prevent infection and transmission eroded public trust in the COVID-19 vaccine.

The loss of trust in the COVID vaccines coincided with less adherence to the full CDC childhood vaccine schedule, which has resulted in lower immunization rates of well-established vaccines, such as those for measles, rubella, pertussis, and polio.

Current Problem: Knowledge Gaps Concerning Safety

The Institute of Medicine (IOM) stated in a report that “vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective.” The United States administers significantly more doses of childhood immunizations than its peer nations, yet there is a significant knowledge gap due to a dearth of randomized vaccine trials and limited post-licensure infrastructure for monitoring potential adverse reactions and long-term chronic events.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS), but the two key components are CDC’s Vaccine Safety Datalink (VSD) and FDA’s Biologics Effectiveness and Safety (BEST) System. These systems typically conduct limited safety review using risk windows after vaccination which inject significant bias and severely limits the potential to detect serious harms, but despite this and other serious limitation, these systems within a year of vaccine approval have confirmed serious harm, including intussusception after rotavirus

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vaccines, febrile seizures after the MMRV vaccine, and anaphylaxis and myocarditis after the mRNA COVID-19 vaccines. Additionally, current surveillance systems are underutilized to detect long-term harms.

International Comparison of Childhood Vaccine Schedules

As illustrated in Table 2 on page 15 of TAB 1, the United States currently recommends more childhood vaccines than any peer nation, and more than twice as many vaccine doses as some European nations.

While a set of consensus vaccines is consistently recommended in all peer countries, several vaccines included in the current CDC childhood and adolescent immunization schedule (e.g., hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries. Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of threat varies widely by disease and sometimes by individual underlying risk factors. The mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify universal vaccination.

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, 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. Disagreement among states and professional societies in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Broad-based insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the vaccine schedule. Identifying the consensus vaccines on the schedule would help Americans follow the schedule while making all vaccines available for parents also wanting non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

Recommended Immunization Schedule Based on Assessment of Peer Nations and Scientific Evidence

Immunizations Recommended for All Children: These are immunizations that are important for all children to receive. They include measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines. These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the exception of mumps in Japan. While the safety/risk profile is not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake of these vaccines.

In addition to the vaccines listed above for which there is nearly unanimous peer nation agreement, HPV and varicella vaccines should also be included.

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The scientific evidence for the HPV vaccine—increasingly recognized by peer nations in their own recommendations—supports one dose instead of two when given to children. Australia, parts of Canada, Ireland, Spain, and the United Kingdom have already changed their recommendations to one dose.

The varicella zoster virus causes chickenpox (typically in children) and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule, but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine. The rate of two dose vaccination for varicella among American children is estimated at 92%. Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications. For these reasons, the varicella vaccine should remain a consensus vaccine.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. TAB 1 does not propose any changes in immunization recommendations for high-risk populations.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian, something that should occur for all vaccines. It is not always possible or pragmatic for public health officials to clearly define who will benefit from a vaccine, who has the relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine. While non-consensus immunizations are not routinely recommended for all children, all these vaccines will continue to be available for anyone who wants them and will be covered by Medicaid, CHIP, the Vaccines for Children Program, and private health insurance.

- Hepatitis A: When hepatitis A vaccines were approved in the 1990s, the primary candidates for vaccination were “travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one.” Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A

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was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation. Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.

- **Hepatitis B:** Together with hepatitis B immune globulin, it is important that infants are administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend routine vaccination at birth: Australia and Portugal, while two countries do not recommend it at all. At their December 2025 meeting, the ACIP followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.
- **Rotavirus:** Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad. In the developing world, many children die from dehydration after catching the virus, and there is a greater opportunity for benefit from vaccination. In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity.

Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005. This was after the RotaShield vaccine was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020. There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices, or random fluctuations.

RotaShield was removed from the market due to an excess risk of intussusception. The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children. Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule.

- **Meningococcal disease:** Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups. The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy. The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a “large scale meningococcal vaccination program,” while only vaccinating the high-risk population in countries with lower rates. In the

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United States, the current incidence rate is around 0.1 per 100,000 is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.

Considering the low incidence rates of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine.

- **Influenza:** The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits. There are a few post-licensure randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration. They found that “in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)” infections while “inactivated vaccines also reduce influenza (high certainty evidence).” Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

The conclusion of the Cochrane systematic review of randomized trials in children was that “Decision-makers’ attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza.”

There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization, but that is a notoriously biased study design with highly implausible results.

While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome. During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents. The Cochrane systematic review, noted that “the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada” and that “the manufacturers’ refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines.”

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Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group.

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

- **COVID-19:** In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children. Since then, all other peer nations have followed. At their September 2025 meeting, the ACIP voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.

Finally, if you approve the revised schedule, you should also later recommend to the Secretary that HHS agencies fund and conduct gold standard medical research to assess overall health outcomes related to all immunizations on the revised schedule (i.e., immunizations recommended for all children, immunizations recommended for high-risk groups, and immunizations based on shared clinical decision making), the interaction effects between different immunizations as well as other aspects of the immunization schedule—something that is needed to close the knowledge gap.

EXECUTION

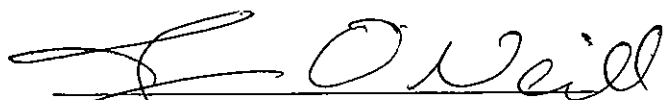
If approved, the revised childhood and adolescent immunization schedule will be published in an upcoming *Morbidity and Mortality Weekly Report*. CDC will also publish the CDC-adopted recommendation on the applicable CDC website and also update the childhood and adolescent schedule in alignment with this decision.

DECISION

After thoroughly reviewing the assessment in TAB 1 and further considering the childhood immunization recommendations based on my discussions with CDC, FDA, and peer, developed nation health officials, I have determined that the CDC will adopt the revised childhood and adolescent immunization schedule, as stated in Figure 1 of TAB 1. Specifically, the CDC immediately recommends: (1) immunization for the measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella for all children; (2) specified immunizations for high-risk groups (Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue); and (3) immunization for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 based on shared clinical decision making, as stated in Figure 1 of TAB 1.

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Approved: ✓ Disapproved: _____ Would like briefing: _____



Jim O'Neill
Acting Director, CDC

January 5, 2025

Date

TABS

1. “Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries”
2. Current CDC Recommended Childhood and Adolescent Immunization Schedule

EXHIBIT 21

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**AMENDMENT
to the
CHARTER
of the
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES**

Advisory Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP).

Authority.

The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §217a), as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.

The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities.

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

The ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the *Morbidity and Mortality Weekly Report (MMWR)*. The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations. Upon the licensure of any vaccine or any new indication for a vaccine, the Committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the Committee does not make a recommendation at the Committee's first regularly scheduled meeting, the Committee shall provide an update on the status of such for the Committee's review.

Description of Duties.

The Committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the Committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The Committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The Committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues. The Committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the Committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Official to Whom the Committee Reports.

The Committee reports to the Director, CDC. The CDC Director informs the Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations.

Support.

Management and support services shall be provided by the Office of the Director, National Center for Immunization and Respiratory Diseases, CDC.

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Estimated Annual Operating Costs and Staff Years.

Estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is \$409,922. Estimate of annual person-years of staff support required is 9.40, at an estimated annual cost of \$1,760,637.

Designated Federal Officer.

CDC will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting policies and agendas, call all of the committee and subcommittee meetings, adjourn any meeting when the DFO deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees. In the event that the DFO cannot fulfill the assigned duties of the Committee, one or more full-time or permanent part-time employees will be assigned as DFO and carry out these duties on a temporary basis.

Estimated Number and Frequency of Meetings.

Meetings shall be held approximately three times per year at the call of the DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Director, CDC, or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. § 552b(c)) and Section 10(d) of the Federal Advisory Committee Act ((5 U.S.C. § 1009(d)). Notice of all meetings shall be given to the public.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, the ACIP will terminate two years from the date this charter is filed.

Membership and Designation.

The Committee shall consist of up to 19 Special Government Employees, including the Chair and Vice Chair. Members shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The Committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The Committee also shall consist of six non-voting ex-officio members from the Health Resources and Services Administration; the Food and Drug Administration; Centers for Medicare and Medicaid Services; National Institutes of Health; Indian Health Service; and the Office of Infectious Disease and HIV/AIDS Policy, HHS; or their designees.

If fewer than a quorum of ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representatives from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Associates; American College Health Association; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Innovation Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; International Society of Travel Medicine; National Association of County and City Health Officials; National Association of Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research and Manufacturers of America; Society for Adolescent Health and Medicine; Society for Healthcare Epidemiology of America and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the Committee. Liaisons shall be deemed representatives.

Members, including the Chair and Vice Chair, shall be selected by the Secretary and shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

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Subcommittees.

Subcommittees composed, in part, of members of the parent committee and other subject matter experts may be established with the approval of the Secretary, HHS, or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping.

The records of the committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

Filing Date.

April 1, 2026

Amended Filing Date.

Approved:

12/3/2025
Date

Rec'd Kennedy

Robert F. Kennedy, Jr.

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

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; *et al.*,

Defendants.

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

**PLAINTIFFS' UNOPPOSED MOTION FOR LEAVE
TO FILE A CORRECTED MEMORANDUM OF LAW IN
SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION**

Plaintiffs, American Academy of Pediatrics, *et al.*, by and through their attorneys, hereby move this honorable Court for leave to file a Corrected Memorandum of Law in Support of Their Motion for Preliminary Injunction. In support of their Motion, Plaintiffs state:

1. Plaintiffs filed their Memorandum of Law in Support of Their Motion for Preliminary Injunction (the "Memorandum") on January 26, 2026. *See* ECF No. 184. Defendants' opposition to Plaintiffs' Motion for Preliminary Injunction is due February 9, 2026. Plaintiffs seek leave to file a Corrected Memorandum of Law in Support of Their Motion for Preliminary Injunction (the "Corrected Memorandum") to correct the citations as to three district court decisions.

2. The Court may correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in part of the record. *See e.g.* FED. R. CIV. P. 60(a). Plaintiffs bring this Motion to correct mistakes in the record.

3. After filing their brief, Plaintiffs identified three citations that require correction to reflect subsequent procedural developments and to ensure the accuracy of the record before the Court. Specifically, Plaintiffs have removed or updated citations to account for intervening case history and have substituted alternative authorities where appropriate.

4. None of these citation corrections alter Plaintiffs’ factual assertions, legal standards, or substantive arguments in any way. The corrections do not add new arguments, expand the scope of relief requested, or otherwise change Plaintiffs’ position. The purpose of this filing is simply to ensure that the Court has an accurate and current set of authorities before it.

5. Granting this Motion will not prejudice Defendants, who will not be required to respond to any new arguments, nor will it delay the Court's consideration of the pending motion.

6. To promote transparency and to assist the Court in identifying the proposed changes, Plaintiffs have attached a redline showing all changes to the Memorandum, which are limited to the three corrected citations.

7. Counsel for Plaintiffs conferred via email with counsel for Defendants on February 9, 2026. Defendants do not oppose this Motion. Plaintiffs' Local Rule 7.1 Certification is attached hereto.

8. The proposed Corrected Brief is attached as **Exhibit A**.

9. An errata sheet detailing the corrections is attached as **Exhibit B**.

WHEREFORE, Plaintiffs respectfully request that the Court grant leave to allow Plaintiffs to file their Corrected Memorandum of Law in Support of their Motion for Preliminary Injunction.

Dated: February 9, 2026

Respectfully submitted,

By: /s/ *James J. Oh*

James J. Oh (admitted *pro hac vice*)

Kathleen Barrett (admitted *pro hac vice*)

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**LOCAL RULE 7.1 CERTIFICATE REGARDING PLAINTIFFS' MOTION FOR LEAVE
TO FILE A CORRECTED MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION FOR PRELIMINARY INJUNCTION**

Per Local Rule 7.1, counsel for Plaintiffs state that they conferred with counsel for Defendants via email on February 9, 2026, and counsel for Defendants do not oppose the filing of Plaintiffs' Motion for Leave to File a Corrected Memorandum of Law in Support of Their Motion for Preliminary Injunction.

/s/ James J. Oh

James J. Oh

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 9th day of February 2026:

Robert F. Kennedy, Jr., in his official capacity
as Secretary of Health and Human Services

Jim O'Neill, in his official capacity as Acting
Director Centers for Disease Control and
Prevention

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/s/ James J. Oh
James J. Oh

E HIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS,
AMERICAN COLLEGE OF PHYSICIANS,
INC., AMERICAN PUBLIC HEALTH
ASSOCIATION, INFECTIOUS DISEASES
SOCIETY OF AMERICA, MASSACHUSETTS
PUBLIC HEALTH ASSOCIATION D/B/A
MASSACHUSETTS PUBLIC HEALTH
ALLIANCE, SOCIETY FOR MATERNAL-
FETAL MEDICINE, THE MASSACHUSETTS
CHAPTER OF THE AMERICAN ACADEMY
OF PEDIATRICS, JANE DOE 1, JANE DOE 2,
and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; JIM O'NEILL, in his official capacity
as Acting Director of Centers for Disease Control
and Prevention; CENTERS FOR DISEASE
CONTROL AND PREVENTION; and DOES 1
50, inclusive,

Defendants.

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

**PLAINTIFFS' CORRECTED
MEMORANDUM OF LAW IN
SUPPORT OF THEIR MOTION FOR
PRELIMINARY INJUNCTION**

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

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INTRODUCTION

Since his confirmation as Secretary of the United States Department of Health and Human Services (“HHS”) on February 13, 2025, Defendant Robert F. Kennedy, Jr. (the “Secretary”), along with HHS and the agencies and officials acting under his leadership (collectively, “Defendants”), have engaged in a series of final agency actions to significantly change the nation’s vaccine policy. These arbitrary and capricious actions sow confusion and undermine public health, purposefully disregard and contravene required process, and ignore decades of established science. Because the Defendants have failed to “examine the relevant data and articulate a satisfactory explanation for their action s,” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983) (“*State Farm*”), the final actions challenged herein violate the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*, and must be set aside.

The final agency actions that Defendants, including the Secretary and co-Defendant Jim O’Neill, Acting Director of the Centers for Disease Control and Prevention (“O’Neill” or “Acting CDC Director”), have taken to date to change vaccine policy include (collectively, the “Challenged Actions”):

1. A Secretarial Directive, announced in a video posted on **May 7**, instructing the Centers for Disease Control and Prevention (“CDC”) to remove the recommendations from CDC immunization schedules that pregnant women and children receive the Covid vaccine (the **May 7** **Advisory**);¹
2. The terminations of all 17 sitting members of the Advisory Committee on Immunization Practices (“ACIP”) on **June 17**, and replacement of them, starting

¹ Plaintiffs submit their Appendix of Evidence with this Motion, containing Exhibits 1-53. **May 7** **Advisory** materials are attached as Exhibits 1-4. See *Secretarial Directive on the Pediatric and Adolescent Immunization Schedules for Children 12 Years of Age and Pregnant Women* (May 19, 2025) (attached as Ex. 1); Robert F. Kennedy, Jr., @SecKennedy, (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138> (attached as Ex. 2); *Recommended Child and Adolescent Immunization Schedule for Ages 12 Years or Older, United States*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 3); *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States*, 2025, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 4).

- on **J** **11** , with new members who either do not possess the requisite qualifications or expertise or who have publicly stated anti-vaccine views that align with the Secretary's (the **ACIP A** **i** **t** **t** ").²
3. A **J** , vote of the ACIP to remove thimerosal from all influenza vaccines distributed in the U.S., adopted by the Secretary³ on July 23, 2025 (the "**J** **Thi** **r** **A** **ti** ").⁴
 4. A **S** **t** **b** **r** **1** vote of the ACIP to downgrade the Covid vaccine recommendation from routinely recommended for all under age 65 to "shared clinical decision making" ("SCDM"), adopted by the CDC Director on October 6, 2025 (the "**S** **t** **b** **r** **A** **ti** ").⁵
 5. A **D** **b** **r** vote of the ACIP to downgrade the Hepatitis B ("HepB") vaccine recommendation from a routinely recommended three-dose series starting at birth for all children to SCDM for all doses for children born to HepB negative mothers,

² The Secretary made additional unlawful appointments to the ACIP on September 11, 2025, and January 13, 2026.

³ At the time, the CDC director position was vacant. In the absence of a CDC director, the Secretary decides whether to adopt a vote of the ACIP. *A* *P* *ecommendations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 8, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/index.html>.

⁴ The **J** **Thi** **r** **A** **ti** materials are attached as Exhibits 5-9. *See Advisory ommittee on mm ni ation Practices, inal Agenda J ne* , CTRS. FOR DISEASE CONTROL & PREVENTION (June 24, 2025), <https://www.cdc.gov/acip/downloads/agendas/Final-posted-2025-06-24-508.pdf> (attached as Ex. 5); *Meeting of the Advisory ommittee on mm ni ation Practices* (ACIP), June 25-26, 2025 Meeting Summary (June 25-26, 2025), CTRS. FOR DISEASE CONTROL & PREVENTION <https://www.cdc.gov/acip/downloads/minutes/summary-2025-06-25-26-508.pdf> (attached as Ex. 6);

Press Release, U.S. Dep't of Health & Human Servs., *himerosal Merc ry emoved from .S. l accines ollo ing A P ecommendation* (July 23, 2025), <https://www.hhs.gov/press-room/thimerosal-mercury-removed-from-us-flu-vaccines-acip.html> (attached as Ex. 7); *ecommended hild and Adolescent mm ni ation Sched le for Ages ears or o nger, nited States* , CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at <https://web.archive.org/web/20250703123549/https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 8); *ecommended Ad lt mm ni ation Sched le for Ages ears or Older nited States* , CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at <https://web.archive.org/web/20250715024339/https://www.cdc.gov/vaccines/hcp/imzschedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 9).

⁵ The **S** **t** **b** **r** **A** **ti** materials are attached as Exhibits 10-14. *See Advisory ommittee on mm ni ation Practices, inal Agenda Sept.* , CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 19, 2025), <https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-09-19-508.pdf> (attached as Ex. 10); *Meeting of the Advisory ommittee on mm ni ation Practices* (ACIP), Sept. 18-19 2025 Meeting Summary (Sept. 18-29, 2025), CTRS. FOR DISEASE CONTROL & PREVENTION <https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf> (attached as Ex. 11); Press Release, Ctrs. for Disease Control & Prevention, *D mm ni ation Sched le Adopts ndivid al ased Decision Ma ing for O D and Standalone accination for hic enpo in oddlers* (Oct. 6, 2025), <https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html> (attached as Ex. 12); *ecommended Ad lt mm ni ation Sched le for Ages ears or Older nited States* , CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 13); *ecommended hild and Adolescent mm ni ation Sched le for Ages ears or o nger, nited States* , CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 14).

adopted by the Acting CDC Director on December 16, 2025 (the “**D H B A ti**”).⁶

6. A Decision Memo signed by O'Neill on **January 5, 2026**, downgrading immunization recommendations for six (6) conditions on the CDC's Recommended Immunization Schedule for Child and Adolescent Ages 18 Years or Younger (the "Childhood Schedule"): (i) Downgrade to Risk-Based; Hepatitis A, Hepatitis B, MenACWY, RSV; and (ii) Downgrade to SCDM: Hepatitis A, Influenza, MenACWY, Rotavirus. The January 5, 2026 Action also removed from the Childhood Schedule the second dose of the HPV vaccine and the birth dose of HepB for infants in the SCDM recommendation category, and limited the age range of the SCDM recommendation for MenB. (The January 5, 2026 final agency action is hereafter referred to as the **January 5, 2026 Action**).⁷

For both the May 2025 Action and January 2026 Action (collectively, the “Non-ACIP Actions”), the Secretary and Acting CDC Director bypassed without explanation the longstanding process that stakeholders in the health care system have come to rely on by which subgroups of the ACIP, known as Work Groups, study “disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of the evidence reviewed, economic analyses, and implementation issues;”⁸ Work Groups make “Evidence to Recommendation” framework (“EtR”) presentations at public meetings of the ACIP; the ACIP as a whole then

⁶ The **D b r H B A t i** materials are attached as Exhibits 15-17. See *Meeting of the Advisory Committee on Immunization Practices, Agenda Dec.*, , CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 4, 2025), <https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-12-04-508.pdf> (attached as Ex. 15); Press Release, U.S. Dep't of Health & Human Servs., *A P recommends individual based Decision Making for hepatitis vaccine for infants born to women who test negative for the virus* (Dec. 5, 2025), <https://www.hhs.gov/press-room/acip-recommends-individual-based-decision-making-hepatitis-b-vaccine-birth-dose-infants-born-women-test-negative-virus.html> (attached as Ex. 16); Press Release, Ctrs. for Disease Control & Prevention, *D Adopts individual based Decision Making for hepatitis immunization for infants born to women who test negative for hepatitis virus* (Dec. 16, 2025), <https://www.cdc.gov/media/releases/2025/2025-hepatitis-b-immunization.html> (attached as Ex. 17).

⁷ The Joint materials are attached as Exhibits 18-20. See Ex. 18, U.S. Dep’t of Health & Human Servs., *Decision Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf>; Ex. 19, U.S. Dep’t of Health & Human Servs., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf>; Ex. 20, Childhood Immunization Schedule by Recommendation Group, CDC (Jan. 5 2026), <https://www.hhs.gov/childhood-immunization-schedule/index.html>

⁸ See Amendment to the Charter of the Advisory Committee on Immunization Practices, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> (attached as Ex. 21).

considers the evidence, data, and presentations, often at multiple meetings; and, when ready, votes on how immunizations are recommended for use in the U.S. and listed on CDC schedules (the “ACIP Process”). The May 2025 Action targeted vaccines against one infectious disease; the January 2026 Action targeted immunizations against several diseases. These two actions suffer from the same legal defects under the APA: Defendants failed to examine relevant data and failed to provide a reasoned explanation for changing the CDC schedules while bypassing the ACIP Process in doing so. The May 2025 Action injected disruption and confusion into the health care system that has harmed the Plaintiffs specifically, as well as the broader public. The January 2026 Action has significantly amplified these harms.

Plaintiffs also seek to set aside the votes taken by the current ACIP whose members were appointed in violation of the Federal Advisory Committee Act, 5 U.S.C. 1001, et seq. (“FACA”), and the ACIP Charter (the “ACIP Actions”). The current ACIP took those votes without following ACIP best practices, including consulting with Work Groups or following the EtR framework.

Finally, Plaintiffs seek to enjoin the current ACIP from holding a public meeting (the next scheduled meeting is February 25-26, 2026) until an adjudication on the merits of the lawfulness of the appointments of the current ACIP members (the “ACIP Appointments”). The current ACIP held three public meetings in 2025 at which speakers made many false and misleading statements about vaccines and infectious disease that have harmed the Plaintiffs and the public health.

Plaintiff public health organizations, medical associations, and clinician-members have had to divert resources from their core missions of protecting public health to combat the false and misleading statements emanating from the federal advisory committee that is charged with providing “advice and guidance to the Director of the CDC regarding use of vaccines and related

agents for *effective control of vaccine preventable diseases in the civilian population of the United States.*”⁹ The membership and conduct of the current ACIP at public meetings are wholly at odds with this charge. The Plaintiffs and the public are harmed when false and misleading health-related information is spread at a public ACIP meeting. People die from believing health-related misinformation. Future meetings of the ACIP must be enjoined until a decision on the merits of whether the current ACIP membership must be set aside.

BAC GROUND AND STATEMENT OF FACTS

I. U.S. V i A r d R d ti Pr

Two agencies housed inside of HHS—the Food and Drug Administration (“FDA”) and the CDC—oversee the process that results in a vaccine being licensed and recommended for use in the United States. The FDA reviews Biologics License Applications (“BLA”) submitted by manufacturers for approval to market new vaccines for use in the United States. 42 U.S.C. 262(a)(2). A BLA is a comprehensive submission that includes preclinical and clinical data and information, as well as details of the manufacturing process and facilities. Licensure requires a demonstration that (1) the vaccine is safe, pure, and potent, and (2) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent. 42 U.S.C. 262(a)(2)(C).

The CDC, in turn, provides public health guidance for safe use of the vaccine. In 1964, the Surgeon General of the United States established the ACIP due to mounting interest in national immunization policy and the absence of a consistent panel of technical expertise available to advise

⁹ See *A P harter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/about/acip-charter.html> (emphasis added) (ACIP Charter); see also *A P harter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 1, 2024), <https://restoredcdc.org/www.cdc.gov/acip/downloads/acip-charter.pdf> (previous ACIP Charter containing same language).

the federal government on immunization-related issues as they arose.¹⁰ The ACIP was designated a federal advisory committee in 1972.¹¹ The role of the ACIP is “to assist the CDC and the HHS in development of public policy related to immunization of the civilian population in the United States,”¹² and to provide “advice and guidance to the Director of the CDC regarding use of vaccines and related agents for *effective control of vaccine preventable diseases in the civilian population of the United States.*”¹³

The engines that power the ACIP recommendation process are the Work Groups. As stated in the Work Groups Standard Operating Procedures manual:

ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs are intended to augment the effectiveness of ACIP. ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.¹⁴

While the BLA is under review at the FDA, which can take several years, an ACIP Work Group thoroughly reviews public and nonpublic information about the vaccine, so that the Work Group will be prepared to present information to the ACIP about the vaccine as soon as it is licensed. The Standard Operating Procedures manual for ACIP Work Groups provides: s

¹⁰ See Jean Clare Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices*, 63 MORBIDITY & MORTALITY WKLY. REP. 955, 955 (Oct. 24, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm>

¹¹ See *id.*

¹² *Advisory Committee on Immunization Practices or its Standard Operating Procedures*, AGST, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>

¹³ *ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/about/acip-charter.html> (emphasis added).

¹⁴ *Advisory Committee on Immunization Practices or its Standard Operating Procedures*, AGST, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

should begin reviewing data 12-18 months prior to a potential decision on [FDA] licensure the length of time required for the to review data in anticipation of vaccine licensure will depend upon the complexity of the topic, and the amount of available data that exists.

In 2010, the ACIP adopted a best practice called the “GRADE” approach Grading of Recommendations, Assessment, Development, and Evaluation for Work Groups to assess the quality of evidence and develop evidence-based recommendations.¹⁶ The GRADE approach provides a framework for assessing the certainty (*i.e.*, quality or confidence) of the evidence and moving from evidence to decision making (*i.e.*, recommendations).¹⁷

In 2018, the ACIP adopted by unanimous vote another best practice, the Evidence to Recommendation (“EtR”) framework. As explained in the ACIP EtR User’s Guide, the “ACIP has continued to follow and build upon the methodological advances in the GRADE approach and, as a result, has developed a modified Evidence to Recommendation (EtR) framework tailored to the needs of ACIP (Appendix 1). The purpose of the EtR framework is to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.”¹⁸

The 21st Century Cures Act, 130 Stat. 1033, requires the ACIP to take up consideration of a newly-FDA-approved vaccine at the next public ACIP meeting after FDA approval is

¹⁵ *id.* (italics in original, bold added).

¹⁶ See *Introduction in A Practical Approach and More*, CTFS. FOR DISEASE CONTROL & PREVENTION (April 22, 2024) <https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html>.

¹⁷ See *id.*

¹⁸ See *A Practical Evidence to Recommendation Series* *ide*, CTFS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Oct. 1, 2020), <https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide-october-1-2020.pdf>.

announced.¹⁹ By that time, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers.²⁰

Dr. Jason Goldman, current President of Plaintiff American College of Physicians (“ACP”), became an ACP liaison representative to the Pneumonia Vaccine Work Group in 2019 and to the Covid Vaccines Work Group in 2020.²¹ He served on these Work Groups until the Secretary terminated liaison participation in Work Groups on July 31, 2025.²² During his five years of service on the Covid Vaccines Work Group, his Work Group:

would have weekly, robust discussions regarding scientific data about the developing COVID-19 vaccines. These discussions included the creation of the vaccines, how the vaccines were manufactured, and how clinical trials were conducted. We also discussed the triage plan, the distribution plan, and how this critical resource should be allocated. The COVID-19 Vaccines Work Group thoroughly reviewed published works from all over the world, including independent research from various institutions and data from other countries.

Each week, the COVID-19 Vaccines Work Group would have an agenda. We would build upon and adapt our discussions as more data were gathered. As it got closer to each ACIP meeting, each work group, including the COVID-19 Work Group, would use the Evidence-to-Recommendation (EtR) framework to craft our recommendations to the ACIP. The EtR looks at benefits and harms, feasibility, acceptability, health equity, and other similar domains. Each expert in the work group would be polled on each of the domains to reach a recommendation.

Once the COVID-19 Vaccines Work Group came to a consensus on a proposed recommendation to the ACIP, we would put together a presentation that detailed the benefits and harms, feasibility, acceptability, comparators, and other domains to analyze each anticipated question from ACIP and would come up with a specific set of recommendation

¹⁹ 21 U.S.C. 360bbb-4 note (“Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the Advisory Committee’) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting”).

²⁰ See *role of the Advisory Committee on Immunization Practices in Disease Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION RESTORED (Sept. 17, 2024), <https://restoredcdc.org/www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

²¹ See Ex. 35 (Goldman Decl.) 6.

²² Dr. Goldman received an email that liaison organizations were terminated from participating in ACIP Work Groups because liaison organizations like the ACP allegedly were “special interest groups and therefore are expected to have a bias.” See Ex. 35 (Goldman Decl.) 6.

language to present to the ACIP committee. This proposed recommendation, along with our analyses from the evidence gathered, would be presented to the full ACIP committee summarizing this discussion and data ²³

Once the ACIP votes on a recommended use of a vaccine, the CDC director has the authority to adopt ACIP recommendations, and, once adopted, the CDC publishes all ACIP recommendations on its website in a “Policy Note” in the Morbidity and Mortality Weekly Report (“MMWR”) that is authored by the Work Group Chair and other ACIP or Work Group members.²⁴

After the ACIP recommends how immunizations should be used, the FDA, ACIP, and the CDC continue to monitor and review the safety of all vaccines on the CDC’s immunization schedules to ensure they remain up-to-date and comport with emerging peer-reviewed, evidence-based data and studies. For example, the Work Group Standard Operating Procedures manual provides that Work Groups should examine when “updates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage).”²⁵

II. The Final Agency Action Which Plaintiffs Sustain Their Claim

The final agency actions that Plaintiffs challenge here can be separated into three categories: (a) changes to the CDC immunization schedules that bypassed the ACIP Process, (b) votes taken by the current ACIP and subsequently adopted by the CDC Director, and (c) meetings of an unlawfully constituted ACIP.

A. The CDC Initiates and Adopts the ACIP Process

²³ Goldman Decl., ECF No. 75-18 at 16.

²⁴ 45 C.F.R. 147.130(a)(1)(ii); see *Advisory Committee on Immunization Practices or its Standard Operating Procedures*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 16 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

²⁵ *Advisory Committee on Immunization Practices or its Standard Operating Procedures*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

1. The May 2025 Action

On May 27, 2025, the Secretary posted a video on his social media account in which he, FDA Commissioner Marty Makary, and the Director of the National Institutes of Health, Jay Bhattacharya, appeared. In the video, the Secretary announced that he was directing the CDC to remove from its schedules the recommendation that “healthy children” and “healthy pregnant women” receive the Covid vaccine.²⁶ That same day, the Secretary published a Directive, dated May 19, 2025, instructing the CDC to remove these vaccines from the Schedules.²⁷

The Directive does not match the science that was reported only weeks before. A week before this video appeared on , and a day after the Directive is dated, FDA Commissioner Marty Makary published an article dated May 20, 2025 in The New England Journal of Medicine that he co-authored with Vinay Prasad, the Director of the Center for Biologics Evaluation and Research in the FDA, stating that “pregnancy and recent pregnancy” are factors which “increase a person’s risk of severe COVID-19.”²⁸ Thus, the Directive, announced one week later, shows that “ they literally contradicted themselves over the course of a couple of days.’ . . . It appears RFK Jr. reversed his own FDA’s decision.”²⁹

At the April 15, 2025 public meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe

²⁶ See Robert F. Kennedy, Jr., @SecKennedy, (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138> (attached as Ex. 2).

²⁷ See *Secretarial Directive on the Pediatric O D accines for hildren ess han ears of Age and Pregnant omen* (May 19, 2025) (attached as Ex. 1).

²⁸ Vinay Prasad & Martin Makary, *An vidence ased Approach to ovid accination*, 392 NEJM 2484, 2485, fig. 2 (2025).

²⁹ Louis Jacobson, Amy Sherman, Jr. *nded O D accine ecommendation for ids, Pregnant omen. hat do acts Sho A o t is* POLITIFACT (May 29, 2025), <https://www.politifact.com/article/2025/may/29/COVID-19-vaccine-RFK-children-pregnant/>.

illness from the Covid virus.³⁰ Dr. Panagiotakopoulos noted that pregnant individuals continued to face an increased risk of severe outcomes from contracting Covid.³¹ Not only does a Covid vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid vaccine administered during pregnancy.³² Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid on children in the United States in the past year. “She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, half were previously healthy, virtually none had been vaccinated, and 152 had died, most less than 4 years of age. The conclusion was clear; all children in the United States, whether they were previously healthy or not, should receive the primary series of Covid vaccines.”³³

Despite these findings, the CDC’s immunization schedules were changed the same day as the May 27 announcement. Although the Directive ordered the CDC “to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age,” the CDC, did not remove the recommendation that children be routinely vaccinated against Covid. Instead, on May 29, 2025, the CDC downgraded the designation for children to SCDM without explanation or supporting scientific evidence.³⁴

³⁰ See Lakshmi Panagiotakopoulos, *Use of COVID Vaccines or Other Considerations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 15, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf>.

³¹ See *id.* at 11.

³² See *id.*

³³ Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July, 8, 2025) <https://pauloffit.substack.com/p/this-cdc-resignation-should-scare>.

³⁴ See *Child and Adolescent Immunization Schedule by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 29, 2025), <https://web.archive.org/web/20250530173732/https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html>.

2. The January 2026 Action

On January 5, 2026, Defendants announced that immunization recommendations for six diseases had been downgraded, effective immediately.

- Downgrade from Routine Recommendation to Certain High-Risk Groups or Populations only: Hepatitis A (“HepA”), HepB, Meningococcal ACWY (“MenACWY”), Respiratory Syncytial Virus (“RSV”)
- Downgrade from Routine Recommendation to SCDM: HepA, Influenza, MenACWY, Rotavirus

The January 2026 Action made other substantive changes to the Childhood Schedule:

- Prior to the January 2026 Action, the Human Papillomavirus (“HPV”) vaccine was routinely recommended in a two-dose or three-dose series, with the first dose recommended to be given as early as 9 years old. The January 2026 Action increases the minimum age for the first dose to 11 years old and removes recommendations for any subsequent doses.
- Prior to the January 2026 Action, the HepB vaccine was recommended on the basis of SCDM, including the birth dose. The January 2026 Action removes the option for a birth dose of HepB vaccine and instead increases the minimum age of the first dose to two months old.
- Prior to the January 2026 Action, Meningococcal B (“MenB”) vaccines were recommended on the basis of SCDM for adolescents aged 16-23 years old. The January 2026 Action changes the recommendation for the MenB vaccine to certain high-risk groups or populations aged 10-17 years old and limits the SCDM recommendation to adolescents aged 16-17 years old only.

For each of these newly downgraded immunizations, before FDA approval and subsequent ACIP recommendation on use, both the FDA and the ACIP thoroughly evaluated the evidence on the immunizations against the target diseases. All were rigorously evaluated before licensing and recommendation for use and have, since then, been carefully monitored. The Decision Memo announcing the January 2026 Action, however, does not cite any new data that calls into question the safety or efficacy of any of the downgraded immunizations.

Like the May 2025 Action, the January 2026 Action bypassed the ACIP Process to change the CDC's Childhood Schedule.³⁵ Defendants have provided no explanation for why they bypassed the ACIP Process and instead resorted to relying on individuals who have no responsibility for determining how a vaccine is recommended for use and listed on a CDC schedule. The authors of the Decision Memo to O'Neill are Jay Bhattacharya, Director of the National Institutes of Health, Mehmet Oz, Administrator of the Centers for Medicare and Medicaid Services, and Marty Makary, FDA Commissioner. Neither the CMS Administrator, the FDA Commissioner, the NIH Director, nor the agencies they run have any responsibility for revising the CDC's immunization schedules.

The Decision Memo articulates three bases for changing the Childhood Schedule:

- (a) O'Neill's discussions of childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark;
- (b) O'Neill's discussions with CDC and FDA officials with duties and responsibilities related to vaccine safety and efficacy; and
- (c) a document titled "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," (the "Assessment") authored by Hoeg and Martin Kulldorff, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation whom the Secretary appointed Chair of the ACIP in June, 2025.

The Decision Memo does not state what O'Neill discussed with health officials from Japan, Germany, and Denmark; nor does it state what O'Neill discussed with CDC and FDA officials. Neither the Decision Memo nor the Assessment state what "scientific evidence underlying the practices" of peer countries was evaluated, what conclusions were drawn from that evaluation, and what, if any, best practices of peer countries were superior to those of the United States, as the Presidential Memoranda instructed. Neither document discusses or cites new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. The Assessment is not

³⁵ The events leading up to the January 5 Action are set forth in the pending Fourth Amended Complaint, 38 57.

peer reviewed. Neither document states that Defendants considered important factors such as differences in health care systems and populations between countries, the impact on the U.S. health care system, or input from the public or independent experts. Despite the failure to consider these and many other factors, the Secretary proclaimed that an “exhaustive review of the evidence” had been conducted before changing the Childhood Schedule.³⁶

B. V t T b th C rr t ACIP Th ACIP A ti

The second category of final agency actions challenged in this case are the votes by the current ACIP and subsequently adopted by the CDC Director. Pertinent facts regarding the appointments of the current ACIP members are as follows. On June 9, 2025, the Secretary sent shockwaves through the U.S. health care system when he announced in a *Wall Street Journal* Opinion Commentary that he was “totally reconstituting the ACIP ” and “retiring the 17 current members of the committee,” based on alleged “persistent conflicts of interest.”³⁷ Two days later, the Secretary announced the appointment of eight new members to the ACIP whom he claimed were “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.”³⁸ He has made two subsequent sets of appointments: four more members on September 11, 2025, and two on January 13, 2026.³⁹

³⁶ *D Acts on Presidential Memorandum to Update Childhood Immunization Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 5, 2026), <https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html>.

³⁷ Robert F. Kennedy, Jr., *S Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

³⁸ *Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 14–15 (June 2022), <https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf> <https://perma.cc/93W-2J68>.

³⁹ See Robert F. Kennedy, Jr. (@SecKennedy), (June 11, 2025, 4:36 PM), <https://x.com/SecKennedy/status/1932899858920120692> s. 20.

Although members of the ACIP should have expertise in “*vaccines and related agents for effective control of vaccine preventable diseases*,”⁴⁰ the Secretary’s appointees to the ACIP include three obstetrician-gynecologists, one psychiatrist, one operations management professional, a cardiologist, and an emergency medical physician.⁴¹ Ten of the 14 ACIP members have publicly stated views on vaccines that align with the Secretary’s anti-vaccine views.⁴² At least four are members or otherwise affiliated with openly anti-vaccine organizations, including the Independent Medical Alliance, the National Vaccine Information Center, and Children’s Health Defense, which was founded by Robert F. Kennedy, Jr. himself.⁴³

The current ACIP members’ credentials pale in comparison to those of the ACIP members terminated on June 9, 2025, all of whom had relevant subject-matter expertise and credentials.⁴⁴ The Secretary’s termination of the ACIP and the ACIP Appointments are consistent with his publicly stated distrust of experts.⁴⁵

Accordingly, the votes taken by the current ACIP that Plaintiffs request that the Court set aside are as follows:

1. The June 2025 Thimerosal Action

At the first meeting of this ACIP in June 2025, Lyn Redwood, the former long-time President of Children’s Health Defense, gave a presentation on thimerosal that resuscitated the

⁴⁰ See *Advisory Committee on Immunization Practices Policies and Procedures*, CTRS. FOR DISEASE CONTROL & PREVENTION 1,4 (June 2022), <https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf>.

⁴¹ See Fourth Amended Complaint for Declaratory & Injunctive Relief, *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026), ECF 180-1, 77.

⁴² See *id.* at 78.

⁴³ See *id.*

⁴⁴ See *Advisory Committee Members July 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), <https://archive.cdc.gov/details?url=https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html>.

⁴⁵ Very recently (Jan. 13, 2026), the Secretary said on *Katie Miller Podcast*: “we need to stop trusting the experts,” and “this idea that you should trust the experts. A good mother doesn’t do that.” The Katie Miller Podcast, *Jr. on Dietary Guidelines, Vaccines & More*, at 16:52–17:17 (Jan. 13, 2026), https://www.youtube.com/watch?v=w_fzlwXJAA&t=843s.

long-debunked, settled issue of whether thimerosal in vaccines caused autism a theory that Children’s Health Defense has long-promoted and that was an impetus for its founding.⁴⁶ At that meeting, Redwood made that claim that thimerosal is not an effective preservative and was never adequately tested before widespread use. She said: “ they also found evidence that thimerosal was no better than water in protecting mice from potential fatal streptococcal infections,” and the “FDA grandfathered in thimerosal without formal submission of any animal safety data.”⁴⁷ However, Redwood’s presentation on thimerosal was highly misleading:

Thimerosal was introduced after repeated outbreaks of fatal bacterial contamination associated with multi-dose vaccine vials in the early 20th century. Multiple studies demonstrated that thimerosal was highly effective at preventing bacterial and fungal growth, outperforming alternative preservatives available at the time and doing so at much lower concentrations. Following the introduction of thimerosal, contamination-related deaths linked to vaccination dramatically declined. Claims that it is “no better than water” selectively reference short-term vial-entry experiments while ignoring real-world evidence and decades of safe use in vaccines. No evidence shows higher contamination rates in thimerosal-containing vaccines compared with alternatives.

The claim that thimerosal was ‘grandfathered in’ without adequate testing misrepresents the regulatory and scientific history. Before widespread use, thimerosal underwent extensive animal testing. Following licensure, thimerosal-containing vaccines were among the most intensively studied products in vaccinology, with large epidemiologic studies conducted across multiple countries. Post-licensure surveillance and population-based studies consistently found no association between thimerosal-containing vaccines and neurologic, developmental, or systemic harms. Characterizing this as ‘insufficient testing’ ignores both preclinical toxicology and decades of real-world safety data.⁴⁸

⁴⁶ See *History of CHD*, CHILD.’S HEALTH DEF., <https://childrenshealthdefense.org/about-us/history-of-chd/> (last visited Jan. 25, 2026).

⁴⁷ Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices A P Day of*, YOUTUBE, at 2:34:24, 2:32:38 (June 26, 2025), https://www.youtube.com/watch?v=z-16fIm_oEc.

⁴⁸ Marisa Donnelly, et al., *Summary Of A P Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), (emphasis added), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap+Highlights.pdf>.

Nonetheless, on June 26, 2025, the ACIP, whose members had been appointed only two weeks before, “passed three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults. There was no explanation for why three separate recommendations were voted on or when the end goal was to stop using the preservation in all flu vaccines brought to the U.S. market.”⁴⁹ No new data or study on the presence of thimerosal in vaccines was presented at the meeting.

2. The September 2025 Action

On September 19, 2025, the ACIP voted to change the Covid vaccine recommendation for adults from routine to SCDM, consistent with the May 2025 Directive. At that meeting, misleading information was presented that the Covid vaccine contained unacceptable amounts of DNA contaminant.⁵⁰ The ACIP did not apply the GRADE Approach or follow the EtR framework, and it did not consult with the Covid Work Group prior to the vote. The CDC Director adopted the September 19 vote on October 6, 2025.⁵¹ Unlike the four previous occasions that the ACIP voted to designate a vaccine as SCDM,⁵² the CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

⁴⁹ See Helen Branswell, *S Secretary Jr. accepts recommendations to drop thimerosal from .S. fl vaccines*, STAT (July 23, 2025), <https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/>.

⁵⁰ See *infra* Section III.C.

⁵¹ See *D. mm ni ation Sched le Adopts ndivid al ased Decision Ma ing for O D and Standalone accination for hic enpo in oddlers*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 6, 2025), <https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html>.

⁵² See Lauren E. Roper, et al., *Use of Additional Doses of Quadrivalent Human Papillomavirus Vaccine for Adolescent Males*, 73 MORBIDITY & MORTALITY WKLY REP. 1118, 1121, (Dec. 12, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a2-H.pdf>; Sarah Schillie, et al., *Recommended Dosing Interval and Schedule for the Quadrivalent Human Papillomavirus Vaccine: Updated Recommendations of the Advisory Committee on Immunization Practices – United States, October 2024*, 73 MORBIDITY & MORTALITY WKLY REP. 1124, 1124–1125 (Dec. 12, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a3-H.pdf>; Almea Matanock, et al., *Use of Quadrivalent Pneumococcal Conjugate Vaccine and Quadrivalent Pneumococcal Polysaccharide Vaccine Among Adolescent Males*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf>; Elissa Meites, et al., *Human Papillomavirus*

3. The December 2025 HepB Action

On December 4, 2025, a current member of the ACIP and two outside presenters presented on the HepB vaccine. The first outside presenter, Cynthia Nevison, a climate scientist, presented on the “Burden of Disease.” The second, Mark Blaxill, who has no medical training or professional experience, presented on the safety of the HepB vaccine.⁵³ None of the presenters on the HepB vaccine presented new safety concerns or effectiveness issues that would prompt reconsideration of the HepB vaccine birth dose. Instead, “panelists said the review was prompted by parents concerned about the shot, the fact that most European countries give the immunization a few months after birth, and the length of time since ACIP last reviewed the topic.”⁵⁴ No Work Group presented at this ACIP meeting on HepB (or on any other vaccine). No EtR analysis was conducted or presented at this meeting.

The next day, the ACIP voted “8 to 3 to recommend individual-based decision-making for parents deciding whether to give the HepB vaccine, including the birth dose, to infants born to women who test negative for the virus.”⁵⁵ The new recommendation is that parents discuss with their doctors whether to give the HepB vaccine at birth, or at all, and that those who choose to do so should wait to begin the vaccine series until their baby is at least two months old. This deviates from the recommendation (in place since 1991) that all babies receive a dose of the HepB vaccine within 24 hours of birth, including mothers who test negative for the HepB surface antigen

accination for Ad lts, 68 MORBIDITY & MORTALITY WKLY REP. 698, 700 (Aug. 16, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf>.

⁵³ Nevison and Blaxill were co-authors of an article connecting autism to vaccines that the journal later retracted because of misrepresentations of data. See Mark Blaxill, Toby Rogers, & Cynthia Nevison, *etraction ote A tism he mpact of ising Prevalence on the Societal ost of A tism in the nited States*, 53 J. AUTISM DEV. DISORD. 3315 (2023).

⁵⁴ Helen Braswell, *D panel recommends delaying irth dose of hepatitis vaccine*, STAT (Dec. 5, 2025), <https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturms-30-year-policy/>.

⁵⁵ *A P ecommends ndivid al ased Decision Ma ing for epatitis accine for nfants orn to omen ho est egative for the ir s*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>.

(HBsAg-negative).⁵⁶ No evidence or data was presented justifying the two-month age restriction for the first dose of the HepB vaccine.

C. M t i Th U C t i t t d ACIP

The current ACIP's public meetings have been filled with false and misleading statements on vaccines and infectious disease. The presentation on thimerosal at the June 2025 meeting discussed above is a case in point.

At the September 2025 ACIP meeting, more inaccurate and misleading statements were made. At least 50 falsehoods were stated at the September meeting on the MMRV (measles, mumps, rubella, varicella) vaccine, the HepB vaccine, the Covid vaccine, and other topics.⁵⁷ For example, a claim was made at the September meeting that Covid vaccines contain dangerous levels of DNA contaminant exceeding regulatory limits. The truth, however, is that "m anufacturing impurities, including DNA, are carefully monitored because the FDA requires that residual DNA in vaccines be below 10 ng per dose. The presence of DNA fragments used in the manufacturing process is expected, found at acceptable levels, and is accounted for in safety standards. Multiple independent analyses have confirmed that mRNA vaccines meet these stringent requirements. Claims of dangerous DNA contamination typically arise from studies that use inappropriate detection methods or misinterpret the significance of trace amounts that are orders of magnitude below safety thresholds. Moreover, the work that initially flagged the concern used inappropriate

⁵⁶ See Aliza Rosen, *epatitis accination is an ssential Safety et for e orns*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUB. HEALTH (Sept. 24, 2025), <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth/>; *epatitis Perinatal accine nformation*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 27, 2025), <https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/vaccine-administration.html> :text Birth 20dose,a 20parent 20with 20HBV 20infection.

⁵⁷ See Marisa Donnelly, et al., *Sept A P Meeting act hec ing Days*, THE EVIDENCE COLLECTIVE (Sept. 19, 2025), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/68cde5ebaf4b826126e40899/1758324203698/Sept+ACIP+days+1+and+2.pdf>.

methods. Despite this, they found that vaccine lots with DNA levels above regulatory limits had fewer VAERS reports than those below the limits.”⁵⁸

The December 2025 meeting was even worse. There, “ACIP members and presenters made at least 60 (we lost count after this) false, misleading, or unsupported claims about vaccine-preventable disease epidemiology, vaccine safety, and the rationale for universal vaccination.”⁵⁹ Many false claims were made that testing before licensing and marketing of the HepB vaccine was inadequate and that surveillance has been inadequate since listing on CDC schedules. In fact, however, more than 15 safety studies were conducted on HepB vaccines, including randomized control studies, and there has been continuous safety monitoring in millions of recipients post-marketing.⁶⁰ In addition, Nevison made the claim that “targeted measures” to vaccinate against Hepatitis B have been more effective than universal vaccination for Hepatitis B disease. Nevison either does not know or ignores the historical fact that:

“ a targeted strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.’ ***This makes targeted approaches ineffective.*** Similarly, 35
65 <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm> of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. ***The 1991 switch to universal vaccination reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually)***”.⁶¹

⁵⁸ Marisa Donnelly, et al., *Summary Of ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap+Highlights.pdf>

⁵⁹ Marisa Donnelly, et al., *Defining December Meeting of the Advisory Committee on Immunization Practices ACIP*, THE EVIDENCE COLLECTIVE (Dec. 5, 2025), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/693347ab2b70aa78cc908df3/1764968363179/Dec+ACIP+TEC+Brief.pdf>.

⁶⁰ *See id.*

⁶¹ Marisa Donnelly, et al., *Summary Of ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), (emphasis added), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap+Highlights.pdf>.

ARGUMENT

I. P i t i M t t h E t r P r i i r I t i

A. P r i i r I t i S t d r d

For the Court to grant a preliminary injunction, plaintiffs must show four elements: “(i) the movant’s likelihood of success on the merits of its claims; (ii) whether and to what extent the movant will suffer irreparable harm if the injunction is withheld; (iii) the balance of hardships as between the parties; and (iv) the effect, if any, that an injunction (or the withholding of one) may have on the public interest.” *orp. echs., nc. v. arnett*, 731 F.3d 6, 9 (1st Cir. 2013). Where the Government opposes the preliminary injunction, the last two factors merge. *en v. older*, 556 U.S. 418, 435–36 (2009). The most important of the four elements is the likelihood of success on the merits. *See Massach setts v. at l nsts. of ealth*, 770 F.Supp.3d 277, 295 (D. Mass. 2025) (“ ”).

B. P i t i r L i t S d t h M r i t .

1. Plaintiffs Have Standing to Seek the Requested Injunctive Relief.

In its January 6, 2026 Memorandum and Order on Defendants’ Motion to Dismiss (ECF No. 168), this Court denied Defendants’ Motion to Dismiss the Third Amended Complaint that was premised largely on the argument that Plaintiffs did not have standing to continue with any of their claims.⁶² The Third Amended Complaint alleged that the following final agency actions violated the APA: (a) the May 2025 Action (one of the Non-ACIP Actions); (b) the September 2025 Action (one of the ACIP Actions); and (c) the ACIP Appointments for violations of FACA. In the Order on the Motion to Dismiss, this Court held that “there is no question that, but for the

⁶² The Court also denied Defendants’ Federal Rule of Civil Procedure 12(b)(6) motion on Plaintiffs’ FACA claim.

change in vaccine recommendations and ACIP appointments, AAP would not have expended the resources that it did.” Order on Defs.’ Mot. to Dismiss, at 13, ECF No. 168.

If the Court grants leave to file the Fourth Amended Complaint, the allegations in that complaint will likewise be sufficient to establish standing as to the additional challenged actions.⁶³ The additional Non-ACIP Actions and ACIP Actions continue and magnify the harm that the Plaintiffs identified in the Third Amended Complaint,⁶⁴ since they impacted the immunizations for several additional conditions, whereas the May 2025 Action and September 2025 Action changed the recommendation regarding the immunization for *one* condition.

And as to the ACIP Appointments, Defendants’ dismantling of Charter-mandated liaison groups, including AAP, deprived Plaintiffs of their legal right to participate in ACIP activities. *See AA P egal Defense nd, nc. v. arr*, 496 F.Supp.3d 116 (D.D.C. 2020) (plaintiffs’ membership denial was sufficient to confer fair balance claim under FACA) (citing *at l Anti nger oal. v. ec. omm. of President s Private Sector S rvey on ost ontrol*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983) (denial of access to representation on an advisory committee is a sufficiently concrete harm to constitute an injury in fact)); *see, e.g., at. es. Def. o ncil v. Dep t of nterior*, 410 F. Supp. 3d 582, 601 02 (S.D.N.Y. 2019) (noting that “the weight of the caselaw” holds that parties with direct interests in an advisory committees work is denied membership, then the party has standing to challenge). Further compounding the harm is the fact that the current

⁶³ *See* Fourth Am. Compl., *Am. Acad. Of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶¶ 16, 35, 38, 42, 44, 45, 49, 52, 71, 74, 79, 82, 119; *see also* Ex. 27 (Kressly Decl.), ¶¶ 13, 15, 18, 26, 31, 36, 39, 42, 51; Ex. 34 (Racine Decl.), ¶¶ 11, 13, 18, 20, 39, 40; Ex. 42 (Pring Decl.), ¶¶ 10, 12, 14, 16, 19, 23, 31, 39, 40, 46, 47; Ex. 43 (Bornstein Decl.), ¶¶ 9, 13, 15, 17, 19, 22, 26, 33, 40, 45, 50; Ex. 31 (Berman Decl.), ¶¶ 8, 19; Ex. 40 (Nahass Decl.), ¶¶ 12, 13, 15, 17; Ex. 41 (Chen Decl.), ¶¶ 22, 24, 25; Ex. 45 (Jaeger Decl.), ¶¶ 10, 11, 13, 16, 26, 31, 33, 34; Ex. 44 (Pavlos Decl.), ¶¶ 16, 20, 22, 24, 29, 30, 32, 33, 35, 37; Ex. 25 (Benjamin Decl.), ¶¶ 20, 27, 29, 32; Ex. 39 (Martinello Decl.), ¶¶ 8, 10, 12, 13; Ex. 46 (Srinivas Decl.), ¶¶ 14; Ex. 28 (O’Shea Decl.), ¶¶ 19, 23, 26; Ex. 38 (Wheeler Decl.), ¶¶ 17; Ex. 37 (Jhaveri Decl.): ¶¶ 25, 28; Ex. 49 (Jane Doe 3 Decl.) ¶¶ 24-25; Ex. 50 (Jane Doe, MD Decl.) ¶¶ 13-14, 20; Ex. 53 (Jane Doe 2 Decl.) ¶¶ 31, 32.

⁶⁴ *See id.*, ¶¶ 120, 45.

ACIP has continued to spread significant misinformation at their public meetings, which creates more confusion, uncertainty, and disruption to the operations of the Plaintiffs and causes them to divert more resources to address the increased confusion and misinformation.⁶⁵

In short, the key standing issues in this case regarding both a Non-ACIP Action and an ACIP Action, as well as the ACIP Appointments, have already been litigated and decided, so it is now the law of the case. *See* .S. v. *igneia* , 337 F.3d 62, 67 (1st Cir. 2003) (noting that the law of the case doctrine “is a prudential principle that precludes relitigation of the legal issues presented in successive stages of a single case once those issues have been decided”).

2. The Challenged Actions are Final Agency Actions.

Each of the Challenged Actions in this case are final agency actions because they (1) “mark the consummation of the agency’s decision making process”; and (2) are those “by which rights or obligations have been determined, or from which legal consequences will flow.” *ennett v. Spear*, 520 U.S. 154, 177 78 (1997). As a preliminary matter, the Defendants have waived any contention that the Challenged Actions are not final agency actions: they did not argue in their Motion to Dismiss that any of the final agency actions identified in the Third Amended Complaint which included a Non-ACIP Action, an ACIP Action, and the ACIP Appointments were not final agency actions, and, consistent with that position, Defendants conceded the challenged actions were final agency actions at the January 12, 2026 status conference before the Court (“ Mr. Belfer I think something to keep in mind is that this case is really almost four cases ripened into one. We’ve got many different final agency actions”/ “So that’s at least five different final agencies actions, each of which has its own record . . . we’re basically talking about five

⁶⁵ Ex. 27 (Kressly Decl.), 16, 26 31, 39; Ex. 25 (Benjamin Decl.), 31; Ex. 42 (Pring Decl.), 16, 23 24, 30, 46 47; Ex. 43 (Bornstein Decl.), 26, 45; Ex. 40 (Nahass Decl.), 12, 16, 17; Ex. 41 (Chen Decl.), 24; Ex. 45 (Jaeger Decl.), 31; Ex. 44 (Pavlos Decl.), 17 18, 22 24, 29, 33, 36 37; Ex. 34 (Racine Decl.), 13 18, 39.

different agency actions that are potentially being challenged.”⁶⁶ In addition, in the Joint Status Report filed on January 21, 2026, which was filed after Plaintiffs’ Motion for Leave to File a Fourth Amended Complaint, Defendants stated that, of the actions challenged in the Fourth Amended Complaint, they “may explain why ACIP’s June 26, 2025, and December 5, 2025, recommendations are not final agency actions,”⁶⁷ but were silent as to any other action. Joint Status Report, at 3 ECF No. 181. As such, any objection on this ground has been waived.

In any event, the Challenged Actions have imposed immediate and irreparable legal consequences on Plaintiffs, who are forced to grapple with the daily and long-term public health and economic effects that flow from (1) Defendants’ deliberate decision not to follow well-established vaccine policy and procedures, and (2) the improper ACIP Appointments. These actions are ripe for review by the court to determine “an actual or immediately threatened effect.” *See reater os. egal Servs. v. nited States Dep t of omeland Sec.*, No. 21-CV-10083-DJC, 2023 WL 2540892, at 2 (D. Mass. Mar. 16, 2023) (citation modified); *see also iden v. e as*, 597 U.S. 785, 808 09 (2022) (holding agency memoranda were final agency action, noting they “bound” agency staff by preventing them from continuing certain programs); *St dent oan Mar eting Ass n v. iley*, 104 F.3d 397 (D.C. Cir. 1997) (finding agency letter had all of the indicia of finality because (1) it was signed by the Acting General Counsel on behalf of the Secretary of Education; (2) it was based on full deliberation at the highest level and reflected the agency’s consideration of the contrary views expressed by the petitioner; and (3) the position was stated unequivocally).

⁶⁶ Transcript of Hearing at pp. 28:9–22:25; 29:5–13, *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 12, 2026) (ECF No. 178).

⁶⁷ For the purposes of this analysis under *ennett*, these two ACIP Actions are indistinguishable from the ACIP Action referenced in the Third Amended Complaint—the September 2025 Action—that Defendants previously conceded are final agency actions.

3. Both the Non-ACIP Actions and the ACIP Actions Violate the APA Because They are Arbitrary and Capricious.

When determining whether an agency acted arbitrarily or capriciously, the court must conduct “a thorough, probing, in-depth review” through a “searching and careful inquiry into the record.” *Peno Scot Air Servs., Ltd. v. AA*, 164 F.3d 713, 720 (1st Cir. 1999) (citation modified). An agency action is arbitrary and capricious under 5 U.S.C. 706 (2)(A) if it “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *State Farm*, 463 U.S. at 43; see also *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020). Agency action must be “founded on a reasoned evaluation of the relevant factors.” See _____, 770 F.Supp.3d at 304. At bottom, arbitrary and capricious review is a search for “a satisfactory explanation” for an agency’s action. ~~*Am. People’s Health Ass’n v. Nat’l Inst. of Health* (“_____”), 791 F.Supp.3d 119, 178 (D. Mass. 2025) (quoting *Ohio v. Nat’l Prot. Agency*, 603 U.S. 279, 292 (2024) (quoting *State Farm*, 469 U.S. at 43); see also *Nat’l Industries for the Environment v. Donovan*, 722 F.2d 795, 814 (D.C. Cir. 1983) (“The agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.”).~~

Further, when an agency changes its policy, not only must it provide a reasoned explanation; it must also “be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.” *Dep’t of Homeland Sec.*, 591 U.S. 1 at 30 (quoting *Encino Motorcars, Inc. v. Navarro*, 579 U.S. at 222); see *Food & Drug Admin. v. Brown & White Lion Nvs.*, _____, 604 U.S. 542, 570 (2025); *Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 106 (2015) (“The APA requires an agency to provide more substantial justification when . . . its

prior policy has engendered serious reliance interests that must be taken into account. It would be arbitrary and capricious to ignore such matters.”). When a challenged action constitutes a change in policy, the question is: “Did Defendants display awareness that they were changing position and offer good reasons for the new policy ” See *ages hite ion nvs.*, 604 U.S. at 570.

First, both the Non-ACIP Actions and the ACIP Actions were arbitrary and capricious because the Defendants failed to engage in reasoned decision-making as required by the APA. In the context of immunization actions, the ACIP Process provides a framework for engaging in a “reasoned evaluation of the relevant factors” through the GRADE approach, the EtR framework, and consultation with ACIP Work Groups. See *_____*, 770 F.Supp.3d at 304. For decades, the CDC schedules have been governed by these processes, which provide a structured, transparent, evidence-based review process requiring the ACIP to evaluate disease burden, morbidity and mortality, vaccine effectiveness, safety, and population-level impact under established analytical frameworks before adopting or modifying a recommendation.

Before prior ACIPs voted to adopt the routine recommendations for each of the now-downgraded vaccines, those ACIPs conducted multi-stage, data-driven reviews over multiple meetings, with the evidentiary basis for each recommendation documented and transparently evaluated. The charts attached as Exhibits 23⁶⁸ and 24⁶⁹ detail these processes as to two of the downgraded vaccines to serve as exemplars: HepB and RSV, respectively.

⁶⁸ As demonstrated in Ex. 23, ACIP subjected HepB vaccines to a long and rigorous evidence-based process, beginning in 1981 with review of double-blind, placebo-controlled clinical trial data even before FDA licensure. Over the next decade, ACIP revisited HepB vaccination recommendations in more than 20 formal meetings, repeatedly evaluating factors including safety, immunogenicity, duration of protection, adverse event reports, cost-effectiveness, and real-world implementation data across infants, children, adolescents, and high-risk adults. This spanned roughly 10 years from first data review to the unanimous 1991 universal recommendation. Even after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations, expanding the recommendation to all unvaccinated children aged 0-18 years of age in 1997.

⁶⁹ As demonstrated in Ex. 24, RSV monoclonal antibodies were recommended only recently by ACIP, with the first recommendation coming from ACIP on August 3, 2023, and the most recent recommendation for a monoclonal antibody coming on June 25, 2025. The monoclonal antibodies went through rigorous review by ACIP, including

The one time a routine vaccine was downgraded on a CDC schedule to SCDM the Prevnar vaccine (“PCV13”), which treats pneumococcal pneumonia the ACIP went through the same rigor and analysis it would go through for any newly issued recommendation.⁷⁰ PCV13 was recommended for routine use on June 20, 2012. By June 2015, ACIP was already revisiting that recommendation and considering rigorously constructed Work Group presentations and rationale on proposed changes to the PCV13 recommendation. The Work Group presented numerous times on not only the vaccine, but the disease it was designed to prevent, and the effects of the disease within particular age groups over the years since PCV13’s routine recommendation. ACIP voted to change the recommendation on June 26, 2019, after considering no less than 34 such presentations on PCV13 and pneumococcal pneumonia. These presentations covered topics including suggested intervals between vaccinations, changes in the epidemiology of pneumococcal pneumonia, policy considerations, safety and efficacy of PCV13, direct and indirect effects of PCV13, the incidence and burden of pneumococcal pneumonia amongst adults in the US, EtR framework analyses for differing adult age groups, economic analyses of the current and adjusted recommendations, and alternative recommendations. Further, as with every prior instance in which the ACIP adopted an SCDM designation, PCV13’s downgrade from routine to SCDM was accompanied by explanatory guidance published in the MMWR, describing both the evidentiary

through the EtR Framework. The ACIP Maternal & Pediatric RSV Work Group met regularly leading up to the August 3m, 2023 ACIP vote, with presentations beginning at ACIP meetings as early as February 23, 2022, well before the monoclonal antibody received FDA approval on July 17, 2023. At least 19 presentations on topics including numerous presentations on clinical considerations of the immunization, safety and efficacy, economic analyses, the ability of the monoclonal antibody to prevent RSV in all infants, the feasibility of the product, implementation considerations, the interplay between maternal and infant immunization, numerous EtR Framework presentations, and regular presentations on analyses conducted by the ACIP Maternal & Pediatric RSV Work Group. This rigorous, years-long process ultimately culminated in a vote and recommendation for the regular use of the RSV monoclonal antibody in infants, which itself resulted in numerous follow-up research and real-world studies of the effects of the immunization.

⁷⁰ See Plaintiff’s FED. R. EVID. 1006 Summary Chart for Prevnar-13 (attached as Ex. 22)

basis for the designation and providing guidance on how SCDM should be applied in practice for that recommendation.⁷¹

Defendants have not offered a scintilla of explanation for why they bypassed the ACIP Process entirely as to the Non-ACIP Actions. Nor have they explained why they did not apply the GRADE approach, utilize the EtR framework, or consult with ACIP Work Groups to examine relevant data before adopting the ACIP Actions. This blatant disregard for the established process for methodically assessing and reviewing evidence-based data to adopt or modify immunization recommendations is exactly the kind of “unexplained inconsistency” that espouses arbitrary and capricious action. *See Incino Motorcars*, 579 U.S. at 222; *see also Data Marketing P v. S. Dep t of a or*, 45 F.4th 846, 857 (5th Cir. 2022) (holding that an advisory opinion that adopted a definition of “working owner” that was materially different from the definitions in prior opinions was arbitrary and capricious because of the unexplained inconsistency).

Second, regardless of this failure of process, Defendants have failed to otherwise provide a satisfactory explanation for their actions based on any sort of reasoned evaluation or rational connection between the facts found and choices made. In the May 27 video posted on , the Secretary justified the May 2025 Action with the conclusory assertion that “healthy kids” and “healthy pregnant women” don’t need the Covid vaccine.⁷² This explanation “fails under the APA because it is merely conclusory.” *See Ass n of Am. nvs. v. Dep t of Defense*, 792 F.Supp.3d 143, 171 (D. Mass. 2025) (holding that the Department of Defense’s justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because its

⁷¹ See Almea Matanock, et al., *se of alent Pne mococcal on gate accine and alent Pne mococcal Polysaccharide accine Among Ad lts*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf>.

⁷² Robert F. Kennedy, Jr. (@SecKennedy), (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138>.

conclusory justification did not provide a reasoned basis for the change); *Id.*, 770 F.Supp.3d at 305 (holding that NIH’s justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because it was conclusory given that it did not “provide any reasoning, rationale, or justification at all”).

Moreover, at the ACIP meeting the month before, CDC subject-matter experts reported that healthy children and pregnant women were very much still at risk from Covid and presented a wealth of uncontroverted data on the safety and efficacy of Covid vaccines for these populations. Fourth Am. Compl., 98, ECF 180-1. Accordingly, the Secretary’s claim that there isn’t “any clinical data to support the repeat booster strategy in children”⁷³ lacks any foundation. As in *Department of Commerce v. Healy*, 588 U.S. 752 (2019), “the evidence tells a story that does not match the explanation the Secretary gave for his decision.” 588 U.S. at 784 (holding pretextual the Secretary of Commerce’s explanation why he decided to reinstate a citizenship question on the census).

Nor is there any reasoned explanation for the January 2026 Action. As noted above, the changes to the Childhood Schedule identified in the January 2026 Action were based only on (a) discussions with health officials in Japan, Germany, and Denmark and with CDC and FDA officials⁷³; (b) a Decision Memo signed by Defendant O’Neill⁷⁴; and (c) an allegedly scientific Assessment drafted by two individuals who are not part of the CDC and who lack education and professional backgrounds in vaccine science.⁷⁵ None of the stated reasons for the January 2026

⁷³ See *Decision Making Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule*, U.S. DEPT OF HEALTH & HUMAN SERVS., 1 (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule/index.html> (attached as Ex. 18).

⁷⁴ See *Id.*

⁷⁵ See *Id.*

Action offer a reasoned evaluation or rational connection between the facts found and choices made.

As also noted above, the Decision Memo does not state what Acting Director O’Neill discussed with health officials from Japan, Germany, and Denmark, nor does it state what Acting Director O’Neill discussed with CDC and FDA officials. The Assessment cites no new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. Additionally, neither the Decision Memorandum nor the Assessment document which were apparently created in only a few weeks were peer-reviewed before they were used as the basis to significantly change the Childhood Schedule. They also fail to explain why Japan, Germany, and Denmark serve as good immunization models for the United States. Therefore, Defendants have failed to offer any satisfactory explanation for the January 2026 Action to suggest it was the product of reasoned decision-making. *See State Farm*, 463 U.S. at 51 (holding that the National Highway Traffic Safety Administration (“NHTSA”)’s decision to rescind the rule that new motor vehicles be equipped with automatic seatbelts or airbags was arbitrary and capricious because the agency was “too quick to dismiss the safety benefits of automatic seatbelts” for the court to conclude that the rescission was the product of reasoned decision-making); *see also* _____, 770 F.Supp.3d at 306 (holding that the failure to explain why bringing the federal government in line with private foundations in terms of funding indirect cost rates in the research grant context rendered the policy change arbitrary and capricious).

There is also no satisfactory explanation for the Defendants’ actions relative to the ACIP Actions. The process that the ACIP followed leading up to the June 2025 Thimerosal Action, the September 2025 Action, and the December 2025 HepB Action demonstrate additional failures to examine relevant data or to provide reasonable explanation for the Defendants’ actions. No new

data or studies were reviewed, considered, or identified to justify or provide any reasonable connection to the decisions on these three actions. Again, “the evidence tells a story that does not match the explanation the Secretary gave for his decision.” *Dept of Commerce*, 588 U.S. at 784.

Third, the Non-ACIP Actions and the ACIP Actions are arbitrary and capricious because they fail to consider important aspects of the problem the agency itself said it was trying to solve. For example, the purported problem the Defendants were trying to solve with the January 2026 Action was: to “restore trust in public health recommendations made by the CDC” that allegedly was lost because of governmental action during the pandemic.⁷⁶ In *Lee v. Trump*, 769 F.Supp.3d 119, 141 (D.R.I. 2025), the court held that the defendants federal funding freeze was arbitrary and capricious because the defendants failed to provide “a rational reason for how their alleged goal of safeguarding taxpayer funds justified a de facto suspension of nearly all federal funding.” Likewise, here, the Non-ACIP and ACIP Actions are arbitrary and capricious because Defendants have failed to provide a rational reason for how their alleged goal of “restoring trust in the public health” justifies dramatic changes to the CDC schedules. None of the documents or statements supposedly justifying the Non-ACIP Actions or the ACIP Actions—including the May 2025 Directive; the Decision Memo; the Assessment; and the presentations during the June, September and December ACIP meetings—cite to any surveys, studies, or data to support Defendants’ assertion that their actions will “restore trust in public health.” Indeed, doctors who see patients every day report that the Non-ACIP Actions and ACIP Actions have made their patients *more* distrustful of the public health system, not less.⁷⁷

⁷⁶ Tracy Beth Heg, MD, Ph.D and Martin Kulldorff, Ph.D., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Jan. 2, 2026), <https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf> (attached as Ex. 19).

⁷⁷ See Ex. 25 (Benjamin Decl.), 11, 15–16, 20, 31–32; Ex. 27 (Kressly Decl.) 13, 26; Ex.40 (Nahass Decl.) 13–15; Ex. 41 (Chen Decl.) 22, 24–25; Ex. 43 (Borenstein Decl.) 9; Ex. 45 (Jaeger Decl.) 10, 33–34; Ex. 44 (Pavlos Decl.) 16–18, 20, 22, 33.

Further, neither the Decision Memo nor the Assessment considered any of the following essential factors for evaluating immunization recommendation decisions: (1) epidemiological data comparing the incidence and prevalence of diseases on the schedule in the United States and other countries; (2) socioeconomic data demonstrating that the populations of the alleged peer nations are comparable; (3) data establishing that any of the vaccines on the schedule are harmful; (4) data on screening programs for diseases in other countries; (5) citations to peer-reviewed published research concluding that the vaccines administered under prior iterations of the schedule were ineffective in preventing disease or mitigating symptoms of disease or the need for hospitalization; (6) any evidence from the FDA that any of the vaccines are not safe and effective; (7) changes to practice guidelines published by Plaintiffs or other professional organizations; (8) evidence of consultations with professional organizations; (9) modeling of potential outbreaks if there is a reduction in vaccination rates or loss of herd immunity; (10) cited evidence of superior outcomes in other nations, (11) consideration of other variables in other nations such as widespread screening for diseases that confound nation to nation comparisons such as universal health access; and (12) data on the reductions of the incidence and prevalence of diseases following widespread vaccination.⁷⁸ The same is true for the May 2025 Directive and the presentations at the ACIP meetings that preceded the ACIP Actions.

The outright failure to address or even consider these important issues before undertaking dramatic changes to the CDC schedules renders the Defendants' actions arbitrary and capricious. In *State arm*, the agency, NHTSA, did not "cast doubt" on the "efficacy of airbag technology" or on "the need for a passive restraint standard." 463 U.S. at 47. Therefore, because of NHTSA's prior position that "airbags are an effective and cost-beneficial lifesaving technology," the

⁷⁸ See Ex. 34 (Racine Decl.), 29 38; Ex. 27 (Kressly Decl.), 25, 30, 33.

Supreme Court held that it would be arbitrary and capricious to abandon the mandatory passive restraint rule “without any consideration whatsoever of an airbags-only requirement.” *See id.* at 51. Likewise here, because none of the stated justifications for the Non-ACIP Actions or the ACIP Actions included new data or evidence-based analysis casting doubt on the safety or efficacy of the subject immunizations and vaccine ingredient, and because the CDC’s prior position was that the immunizations and vaccine ingredient were safe and effective, the recommendation and use of the immunizations and vaccine ingredient cannot be modified without consideration of the relevant data, evidence, analyses, and public health impacts related to such decisions. *See id.* Put simply, Defendants provide no “reasoned analysis for the change s .” *See id.* at 42.

Finally, with respect to both the Non-ACIP Actions and the ACIP Actions, Defendants failed to take into account serious reliance interests before unleashing devastating consequences on Plaintiffs, their members, and the U.S. public health system. These Actions set into motion a vaccine policy that disrupts multiple parts of the American health care ecosystem. These changes have wide-ranging effects far beyond when and to whom a vaccine may be administered. The complex landscape of federal and state laws that govern American health care rely on the CDC schedules to inform many aspects of operations. For example, VFC providers are only required to stock vaccines designated as “routine.”⁷⁹ The change in classification of multiple vaccines from “routine” to SCDM jeopardizes access to these vaccines for children in the VFC program,⁸⁰ and more broadly.⁸¹

⁷⁹ *See Operations ide*, CTRS. FOR DISEASE CONTROL & PREVENTION at 82 (July 1, 2024), https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/vfc-ops-guide_version-4.0_july-2024_low-res-508-rev-2.pdf.

⁸⁰ *See* Ex. 42 (Pring Decl.) 17 (describing the delay in children covered by the VFC program receiving access to the 2025 26 Covid vaccine).

⁸¹ *See, e.g.*, Ex. 34 (Racine Decl.) 17; Ex. 44 (Pavlos Decl.) 24.

Similarly, how immunizations are listed on the CDC schedules can affect health insurance coverage and cost-sharing obligations under the Affordable Care Act. Children and pregnant women who were previously able to receive the vaccine free of charge or without difficulty may now face potential out-of-pocket expenses or an outright inability to receive life-saving vaccinations because of the Defendants' actions. And perhaps most importantly, the public at large relies on the safety and efficacy of routine immunizations to protect our population from serious illness, hospitalization, and death.

The APA requires the Secretary to consider these reliance interests when changing its mind, but the Defendants failed to do so here. *See Dept of Homeland Sec.*, 591 U.S. 1 at 30; *see also* _____, 770 F.Supp.3d at 308–11 (holding that the NIH's change from individually negotiated indirect cost rates to a flat indirect cost rate for grant awards related to biomedical research was arbitrary and capricious because the NIH's "conclusory" explanation "plainly failed to sufficiently consider the substantial reliance interests at stake" for grant recipients); *see also Orr v. _____*, 778 F.Supp.3d 394, 423–24 (D. Mass. 2025) (holding that the State Department's passport policy removing the options for individuals to receive a passport with a sex marker reflective of their gender identity or to select a sex marker of "_____" rather than "M" or "F" was arbitrary and capricious because there was no evidence that, in adopting the policy, the defendants "took steps to identify facts bearing on the policy change, attempted to identify potential reliance interests, or sought to determine how any such interests may be impacted by the policy changes").

For these reasons, Plaintiffs are likely to succeed on their arbitrary and capricious claims regarding the Non-ACIP Actions and ACIP Actions.

4. The ACIP Appointments Violate the APA Because They Were Not Made in Accordance with FACA.

With a growing number of advisory committees appointed to guide national policy and decision making, concerns mounted that advisory committees' operations were not consistent or transparent across all committees. Congress responded by enacting FACA in 1972 to impose "administrative guidelines to justify the investment of time, effort and expense in the use of advisory groups as an instrument of Government."⁸² Congress recognized the value of having non-governmental individuals "furnish expert advice, ideas and diverse opinions to the Federal Government," *mmoc v. ore*, 180 F.3d 282, 284 (D.C. Cir. 1999), and, through FACA, implemented mandatory requirements to ensure committees did not go unchecked.⁸³ The APA provides a cause of action for review of agency decisions that violate federal law, including FACA. *See* 5 U.S.C. 706(2)(A), (C) (authorizing review of and "set aside" relief for agency actions taken "not in accordance with law" or taken "in excess of statutory jurisdiction, authority, or limitations"); *nion of oncerned Scientists v. heeler*, 954 F.3d 11, 19 (1st Cir. 2020); *see also Physicians for Soc. esp. v. heeler*, 956 F.3d 634, 643 (D.C.C. 2020).⁸⁴

Not only do courts have the authority to review FACA violations, an advisory committee's work product that resulted from FACA violations may be enjoined. *See, e.g., Ala ama om ig ee ivers oal. v. Dep t of nterior*, 26 F.3d 1103, 1107 (11th Cir. 1994) ("We find injunctive relief

⁸² *See the Federal Advisory ommittee Act A A Overvie and onsiderations for ongress*, Cong. Rsch. Servs., *citing earing on the ole and ffectiveness of ederal Advisory ommittees efore the . omm. on ov t Op.*, 91st Cong. (1970).

⁸³ The APA provides a vehicle for reviewing agency decisions that violate federal law. *nion of oncerned Scientists v. heeler*, 954 F.3d 11 (1st Cir. 2020) (*citing o els v. ed. rea of nvestigation*, 936 F. 3d 62, 66 (1st Cir. 2019) and other cases). Where, as here, plaintiffs allege that change to membership on an advisory committee alters the balance and role of special influence over that committee, courts rely on FACA to inform "what Congress intended the Secretary to consider;" and the "APA's reasoned decision-making standards" inform the rationality of any changes to policy that the committee recommends. *d.* at 20.

⁸⁴ The Court acknowledged this in denying the Defendants' Motion to Dismiss the Third Amended Complaint. *See* Memorandum and Order on Defendant's Motion to Dismiss, No. 25-11916-BEM (D. Mass. Jan. 6, 2026), ECF No. 168, at 20-22.

as the only vehicle that carries the sufficient remedial effect to ensure future compliance with FACA’s clear requirements. Anything less would be tantamount to nothing.”); *al. Forestry Ass’n v. U.S. Forest Serv.*, 102 F.3d 609, 614 (D.C.C. 1996) (injunctive relief is appropriate if the absence of a remedy renders FACA a nullity); *Western Org. of Resource Officials v. Bernhardt*, 412 F.Supp.3d 1227, 1243–44 (D. Mont. 2019) (“A use injunction preventing the agency from relying on an advisory committee’s recommendations or work product is the only way to achieve FACA’s purpose of enhancing public accountability . . .”).

i. FACA and Its Regulations Require Safeguards Against Inappropriate Influence.

Just as the binding regulations require FACA committees to be fairly balanced, the agency head “must” safeguard against inappropriate influence by the agency or any special interest. 41 C.F.R. 102-3.105(g). The word “must” denotes a nondiscretionary obligation. *an of ova Scotia v. United States*, 487 U.S. 250, 255 (1988). FACA requires federal agencies to make “appropriate provision 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.” 41 CFR 102-3.105(g). Advisory committee members whose professional interests or job prospects are directly affected by the committee’s output raise a strong potential for inappropriate influence. *See Argill, Inc. v. United States*, 173 F.3d 323, 339–340 (5th Cir. 1999) (expressing concern that committee members were negotiating job positions with agencies whose regulatory authority will be directly affected by the results of the committee’s study).

ii. The ACIP Appointments Have Resulted in an Unfairly Balanced Federal Advisory Committee in Violation of FACA.

The Secretary’s appointments to the ACIP contravene FACA in at least three different ways. The ACIP’s operative document on membership the Membership Balance Plan

(“MBP”) implements written safeguards to ensure the committee operates in a fairly balanced manner.⁸⁵ The Secretary failed to follow the MBP’s Candidate Identification Process, which requires widespread solicitation and ACIP Steering Committee review of proposed ACIP members.⁸⁶ The Secretary failed “to ensure the committee is balanced” consistent with the MBP’s “Point of View” and “Other Balance Factors” requirements.⁸⁷ As a result, the Secretarial appointment process filled the ACIP with individuals publicly espousing similar (anti-vaccine) views and preconceived hypotheses that vaccines are categorically unsafe to the exclusion of vaccinologists, epidemiologists, and other expert specialists and clinicians who do not hold such views.

First, the Secretary failed to follow the Candidate Identification Process. The MBP provides a detailed candidate identification process that “describe s the process” for achieving and evaluating ACIP balance as well as “how ACIP vacancies, if any, will be handled by the agency.”⁸⁸ The Candidate Identification Process provides three methods through which the Secretary can solicit names for new ACIP members: (1) email solicitation “distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations , academic centers, and other contacts in the field of vaccinology; (2) annual postings on the Federal Register; (3) announcements at ACIP meetings via a web link broadcast to all virtual attendees. Membership applications must be reviewed by the ACIP Steering Committee, which in turn, selects two candidates for each vacant position based on “the quality of the candidate’s technical expertise, balance of specialty areas , and geographic

⁸⁵ See U.S. DEP'T OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024).

⁸⁶ *See id.* at 6.

⁸⁷ *d.* at 4-5.

⁸⁸ *d.* at 4-6.

distribution.”⁸⁹ The ACIP Steering Committee must “finalize a proposed nomination package annually during November or December.”

The Secretary’s appointments of new ACIP members has occurred completely outside this framework. On June 9, 2025, the Secretary announced to the Wall Street Journal that he was “totally reconstituting the ACIP.”⁹⁰ Two days later, the Secretary appointed eight new members. Subsequent ACIP members were appointed on September 15, 2025, and January 13, 2026.⁹¹ For each set of appointments, no email solicitations were sent out, including not to liaison organizations, who were all terminated and cut off from participation by June 9, 2025. No notices were posted in the Federal Register. No applications were reviewed by the ACIP Steering Committee nor, upon information and belief, were two candidates identified for each vacancy before selecting one. Rather, the Secretary, upon information and belief, sought out individual members through a targeted campaign based on political affiliation and lack of public criticism of the President or Secretary.

This practice violates the core of the MBP whose purpose is to ensure fair balance across ACIP. The Secretary’s unequivocal failure to properly identify candidates consistent with the MBP’s objectives alone renders the resulting ACIP (the current ACIP membership) not fairly balanced.

Second, the Secretary failed to obtain fair point-of-view balance. The MBP’s “Points of View” section “describes the process that will be used to ensure the committee is balanced, and

⁸⁹ *d.*

⁹⁰ Robert F. Kennedy, Jr., *S Moves to restore Public trust in vaccines*, WALL ST. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

⁹¹ *S. D Announce ACIP Members*, U.S. DEP’T OF HEALTH & HUM. SERVS. (Sept. 15, 2025), <https://www.hhs.gov/press-room/hhs-cdc-announce-new-acip-members-sept-2025.html>; *Secretary Kennedy Appoints Obstetricians to CDC’s Advisory Committee on Immunization Practices*, U.S. DEP’T OF HEALTH & HUM. SERVS. (Jan. 13, 2026), <https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-ob-gyns-cdc-advisory-committee-immunization-practices.html>.

identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered.”⁹² The MBP explicitly states that “ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the Committee’s objectives.”⁹³ The requisite expertise and experience is captured through the four-part criteria upon which members are selected: (1) expertise in the field of immunization practices;” (2) “multi-disciplinary expertise in public health;” (3) “expertise in the use of vaccines and immunologic agents;” (4) “knowledge of vaccine development, evaluation, safety and delivery;” or (5) “in the case of a consumer representative knowledge about consumer perspectives and/or social and community aspects of immunization programs.”⁹⁴

With one exception,⁹⁵ the remaining ACIP members appointed by the Secretary categorically do not meet the requirement in the MBP. The Secretary’s appointments to the ACIP lack the requisite expertise, background, and credentials: three are obstetrician-gynecologists, one is a psychiatrist, one is an operations management professor, one is a cardiologist, and one is an emergency medical physician. Five current members have never engaged in vaccine-related research or publication. Another member (Levi) has published only two papers in which vaccines are discussed, both in 2025, just months before his appointment. In fact, at least three members (Blackburn, Pagano, and Pollack) have no discernable vaccine related experience at all.⁹⁶ To appreciate the extent to which the current ACIP members fail to satisfy this requirement, one need only look to the credentials of the ACIP members whom the Secretary fired on June 9, 2025. Those

⁹² U.S. DEP’T OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024) at 4.

⁹³ *d.*

⁹⁴ *d.*

⁹⁵ H. Cody Meissner, M.D., is professor of pediatrics at the Geisel School of Medicine at Dartmouth College and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. Fourth Am. Compl., *Am. Acad. Of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, 77.

⁹⁶ *See id.*

17 former ACIP members held a variety of positions in infectious diseases; epidemiology; vaccinology; immunology; and pediatrics, geriatrics, or maternal health.⁹⁷

Finally, the ACIP Appointments fail to achieve the “Other Balance Factors” set forth in the MBP. A factor that the MBP “identifies as important in achieving a balanced ACIP ” is a “balance of specialty areas.”⁹⁸ The specialty areas enumerated in the MBP that a balanced ACIP

⁹⁷ The positions of the former ACIP members included: (i) Professor of Pediatrics and Infectious Diseases Epidemiology, University of Colorado School of Medicine and Colorado School of Public Health, Jules Amer Chair in Community Pediatrics; (ii) The Gillings Distinguished Professor in Public Health, Department of Health Behavior, Gillings School of Public Health, University of North Carolina; (iii) The Chief Medical Officer at a community health center in Watts, CA; and formerly a clinical professor of pediatrics at the Charles R. Drew University of Medicine and Science and past-president of the California Immunization Coalition; (iv) Director, Mount Auburn Travel Medicine Center, Division of Infectious Diseases and Travel Medicine, Mount Auburn Hospital; Associate Professor of Medicine, Harvard Medical School; Lecturer, Massachusetts Institute of Technology; (v) Professor of Medicine, University of Washington School of Medicine; Professor of Epidemiology, University of Washington School of Public Health; Attending Physician, Harborview Medical Center; (vi) Associate Professor of Medicine, Pediatrics, and Medical Science (Clinical), The Warren Alpert Medical School of Brown University; Associate Program Director, Brown Combined Residency in Internal Medicine and Pediatrics; (vii) Attending Physician and Chief Medical Epidemiologist, Memorial Sloan Kettering Cancer Center; Professor of Medicine, Weill Cornell Medical College; (viii) Professor and Travelers Chair in Geriatrics and Gerontology; Director, UConn Center on Aging; Claude D. Pepper Older Americans Independence Center (OAIC), UConn Health; publisher of articles on vaccines for older adults and influenza vaccines; (ix) Vice President for Medical Affairs, Dean, Carver College of Medicine, University of Iowa, with significant scholarship on maternal health, vaccines and infectious diseases in pregnancy, and vaccine-preventable diseases such as influenza, Ebola, Zika, dengue, and COVID; (x) Owner of a family medicine practice in New York state and former liaison to the ACIP for the American Academy of Family Practitioners; (xi) Chief, Immunization Section, Illinois Department of Public Health, Division of Infectious Diseases; (xii) Senior Associate Dean for Faculty Development and Diversity, Taube Endowed Professor of Global Health and Infectious Diseases; Professor of Pediatrics and of Epidemiology and Population Health; Interim Chair, Department of Medicine, Stanford University School of Medicine; Medical Director, Infection Prevention and Control and Attending Physician, Lucile Packard Children's Hospital at Stanford, Department of Pediatrics; (xiii) Co-Director, Vaccine Education Center, Children's Hospital of Philadelphia; (xiv) Chief, Immunization Branch, California Department of Public Health; (xv) Professor of Medicine, Section of Infectious Diseases, Yale School of Medicine; (xvi) Professor of Medicine, Vanderbilt University, with significant scholarship in influenza and other viral respiratory infections, including studies of vaccine immunogenicity, safety, and effectiveness in older adults; clinical and molecular epidemiology of respiratory viruses; diagnostic testing and antiviral use; immunologic mechanisms of vaccine response and immunosenescence; and vaccine policy, evaluation, and prevention strategies for high-risk populations; (xvii) Adjunct Professor, Department of Community Health Sciences at SUNY Downstate School of Public Health, and former Assistant Commissioner for the Bureau of Immunization New York City Department of Health and Mental Hygiene; former Director of the Vaccine Operations Center for the NYC Health Department's COVID's response; former Epidemic Intelligence Service Officer in the Malaria Branch, Division of Parasitic Diseases, CDC; former Bureau of Immunization as Medical Director. See *A P ommittee Mem ers J ly*, *J ne*, , CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), https://archive.cdc.gov/details_url_https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html.

⁹⁸ U.S. DEPT OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024) at 5.

would have include: “pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, public health perspective, etc.”⁹⁹ Of the Secretary’s appointees, there is one expert in pediatric infectious disease who is operating in academia at Dartmouth College, but no practicing pediatricians or family medicine practitioners. There is one member trained in epidemiology, but not with prior focus on immunology. There are no representatives from state or local health departments, or from public health, or clinician pediatricians. Worse, as described above, there is a dearth of vaccine-related experience at all. The complete absence of experts in key areas critical to ACIP’s mission underscores the manner in which FACA has been ignored. This is exactly the type of imbalance that FACA sought to prevent. *See AA P egal Defense nd, nc. v. arr*, 496 F.Supp.3d at 136 137 (D.D.C. 2020) (finding advisory committee consisting only of law enforcement personnel was not fairly balanced as it related to its role in advising on policing policy changes.)

Additionally, Defendants have failed to avoid inappropriate influence through the ACIP Appointments. Rather, Defendants have created new channels of influence to the ACIP. The 1978 amendment to the ACIP Charter requiring the ACIP chair be appointed from within the committee rather than from a governmental agency (like the CDC, as had been the case) was a deliberate action to depoliticize the ACIP. The ACIP was intended to be an independent body of experts providing independent advice to the federal agencies they serve. But the Secretary’s deliberate appointments of special interest-affiliated persons to the ACIP has undermined this important safeguard.

The ACIP Appointments fails to meet the minimum requirements set forth in the statute requiring the avoidance of special interest groups. *d.* at 136 137 (and citations therein). Ten of

⁹⁹ *See id.*

the 14 ACIP members have publicly stated views on vaccines that align with the Secretary's anti-vaccine views. At least four are members or otherwise affiliated with openly anti-vaccine organizations. The new ACIP members include individuals who have stated that they will not allow their grandchildren to be vaccinated, several individuals who have a history of spreading patently false information about vaccines, and one member who boasted that she has "probably been anti-vax longer than RFK has."¹⁰⁰ These unambiguous facts cannot be squared with the requirement of a fair balance, and there is ample evidence that special interests are being favored by the Secretary's influence.

These multiple instances where the intent of FACA and the directives in the statute and implementing regulations have been disregarded fit well within the scope of those cases where injunctive relief is necessary to prevent an advisory committee from turning FACA's safeguards into a nullity. The composition of the current ACIP and the actions it has taken stand the intent of the law on its head and are no more than a rubber stamp for Defendants' agenda to create and spread public health misinformation. Accordingly, Plaintiffs are likely to succeed on their FACA claim.

II. Plaintiffs Suffered with Cited Serious Irreversible Harm to their Child A

Plaintiffs have endured significant and irreversible harm from the beginning of Defendants' targeted campaign to undermine vaccination protocols in the United States, beginning with the May 2025 Action. Those harms which include the diversion of resources to combat misinformation, confusion, and distrust, as well as non-compensable economic harms and imminent threats to public health have compounded and escalated with each Non-ACIP Action,

¹⁰⁰ See Fourth Am. Compl., *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, 76-77.

ACIP Action, and ACIP meeting. Such harms will continue and compound if the Challenged Actions are not enjoined. *See e Hampshire ndonesian mty. S pport v. r mp*, 157 F.4th 29, 35 (1st Cir. 2025) (citing *inter v. at. es. Def. o ncil, nc.*, 555 U.S. 7, 22 23 (2008)).

A. P i t i H S r d H r r H i t C b t M i r t i C i d D i t r t.

Rule and policy changes that directly impact organizational “burdens, costs, and effectiveness” pose a “real and substantial threat of imminent harm.” *See Mass. air o sing tr. v. .S. Dep t of o s. r an Dev.*, 496 F.Supp.3d 600 (D. Mass. 2020). Further, “o bstacles that unquestionably make it more difficult for the plaintiff to accomplish its primary mission provide injury for purposes of irreparable harm.”~~“actions by a defendant that make it more difficult for an organization to accomplish its primary mission provide injury for purposes of irreparable harm.”~~ *e or v. McMahon*, 784 F.Supp.3d 311, 362 (D. Mass 2025); , 770 F.Supp.3d at 322 (quoting *eag e of omen oters of .S. v. e y*, 838 F.3d 1, 9 (D.C. Cir. 2016) (holding that the degradation of vital infrastructure, loss of imperative staff, loss of human capital, and uncertainty around the ability to sustain future grant applications qualified as irreparable harms to the plaintiff institutions’ primary research missions).

The Non-ACIP Actions, the ACIP Actions, and the misinformation spread by the unbalanced ACIP have caused mass confusion among health care providers and patients.¹⁰¹ The process to effectuate the Non-ACIP Actions and ACIP Actions departed in significant ways from the ACIP’s and Defendants’ typical practices of compiling and evaluating evidence in support of reasoned recommendations. Further, none of the Non-ACIP Actions or ACIP Actions were accompanied by an MMWR publication or comparable guidance explaining the scientific rationale

¹⁰¹ *See* Ex. 27 (Kressly Decl.), 15, 26; Ex. 34 (Racine Decl.), 11, 15, 20, 40; Ex. 42 (Pring Decl.), 12, 14, 19, 24, 31, 46; Ex. 43 (Borenstein Decl.), 9, 19, 26; Ex. 31 (Berman Decl.), 15 17; Ex. 40 (Nahass Decl.), 14; Ex. 41 (Chen Decl.), 22, 24; Ex. 45 (Jeager Decl.), 16, 31, 34; Ex. 44 (Pavlos Decl.), 18, 29, 32, 33, 35.

or clearly defining core elements of vaccination practice, such as dosing, target populations, or the circumstances under which vaccination should be offered under SCDM.¹⁰² The Challenged Actions have resulted in the spread of significant misinformation regarding the safety, efficacy, and utility of vaccines, as well as the erosion of trust between patients and their providers.¹⁰³

As a result, Plaintiff Organizations and their members have been required to divert significant resources—including time, staff attention, and financial resources—from their core initiatives, primary missions, and patient care to engage in emergency mitigation work addressing the Non-ACIP Actions and ACIP Actions; to address the misinformation, confusion, and distrust resulting from the Challenged Actions; and to develop methods for navigating the implications of the same.¹⁰⁴ Such mitigation efforts include urgently working towards developing, revising, and distributing educational materials, guidance, websites, and publications to address the confusion created by the CDC schedule changes and responding to numerous member inquiries about the same.¹⁰⁵ It also includes having to re-examine voluminous clinical practice guidelines that were based on the assumption that children are routinely vaccinated to determine where additional decision points need to be added.¹⁰⁶ This work, which is already extraordinarily extensive, burdensome, and costly (of time, financial resources, and opportunity) is just beginning: Plaintiffs

¹⁰² See Ex. 25 (Benjamin Decl.), 20; Ex. 34 (Racine Decl.) 15; Ex. 43 (Borenstein Decl.) 22, 26; Ex. 31 (Berman Decl.) 9, 14 15; Ex. 41 (Chen Decl.) 25; Ex. 49 (Jane Doe 3 Decl.) 15-16, 17 (child refused vaccine because of confusion caused by a schedule change); Ex. 50 (Jane Doe 1 Decl.) 1-5, 20 (required to navigate a fragmented public health landscape, spanning her providers, pharmacies, and online resources, rife with confusion following a schedule change); Ex. 52 (Jane Doe 2 Decl.) 14, 31 32.

¹⁰³ See Ex. 34 (Racine Decl.) 14, 40; Ex. 42 (Pring Decl.) 24, 46; Ex. 43 (Borenstein Decl.) 9, 15, 19, 26, 33, 45, 50; Ex. 27 (Kressly Decl.) 13, 26, 40; Ex. 31 (Berman Decl.) 12, 16, 18; Ex. 40 (Nahass Decl.) 12, 14; Ex. 41 (Chen Decl.) 22, 24, 25; Ex. 45 (Jaeger Decl.) 10, 16, 31, 33, 34; Ex. 44 (Pavlos Decl.) 16 18, 20, 22, 24, 33, 36.

¹⁰⁴ See Ex. 27 (Kressly Decl.) 16, 26 31, 39; Ex. 25 (Benjamin Decl.) 31; Ex. 42 (Pring Decl.) 16, 23 24, 30, 46 47; Ex. 43 (Borenstein Decl.) 26, 45; Ex. 40 (Nahass Decl.) 12, 16, 17; Ex. 41 (Chen Decl.) 24; Ex. 45 (Jaeger Decl.) 31; Ex. 44 (Pavlos Decl.) 17 18, 22 24, 29, 33, 36 37; Ex. 34 (Racine Decl.) 13 18, 39.

¹⁰⁵ See Ex. 27 (Kressly Decl.) 26 28; Ex. 25 (Benjamin Decl.) 31; Ex. 42 (Pring Decl.) 23 30, 46; Ex. 44 (Pavlos Decl.) 23 24, 29 30, 35, 37; Ex. 31 (Berman Decl.) 14 15; Ex. 40 (Nahass Decl.) 15 17; Ex. 34 (Racine Decl.) 15, 18, 39.

¹⁰⁶ See Ex. 27 (Kressly Decl.) 31.

omen oters, 838 F.3d at 9). And if the February ACIP meeting were to go forward, Plaintiff Organizations and their members anticipate even more confusion, misinformation, and distrust, which would have compounding effects on all of these harms.¹¹²

B. Plaintiff's Harm That Cannot Be Compensated.

This court has recognized that “the costs of complying with challenged regulations” may be irreparable, given the obstacle faced in pursuing monetary damages. *California v. Kennedy*, F.Supp.3d, 2025 WL 2807729, at 6 (D. Mass. Oct. 1, 2025) (citing *Osario Rda v. Ivera Ernande*, 350 F.3d 219, 222 (1st Cir. 2003)). This is especially true in the APA context, where monetary damages are not available. *See id.* (citing *Ent Cy v. Idem*, 23 F.4th 585, 611 (6th Cir. 2022)); *see also*, 770 F.Supp.3d at 319–20. Indeed, economic harm can be irreparable where it is not accurately measurable or adequately compensable, or where the losses are compounding and disruptive. , 770 F.Supp.3d at 325–26.

Plaintiffs Organizations’ members and medical providers more broadly are experiencing and will continue to experience various financial harms due to the Challenged Actions. These harms include extended, largely uncompensated time spent engaging in SCDM discussions with patients during appointments (which also limits the number of patients that can be seen in a day, thereby also reducing compensation from that which pre-dated the Challenged Actions) as well as expenditures related to hiring additional staff to keep up with the demands on provider time resulting from the CDC schedule changes.¹¹³

¹¹² See Ex. 27 (Kressly Decl.) 41–42; Ex. 42 (Pring Decl.) 46–47.

¹¹³ See Ex. 43 (Borenstein Decl.) 9, 13, 15–17, 19, 22, 33; Ex. 27 (Kressly Decl.) 16; Ex. 42 (Pring Decl.) 19; Ex. 31 (Berman Decl.) 11, 13–14, 16–18; Ex. 25 (Benjamin Decl.) 30, 32; Ex. 40 (Nahass Decl.) 13, 15–16; Ex. 41 (Chen Decl.) 22, 24–25; Ex. 45 (Jaeger Decl.) 10, 11, 31, 33, 34; Ex. 51 (Hopkins) 26, 37, 41–43; *see also* Ex. 49 (Jane Doe 3) 25 (stating that schedule changes to shared clinical decision-making for her children can require a physician visit 45 minutes farther than her local pharmacy for her children’s flu and Covid-19 vaccinations, resulting in additional travel and electricity costs to charge her electric vehicle); Ex. 50 (Jane Doe 1) 13–14, 20 (diverting her work time to independently navigate vaccine access amid provider confusion)

Providers will also continue to experience administrative and financial burdens related to stocking, ordering, and supplying childhood vaccines. Stocking vaccines imposes significant financial and operational burdens on providers because vaccines are expensive upfront purchases, carry inventory loss and spoilage risk, and require expensive, refrigerated storage.¹¹⁴ Several childhood vaccines are available as combination vaccines, including (1) the diphtheria-tetanus-acellular pertussis (DTaP)-inactivated poliovirus (IPV)-HepB combination vaccine, (2) the DTaP-IPV-HepB-Haemophilus influenzae type B (Hib) combination vaccine, and (3) the DTaP-IPV-Hib combination vaccine. Previously, all vaccines included in these combination vaccines were routinely recommended. As a result of the new Childhood Schedule implemented on January 5, 2026, which changed the HepB dosing schedule without any consideration of downstream impacts, all HepB-containing combination vaccines are no longer part of routine recommendations.

Physician offices complete vaccine ordering months in advance and may not stock sufficient doses of combination vaccine options that do not contain HepB (*e.g.* Pentacel) or standalone vaccines for DTaP, IPV, and Hib to present as an alternative to parents and caregivers, so they will likely have to dispose of the now-unusable combination vaccines *and* incur additional costs to order more individual vaccines.¹¹⁵ Further, accommodating the stock for more individual vaccines will require ordering more expensive, medical-grade vaccine refrigerators and freezers.¹¹⁶ These economic costs of adapting to the Non-ACIP Actions and ACIP Actions are irreparable because they are compounding, disruptive, and not adequately compensable by a later injunction, and Plaintiffs have no means to obtain money damages from Defendants. *See* _____, 770 F.Supp.3d at 325 (finding harms irreparable because “ e ven for those harms that can be measured in dollars

¹¹⁴ *See* Ex. 25 (Benjamin Decl.) 26; Ex. 42 (Pring Decl.) 10, 39 40; Ex. 43 (Borenstein Decl.) 40.

¹¹⁵ *See* Ex. 27 (Kressly Decl.) 36; Ex. 42 (Pring Decl.) 39 40.

¹¹⁶ *See* Ex. 42 (Pring Decl.) 40.

and cents, the losses are compounding and will result in even greater disruption”); *see also California*, 802 F.Supp.3d at 283 (D. Mass. 2025).

C. Threats to Public Health and Safety

“Threats to public health and safety constitute irreparable harm that will support an injunction.” *Mayor of Providence, Inc. v. Omni Rhode Island*, No. 16-471-WES, 2017 WL 4081899, at 14 (D.R.I. Sept. 14, 2017); *Sierra Club v. U.S. Dept. of Agric., Natural Resources Serv.*, 841 F.Supp.2d 349, 358 (D.D.C. 2012). Plaintiffs need not wait until there is a significant rise in the rates of infection and hospitalizations in order to seek relief; if anything, waiting until then would be too late. *See, e.g., Silva v. East Providence* *proposing A* *uthority*, 390 F.Supp. 691, 695 (D.R.I. 1975).

The vaccines for diseases that have been downgraded from routine recommendations have a long track record of improving public health by reducing disease transmission, hospitalization, and vaccine-preventable deaths.¹¹⁷ Before a vaccine was introduced for rotavirus, there were an estimated 2.7 million rotavirus infections per year in the United States, and rotavirus caused more than 410,000 physician visits and 20–60 deaths annually.¹¹⁸ Since introduction, rotavirus vaccination prevents an estimated 40,000–50,000 hospitalizations per year among infants and young children and has decreased prevalence of rotavirus among older children and adults that are not vaccinated.¹¹⁹

¹¹⁷ See Ex. 25 (Benjamin Decl.) 22–24; Ex. 27 (Kressly Decl.) 13.

¹¹⁸ See Margaret Cortese & Penina Haber, *Chapter Rotaviruses*, in *Texts for Disease Control and Prevention Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 25, 2024).

¹¹⁹ *Rotavirus vaccine recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Jul. 15, 2024), <https://www.cdc.gov/rotavirus/hcp/vaccine-considerations/index.html>.

RSV is the leading cause of hospitalization among infants, and nearly all infants contract RSV by age 2.^{120,121} Before RSV immunizations were introduced, RSV caused approximately 58,000–80,000 hospitalizations and 100–300 deaths in children under 5 each year.¹²² One modeling study estimated that 2.1 million children under 5 years of age with RSV infection required medical attention annually.¹²³ Following the introduction of RSV immunizations, the burden of disease declined: cumulative RSV-associated hospitalization rates among infants 0–7 months of age fell from an estimated 14.8–15.0 cases per 1,000 children in the 2018–2020 seasons to 8.5–10.7 cases per 1,000 children in the 2024–2025 season.¹²⁴ RSV immunization is also demonstrated to be cost-effective; an analysis estimated that if half the US birth cohort received nirsevimab, immunization would avert approximately 100,000 outpatient visits and avert approximately 14,000 hospitalizations per year, at a cost of \$153,517 per quality-adjusted life year (“QALY”) saved.¹²⁵

Similarly, influenza has a significant impact on children; estimates for the 2024-2025 respiratory season indicate that 14.6 million children contracted influenza and 56,000 were

¹²⁰ See Danielle L. Moulia, et al., *vidence to ecommendation rame or lesrovima* , ADVISORY COMM. ON IMMUNI ATION PRACS. (Apr. 16, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf>.

¹²¹ See Danielle L. Moulia, et al., *evidence to recommendation rame or lesrovima*, ADVISORY COMM. ON IMMUNI ATION PRACS. (Apr. 16, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf>.

¹²² See increased respiratory Syncytial virus (RSV) Activity in Parts of the Southeastern United States and Prevention Tools Available to Protect Patients, CTRS. FOR DISEASE CONTROL AND PREVENTION (Sept. 5, 2023), <https://www.cdc.gov/han/2023/han00498.html>.

¹²³ See Caroline Breese Hall, et al., *he rden of espiratory Syncytial ir s nfection in o ng hildren*, 360 NEJM 588 (2009), <https://www.nejm.org/doi/10.1056/NEJMoa0804877> url ver 39.88-2003&rfr id ori:rid:crossref.org&rfr dat cr pub 20 200www.ncbi.nlm.nih.gov.

¹²⁴ See Megan E. Patton, et al., *Interim Evaluation of Respiratory Syncytial Virus Hospitalizations Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products*, *United States, October 2021 to February 2022*, 74 MORBIDITY & MORTALITY WKLY. REP. 421 (May 8, 2025), https://www.cdc.gov/mmwr/volumes/74/wr/mm7416a1.htm?s_cid=mm7416a1.w.

¹²⁵ See David W. Hutton, et al., *ost effectiveness of irsevim for espiratory Syncytial ir s nfants and o ng hildren*, 154 PEDIATRICS (Nov. 5, 2024).

hospitalized.¹²⁶ During the same season, an estimated 17,400 pediatric hospitalizations were prevented due to vaccination.¹²⁷ While influenza causes a continued impact on hospital settings and substantial disease burden, routine vaccination has historically been a proven strategy to reduce severe illness among pediatric populations.¹²⁸

HepA occurred in epidemics, the largest of which peaked in 1971 at nearly 60,000 cases.¹²⁹ Following the introduction of a vaccine, hospitalization rates declined by more than 68%, and ambulatory care visits declined by more than 40%.¹³⁰ Hand-in-hand with a reduction in disease and medical attention was a reduction in medical expenditures: from 1996 to 2004, medical costs associated with HepA dropped by 68%, from \$29.1 million to \$9.3 million.¹³¹

Meningococcal disease has high severity: between 10-15% of individuals who contract meningococcal disease die, and among survivors, 20% have permanent sequelae such as neurologic damage, hearing loss, or loss of a limb.¹³² Before the MenACWY vaccine was introduced in 2005, an estimated 1,400-2,800 cases of meningococcal disease occurred each year in the U.S.¹³³ By contrast, in 2024, there were 503 cases of meningococcal disease (this number represents the highest reported annually since 2013).¹³⁴

¹²⁶ See Influenza Division, Ctrs. for Disease Control & Prevention, *Severity, Disease Burden, and Prevented Burden for the 2025-26 Season*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 25, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-dugan-influenza-508.pdf>.

¹²⁷ See *id.*

¹²⁸ See *id.*

¹²⁹ See *Hepatitis A*, in *Trs. for Disease Control & Prevention Epidemiology and Prevention of Vaccine Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), <https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf>.

¹³⁰ See *id.*

¹³¹ See *id.*

¹³² See Sarah Mbaeyi, et al., *Chapter 14: Meningococcal Disease*, in *Trs. for Disease Control and Prevention Epidemiology and Prevention of Vaccine Preventable Diseases*, THE PINK BOOK (Apr. 25, 2024), <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-14-meningococcal-disease.html>.

¹³³ See *Hepatitis A*, in *Trs. for Disease Control & Prevention Epidemiology and Prevention of Vaccine Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), <https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf>.

¹³⁴ See *Meningococcal Disease Surveillance and Trends*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 9, 2025), <https://www.cdc.gov/meningococcal/php/surveillance/index.html>.

These public health successes are in jeopardy of being reversed quickly, which would in turn overwhelm the U.S. health care system.¹³⁵ Further, if the February ACIP meeting proceeds as scheduled, “it will immediately compound the harms already inflicted on . . . the public health system” by “amplifying confusion, deepening the erosion of trust on which coordinated public health depends, and further destabilizing a stressed public health system.”¹³⁶ Although an agenda has not been released for the February meeting, ACIP members have hinted at potential topics, including downgrading polio and measles vaccines from routine in favor of “freedom of choice” and removing Covid mRNA vaccines from the market.¹³⁷ Regardless of topics discussed, however, based on the documented events of this ACIP’s prior meetings, Plaintiffs’ reasonable fears that future meetings of this ACIP will disseminate further public health misinformation rise above the level of speculation and are sufficient to satisfy the standard for irreparable harm.

Even a modest erosion in vaccination rates could result in immediate increases in preventable illness, morbidity, and death.¹³⁸ And crucially, the arbitrary and capricious Non-ACIP Actions and ACIP Actions are negatively affecting trust and immunization rates for *all* vaccines, not just the downgraded vaccines.¹³⁹ Put simply, “o nce these systems fail and preventable disease

¹³⁵ See Ex. 25 (Benjamin Decl.) 22.

¹³⁶ See *id.* 32–33.

¹³⁷ See Apoorva Mandavilli, *electing Decades of Science, vaccine Panel hair Says Polio and Other Shots Sho ld e Optional*, N.Y. TIMES, Jan. 23, 2026, <https://www.nytimes.com/2026/01/23/health/milhoan-vaccines-optional-polio.html>; see also End Tribalism in Politics (@EndTribalism), (Jan. 21, 2026, 5:09 PM), <https://x.com/EndTribalism/status/2014098027074449438> s 20. (video of ACIP member Dr. Robert Malone).

¹³⁸ See Katherine Wu, *otavir s o ld ome oaring ac ery Soon*, THE ATLANTIC, Jan. 5 2026, <https://www.theatlantic.com/health/2026/01/childhood-vaccine-schedule-rotavirus-paul-offit/685513/>; see also Ex. 45 (Jaeger Decl.) 26 (“As vaccination rates begin to decline, herd immunity will erode, at which point outbreaks will occur more rapidly.”), 31 (“When vaccines are presented as SCDM rather than routine, parents are more likely to delay or decline. Delays increase the likelihood that future vaccines will also be delayed or missed entirely.”); Ex. 27 (Kressly Decl.) 13 (“The Directive removing the COVID-19 vaccine from the routine vaccination recommendations . . . has eroded some patients’ faith and trust in all vaccines, causing them to refuse a myriad of routine vaccinations and creating an even more imminent and severe risk of serious illness, hospitalization, and death.”).

¹³⁹ See Ex. 45 (Jaeger Decl.) 13, 26, 31; Ex. 27 (Kressly Decl.) 13, 40; Ex. 41 (Chen Decl.) 24; Ex. 34 (Racine Decl.) 20.

spreads, no later remedy can restore the lives lost as a result.”¹⁴⁰ That kind of threat to human life is a “quintessentially irreparable” harm. *Am. Soc’y of Mfrs. v. Int’l Paper Co.*, 770 F.Supp.3d at 321 (“The Court is hard pressed to think of a loss more irreparable than the loss of a life There is no question, there can be no do over and no redress.”).

III. The Balance of Equities and the Public Interest Favor Plaintiff.

When deciding whether to grant a preliminary injunction, courts must “balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 129 S.Ct. 365, 367 (2008) (citation modified). Here, both the balance of equities and the public interest overwhelmingly favor Plaintiffs and compel preliminary injunctive relief.

A. The Hardships Favor Plaintiff

The balance of hardships overwhelmingly favor Plaintiffs. Absent preliminary injunctive relief, Plaintiffs will continue to suffer immediate, irreparable, and escalating harms caused by Defendants’ unlawful vaccine policy actions. Those harms include the diversion of limited clinical and public-health resources from patient care and disease prevention; uncompensated time counseling patients and families confused by abrupt and inadequately explained vaccine recommendations; disruption of established vaccination practices and supply chains; and increased risk that children, pregnant individuals, and immunocompromised patients will forgo timely immunization. These harms are not speculative. They are occurring now and will continue to compound absent judicial intervention. Clinicians and public health organizations are already expending extraordinary time and resources to correct confusion, counter unsupported federal messaging, and mitigate declining vaccination confidence. This time and these resources cannot

¹⁴⁰ See Ex. 25 (Benjamin Decl.) 31-33.

B. Th P b i I t r t Str S rt Pr i i r I ti R i

¹⁴¹ See e.g. Ex. 25 (Benjamin Decl.) 26, 30-31 (“APHA has been forced to divert staff and expert contributors to review its flagship publications, including the Control of Communicable Diseases Manual, because those works have utilized the evidence-based ACIP framework that the Defendants have abandoned.”); Ex. 27 (Kressly Decl.) 26-28, 31; Ex. 28 (O’Shea Decl.) 7-9, 15-16, 18-21 (“Based on the 2026 Schedule Change, our practice was forced to change our operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. These changes will impact how we see patients, our availability to patients, and ultimately will harm patient uptake of vaccines.”); Ex 34 (Racine Decl.) 13-19, 39 (“ A significant portion of the AAP’s efforts involves interpreting government recommendations and translating them into toolkits, guidance documents, and communications for pediatricians and the public . . . due to the confusion that the Vaccine Changes have caused.”); Ex. 36 (Pavia Decl.) 40, 41; Ex. 42 (Pring Decl.) 23 24, 45-46; Ex. 44 (Pavlos Decl) 23, 24, 29, 35-36, 40; Ex. 46 (Srinivas Decl.) 17, 18, 25-26

838 F.3d at 12; *see also* *Neighborhood Association of the Academy, Inc. v. Fed. Transit Admin.*, 407 F.Supp.2d 323, 343 (D. Mass. 2005); *Alar v. Office of Fed. Postal Oversight*, 355 F.Supp.2d 56, 66 (D.D.C. 2004) (noting a “substantial public interest” in ensuring that a federal agency “acts within the limits of its authority”).

That public interest is directly implicated here. Plaintiffs have demonstrated that the Defendants’ failure to follow the customary, evidence-based framework for vaccine recommendations has destabilized America’s public health infrastructure and forced Plaintiff Organizations, clinician-members, and patients into a state of confusion, uncertainty, and perpetual crisis-response mode.¹⁴² By altering the CDC immunization schedule without ACIP evidence-based review, or through an improperly constituted advisory committee, Defendants have replaced evidence-based recommendations with unexplained departures that have sown confusion and distrust among public health organizations, medical associations, providers, and patients alike.¹⁴³ Those disruptions materially increase the risk of outbreaks of vaccine-preventable diseases, including HepB and RSV. Such harms cannot be remedied after the fact.¹⁴⁴ The Defendants here are not preventing public-health harm, they are creating it. Where unlawful government action undermines disease-prevention systems and leaves public health professionals unable to anticipate or contain outbreaks, the public interest weighs decisively in favor of injunctive relief. *See Savino v. So. a*, 459 F.Supp.3d 317, 331–32 (D. Mass. 2020).

The public interest is therefore served by restoring lawful decision-making, preserving reliance on evidence-based immunization frameworks, and preventing further irreparable harm to

¹⁴² *See* Ex. 25 (Benjamin Decl.) 20–21, 31–32; Ex. 34 (Racine Decl.) 14–15, 40; Ex. 44 (Pavlos Decl.) 16–18, 32–33; Ex. 46 (Srinivas Decl.) 14–28; Ex. 48 (Moser Decl.) 25.

¹⁴³ *See* Ex. 27 (Kressly Decl.) 13, 40; Ex. 41 (Chen Decl.) 22–25; Ex. 31 (Berman Decl.) 16–17.

¹⁴⁴ *See* Ex. 25 (Benjamin Decl.) 22–25; Ex. 28 (O’Shea Decl.) 23–26; Ex. 26 (Lewis Decl.) 21.

public health while this case is adjudicated. *See* , 770 F.Supp.3d at 326. Accordingly, the public interest weighs decisively in favor of preliminary injunctive relief.

IV. CONCLUSION

This Court should grant the relief requested in the Proposed Order attached hereto as Exhibit A.

Original Dated: January 26, 2026
Corrected Dated: February 9, 2026

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EXHIBIT B

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

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

VS.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*,

Defendants.

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

**PLAINTIFFS' ERRATA SHEET IN SUPPORT OF THEIR
MOTION FOR LEAVE TO FILE A CORRECTED MEMORANDUM OF LAW
IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

PAGE ¹	LINE	TEXT IS	TEXT SHOULD BE	REASON
25	13-15	<i>Am. P. v. Health Ass'n v. at Inst. of Health</i> , 791 F.Supp.3d 119, 178 (D. Mass. 2025) (quoting <i>Ohio v. Nevada Prot. Agency</i> , 603 U.S. 279, 292 (2024))	<i>Ohio v. Nevada Prot. Agency</i> , 603 U.S. 279, 292 (2024) (quoting <i>State arm</i> , 469 U.S. at 43)	Two orders in <i>Am. P. v. Health Ass'n v. at Inst. of Health</i> , 791 F.Supp.3d 119, 178 (D. Mass. 2025) were stayed by the U.S. Supreme Court pending appeal. <i>Ohio v. Nevada Prot. Agency</i> , 603 U.S. 279, 292 (2024) supports the same proposition.
34	9-18	<i>see also Orr v. Rump</i> , 778 F.Supp.3d 394, 423	<i>see also</i> , 770 F.Supp.3d at 308-11	The Supreme Court stayed the

¹ Additional changes were made to the title of the Memorandum, the table of contents, and the table of authorities to reflect the changes identified in this Errata Sheet.

		24 (D. Mass. 2025) (holding that the State Department’s passport policy removing the options for individuals to receive a passport with a sex marker reflective of their gender identity or to select a sex marker of “ ” rather than “M” or “F” was arbitrary and capricious because there was no evidence that, in adopting the policy, the defendants “took steps to identify facts bearing on the policy change, attempted to identify potential reliance interests, or sought to determine how any such interests may be impacted by the policy changes.”)	(holding that the NIH’s change from individually negotiated indirect cost rates to a flat indirect cost rate for grant awards related to biomedical research was arbitrary and capricious because the NIH’s “conclusory” explanation “plainly failed to sufficiently consider the substantial reliance interests at stake” for grant recipients)	preliminary injunction granted in <i>Orr v. r mp</i> , 778 F.Supp.3d 394 (D. Mass. 2025). supports the same proposition.
43	8 14	“actions by a defendant that make it more difficult for an organization to accomplish its primary mission provide injury for purposes of irreparable harm.” <i>e or v. McMahon</i> , 784 F.Supp.3d 311, 362 (D. Mass. 2025);	“ o bstacles that unquestionably make it more difficult for the plaintiff to accomplish its primary mission provide injury for purposes of irreparable harm.” , 770 F.Supp.3d at 322 (quoting <i>eag e of omen oters of .S. v. e y</i> , 838 F.3d 1, 9 (D.C. Cir. 2016) (	<i>e or v. McMahon</i> , 784 F.Supp.3d 311, 362 (D. Mass. 2025) is an order granting a preliminary injunction. That preliminary injunction was later stayed by the U.S. Supreme Court. quoting <i>eag e of omen oters</i> supports the same proposition.
45 46	18 19; 1	<i>McMahon</i> , 784 F.Supp.3d at 362; <i>at l</i>	, 770 F.Supp.3d at 321 (quoting <i>eag e of</i>	The Supreme Court stayed the

		<i>nsts. Of ealth</i> , 770 F.Supp.3d at 322.	<i>omen oters</i> , 838 F.3d at 9)	preliminary injunction granted in <i>e or v. McMahon</i> , 784 F.Supp.3d 311 (D. Mass. 2025). supports the same proposition.
53	9 10	<i>See eag e of omen oters of .S. v. e y</i> , 838 F.3d 1, 12 (D.C. Cir. 2016).	<i>See eag e of omen oters</i> , 838 F.3d at 12.	Change to short cite to reflect that case was introduced earlier in the brief due to the aforementioned changes.
55	6 7	Dated: January 26, 2026	Original Dated: January 6, 2026 Corrected Dated: February 9, 2026	Updated date to reflect filing of Corrected Memorandum.

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**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, address[ed] 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[ing]” 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 States 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 *workgroups*. 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 horrors,” 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.

February 9, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

February 9, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

APPENDIX

VOLUME II OF III

(App. 291–642)

United States Court of Appeals for the First Circuit

No. 26-1503

American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS,
AMERICAN COLLEGE OF PHYSICIANS,
INC., AMERICAN PUBLIC HEALTH
ASSOCIATION, INFECTIOUS DISEASES
SOCIETY OF AMERICA, MASSACHUSETTS
PUBLIC HEALTH ASSOCIATION D/B/A
MASSACHUSETTS PUBLIC HEALTH
ALLIANCE, SOCIETY FOR MATERNAL-
FETAL MEDICINE, THE MASSACHUSETTS
CHAPTER OF THE AMERICAN ACADEMY
OF PEDIATRICS, JANE DOE 1, JANE DOE 2,
and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; JIM O'NEILL, in his official capacity
as Acting Director of Centers for Disease Control
and Prevention; CENTERS FOR DISEASE
CONTROL AND PREVENTION; and DOES 1–
50, inclusive,

Defendants.

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

**PLAINTIFFS' CORRECTED
MEMORANDUM OF LAW IN
SUPPORT OF THEIR MOTION FOR
PRELIMINARY INJUNCTION**

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

**Leave to File Granted on February 10,
2026**

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INTRODUCTION

Since his confirmation as Secretary of the United States Department of Health and Human Services (“HHS”) on February 13, 2025, Defendant Robert F. Kennedy, Jr. (the “Secretary”), along with HHS and the agencies and officials acting under his leadership (collectively, “Defendants”), have engaged in a series of final agency actions to significantly change the nation’s vaccine policy. These arbitrary and capricious actions sow confusion and undermine public health, purposefully disregard and contravene required process, and ignore decades of established science. Because the Defendants have failed to “examine the relevant data and articulate a satisfactory explanation for [their] action[s],” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983) (“*State Farm*”), the final actions challenged herein violate the Administrative Procedure Act, 5 U.S.C. §§ 701, *et seq.*, and must be set aside.

The final agency actions that Defendants, including the Secretary and co-Defendant Jim O’Neill, Acting Director of the Centers for Disease Control and Prevention (“O’Neill” or “Acting CDC Director”), have taken to date to change vaccine policy include (collectively, the “Challenged Actions”):

1. A Secretarial Directive, announced in a video posted on X on **May 27, 2025**, instructing the Centers for Disease Control and Prevention (“CDC”) to remove the recommendations from CDC immunization schedules that pregnant women and children receive the Covid vaccine (the “**May 2025 Action**”);¹
2. The terminations of all 17 sitting members of the Advisory Committee on Immunization Practices (“ACIP”) on **June 9, 2025**, and replacement of them, starting

¹ Plaintiffs submit their Appendix of Evidence with this Motion, containing Exhibits 1-53. **May 2025 Action** materials are attached as Exhibits 1–4. See *Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025) (attached as Ex. 1); Robert F. Kennedy, Jr., @SecKennedy, X (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138> (attached as Ex. 2); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 3); *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 28, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 4).

on **June 11, 2025**, with new members who either do not possess the requisite qualifications or expertise or who have publicly stated anti-vaccine views that align with the Secretary's (the "**ACIP Appointments**").²

3. A **June 26, 2025**, vote of the ACIP to remove thimerosal from all influenza vaccines distributed in the U.S., adopted by the Secretary³ on July 23, 2025 (the "**June 2025 Thimerosal Action**").⁴
4. A **September 19, 2025** vote of the ACIP to downgrade the Covid vaccine recommendation from routinely recommended for all under age 65 to "shared clinical decision making" ("SCDM"), adopted by the CDC Director on October 6, 2025 (the "**September 2025 Action**").⁵
5. A **December 5, 2025** vote of the ACIP to downgrade the Hepatitis B ("HepB") vaccine recommendation from a routinely recommended three-dose series starting at birth for all children to SCDM for all doses for children born to HepB negative mothers.

² The Secretary made additional unlawful appointments to the ACIP on September 11, 2025, and January 13, 2026.

³ At the time, the CDC director position was vacant. In the absence of a CDC director, the Secretary decides whether to adopt a vote of the ACIP. *ACIP Recommendations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 8, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/index.html>.

⁴ The **June 2025 Thimerosal Action** materials are attached as Exhibits 5–9. *See Advisory Committee on Immunization Practices, Final Agenda (June 25–26, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 24, 2025), <https://www.cdc.gov/acip/downloads/agendas/Final-posted-2025-06-24-508.pdf> (attached as Ex. 5); *Meeting of the Advisory Committee on Immunization Practices (ACIP), June 25–26, 2025 Meeting Summary (June 25–26, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION <https://www.cdc.gov/acip/downloads/minutes/summary-2025-06-25-26-508.pdf> (attached as Ex. 6); Press Release, U.S. Dep't of Health & Human Servs., *Thimerosal (Mercury) Removed from U.S. Flu Vaccines Following ACIP Recommendation* (July 23, 2025), <https://www.hhs.gov/press-room/thimerosal-mercury-removed-from-us-flu-vaccines-acip.html> (attached as Ex. 7); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at <https://web.archive.org/web/20250703123549/https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 8); *Recommended Adult Immunization Schedule for Ages 19 Years or Older; United States 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (July 2, 2025), archived at <https://web.archive.org/web/20250715024339/https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 9).

⁵ The **September 2025 Action** materials are attached as Exhibits 10–14. *See Advisory Committee on Immunization Practices, Final Agenda (Sept. 18–19, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 19, 2025), <https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-09-19-508.pdf> (attached as Ex. 10); *Meeting of the Advisory Committee on Immunization Practices (ACIP), Sept. 18-19 2025 Meeting Summary (Sept. 18-29, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION <https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf> (attached as Ex. 11); Press Release, Ctrs. for Disease Control & Prevention, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), <https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html> (attached as Ex. 12); *Recommended Adult Immunization Schedule for Ages 19 Years or Older; United States 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/adult/adult-combined-schedule.pdf> (attached as Ex. 13); *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 7, 2025), <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf> (attached as Ex. 14).

adopted by the Acting CDC Director on December 16, 2025 (the “**December 2025 HepB Action**”).⁶

6. A Decision Memo signed by O’Neill on **January 5, 2026**, downgrading immunization recommendations for six (6) conditions on the CDC’s Recommended Immunization Schedule for Child and Adolescent Ages 18 Years or Younger (the “Childhood Schedule”): (i) Downgrade to Risk-Based; Hepatitis A, Hepatitis B, MenACWY, RSV; and (ii) Downgrade to SCDM: Hepatitis A, Influenza, MenACWY, Rotavirus. The January 5, 2026 Action also removed from the Childhood Schedule the second dose of the HPV vaccine and the birth dose of HepB for infants in the SCDM recommendation category, and limited the age range of the SCDM recommendation for MenB. (The January 5, 2026 final agency action is hereafter referred to as the “**January 2026 Action**”).⁷

For both the May 2025 Action and January 2026 Action (collectively, the “Non-ACIP Actions”), the Secretary and Acting CDC Director bypassed without explanation the longstanding process that stakeholders in the health care system have come to rely on by which subgroups of the ACIP, known as Work Groups, study “disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of the evidence reviewed, economic analyses, and implementation issues;”⁸ Work Groups make “Evidence to Recommendation” framework (“EtR”) presentations at public meetings of the ACIP; the ACIP as a whole then

⁶ The **December 2025 HepB Action** materials are attached as Exhibits 15-17. See *Meeting of the Advisory Committee on Immunization Practices, Agenda (Dec. 4–5, 2025)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 4, 2025), <https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-12-04-508.pdf> (attached as Ex. 15); Press Release, U.S. Dep’t of Health & Human Servs., *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025), <https://www.hhs.gov/press-room/acip-recommends-individual-based-decision-making-hepatitis-b-vaccine-birth-dose-infants-born-women-test-negative-virus.html> (attached as Ex. 16); Press Release, Ctrs. for Disease Control & Prevention, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025), <https://www.cdc.gov/media/releases/2025/2025-hepatitis-b-immunization.html> (attached as Ex. 17).

⁷ The **January 2026 Action** materials are attached as Exhibits 18-20. See Ex. 18, U.S. Dep’t of Health & Human Servs., *Decision Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf>; Ex. 19, U.S. Dep’t of Health & Human Servs., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf>; Ex. 20, Childhood Immunization Schedule by Recommendation Group, CDC (Jan. 5 2026), <https://www.hhs.gov/childhood-immunization-schedule/index.html>

⁸ See *Amendment to the Charter of the Advisory Committee on Immunization Practices*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> (attached as Ex. 21).

considers the evidence, data, and presentations, often at multiple meetings; and, when ready, votes on how immunizations are recommended for use in the U.S. and listed on CDC schedules (the “ACIP Process”). The May 2025 Action targeted vaccines against one infectious disease; the January 2026 Action targeted immunizations against several diseases. These two actions suffer from the same legal defects under the APA: Defendants failed to examine relevant data and failed to provide a reasoned explanation for changing the CDC schedules while bypassing the ACIP Process in doing so. The May 2025 Action injected disruption and confusion into the health care system that has harmed the Plaintiffs specifically, as well as the broader public. The January 2026 Action has significantly amplified these harms.

Plaintiffs also seek to set aside the votes taken by the current ACIP whose members were appointed in violation of the Federal Advisory Committee Act, 5 U.S.C. §§ 1001, et seq. (“FACA”), and the ACIP Charter (the “ACIP Actions”). The current ACIP took those votes without following ACIP best practices, including consulting with Work Groups or following the EtR framework.

Finally, Plaintiffs seek to enjoin the current ACIP from holding a public meeting (the next scheduled meeting is February 25–26, 2026) until an adjudication on the merits of the lawfulness of the appointments of the current ACIP members (the “ACIP Appointments”). The current ACIP held three public meetings in 2025 at which speakers made many false and misleading statements about vaccines and infectious disease that have harmed the Plaintiffs and the public health.

Plaintiff public health organizations, medical associations, and clinician-members have had to divert resources from their core missions of protecting public health to combat the false and misleading statements emanating from the federal advisory committee that is charged with providing “advice and guidance to the Director of the CDC regarding use of vaccines and related

agents for *effective control of vaccine-preventable diseases in the civilian population of the United States.*”⁹ The membership and conduct of the current ACIP at public meetings are wholly at odds with this charge. The Plaintiffs and the public are harmed when false and misleading health-related information is spread at a public ACIP meeting. People die from believing health-related misinformation. Future meetings of the ACIP must be enjoined until a decision on the merits of whether the current ACIP membership must be set aside.

BACKGROUND AND STATEMENT OF FACTS

I. U.S. Vaccine Approval and Recommendation Processes

Two agencies housed inside of HHS—the Food and Drug Administration (“FDA”) and the CDC—oversee the process that results in a vaccine being licensed and recommended for use in the United States. The FDA reviews Biologics License Applications (“BLA”) submitted by manufacturers for approval to market new vaccines for use in the United States. 42 U.S.C. § 262(a)(2). A BLA is a comprehensive submission that includes preclinical and clinical data and information, as well as details of the manufacturing process and facilities. Licensure requires a demonstration that (1) the vaccine is safe, pure, and potent, and (2) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent. 42 U.S.C. § 262(a)(2)(C).

The CDC, in turn, provides public health guidance for safe use of the vaccine. In 1964, the Surgeon General of the United States established the ACIP due to mounting interest in national immunization policy and the absence of a consistent panel of technical expertise available to advise

⁹ See *ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/about/acip-charter.html> (emphasis added) (*ACIP Charter*); see also *ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 1, 2024), <https://restoredcdc.org/www.cdc.gov/acip/downloads/acip-charter.pdf> (previous ACIP Charter containing same language).

the federal government on immunization-related issues as they arose.¹⁰ The ACIP was designated a federal advisory committee in 1972.¹¹ The role of the ACIP is “to assist the [CDC] and the [HHS] in development of public policy related to immunization of the civilian population in the United States,”¹² and to provide “advice and guidance to the Director of the CDC regarding use of vaccines and related agents for *effective control of vaccine-preventable diseases in the civilian population of the United States*.”¹³

The engines that power the ACIP recommendation process are the Work Groups. As stated in the Work Groups Standard Operating Procedures manual:

ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs are intended to augment the effectiveness of ACIP. ... ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.¹⁴

While the BLA is under review at the FDA, which can take several years, an ACIP Work Group thoroughly reviews public and nonpublic information about the vaccine, so that the Work Group will be prepared to present information to the ACIP about the vaccine as soon as it is licensed. The Standard Operating Procedures manual for ACIP Work Groups provides: “*WGs*

¹⁰ See Jean Clare Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 955, 955 (Oct. 24, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm>

¹¹ See *id.*

¹² *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>

¹³ *ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 3, 2025), <https://www.cdc.gov/acip/about/acip-charter.html> (emphasis added).

¹⁴ *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 2 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

*should begin reviewing data **12-18 months prior to a potential decision on [FDA] licensure**; the length of time required for the WG to review data in anticipation of vaccine licensure will depend upon the complexity of the topic, and the amount of available data that exists”.*¹⁵

In 2010, the ACIP adopted a best practice called the “GRADE” approach—Grading of Recommendations, Assessment, Development, and Evaluation—for Work Groups to assess the quality of evidence and develop evidence-based recommendations.¹⁶ The GRADE approach provides a framework for assessing the certainty (*i.e.*, quality or confidence) of the evidence and moving from evidence to decision making (*i.e.*, recommendations).¹⁷

In 2018, the ACIP adopted by unanimous vote another best practice, the Evidence to Recommendation (“EtR”) framework. As explained in the ACIP EtR User’s Guide, the “ACIP has continued to follow and build upon the methodological advances in the GRADE approach and, as a result, has developed a modified Evidence to Recommendation (EtR) framework tailored to the needs of ACIP (Appendix 1). The purpose of the EtR framework is to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.”¹⁸

The 21st Century Cures Act, 130 Stat. 1033, requires the ACIP to take up consideration of a newly-FDA-approved vaccine at the next public ACIP meeting after FDA approval is

¹⁵ *Id.* (italics in original, bold added).

¹⁶ See *Introduction in ACIP GRADE Handbook*, CTBS. FOR DISEASE CONTROL & PREVENTION (April 22, 2024) <https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html>.

¹⁷ See *id.*

¹⁸ See *ACIP Evidence to Recommendation User’s Guide*, CTBS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide_october-1-2020.pdf.

announced.¹⁹ By that time, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers.²⁰

Dr. Jason Goldman, current President of Plaintiff American College of Physicians (“ACP”), became an ACP liaison representative to the Pneumonia Vaccine Work Group in 2019 and to the Covid Vaccines Work Group in 2020.²¹ He served on these Work Groups until the Secretary terminated liaison participation in Work Groups on July 31, 2025.²² During his five years of service on the Covid Vaccines Work Group, his Work Group:

would have weekly, robust discussions regarding scientific data about the developing COVID-19 vaccines. ... These discussions included the creation of the vaccines, how the vaccines were manufactured, and how clinical trials were conducted. We also discussed the triage plan, the distribution plan, and how this critical resource should be allocated. The COVID-19 Vaccines Work Group thoroughly reviewed published works from all over the world, including independent research from various institutions and data from other countries.

Each week, the COVID-19 Vaccines Work Group would have an agenda. We would build upon and adapt our discussions as more data were gathered. As it got closer to each ACIP meeting, each work group, including the COVID-19 Work Group, would use the Evidence-to-Recommendation (EtR) framework to craft our recommendations to the ACIP. The EtR looks at benefits and harms, feasibility, acceptability, health equity, and other similar domains. Each expert in the work group would be polled on each of the domains to reach a recommendation.

Once the COVID-19 Vaccines Work Group came to a consensus on a proposed recommendation to the ACIP, we would put together a presentation that detailed the benefits and harms, feasibility, acceptability, comparators, and other domains to analyze each anticipated question from ACIP ... [and] would come up with a specific set of recommendation

¹⁹ 21 U.S.C. § 360bbb-4 note (“Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the ‘Advisory Committee’) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting”).

²⁰ See *Role of the Advisory Committee on Immunization Practices in CDC’s Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION RESTORED (Sept. 17, 2024), <https://restoredcdc.org/www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

²¹ See Ex. 35 (Goldman Decl.) ¶ 6.

²² Dr. Goldman received an email that liaison organizations were terminated from participating in ACIP Work Groups because liaison organizations like the ACP allegedly were “special interest groups and therefore are expected to have a ‘bias.’” See Ex. 35 (Goldman Decl.) ¶ 6.

language to present to the ACIP committee. This proposed recommendation, along with our analyses from the evidence gathered, would be presented to the full ACIP committee summarizing this discussion and data ²³

Once the ACIP votes on a recommended use of a vaccine, the CDC director has the authority to adopt ACIP recommendations, and, once adopted, the CDC publishes all ACIP recommendations on its website in a “Policy Note” in the Morbidity and Mortality Weekly Report (“MMWR”) that is authored by the Work Group Chair and other ACIP or Work Group members.²⁴

After the ACIP recommends how immunizations should be used, the FDA, ACIP, and the CDC continue to monitor and review the safety of all vaccines on the CDC’s immunization schedules to ensure they remain up-to-date and comport with emerging peer-reviewed, evidence-based data and studies. For example, the Work Group Standard Operating Procedures manual provides that Work Groups should examine when “[u]pdates to existing recommendations are anticipated based on availability of new data (regarding safety, effectiveness, and/or programmatic issues, e.g., vaccine administration or storage).”²⁵

II. The Final Agency Actions for Which Plaintiffs Seek Preliminary Injunctive Relief

The final agency actions that Plaintiffs challenge here can be separated into three categories: (a) changes to the CDC immunization schedules that bypassed the ACIP Process, (b) votes taken by the current ACIP and subsequently adopted by the CDC Director, and (c) meetings of an unlawfully constituted ACIP.

A. Changes to the CDC Immunization Schedules That Bypassed the ACIP Process (the “Non-ACIP Actions”)

²³ Goldman Decl., ECF No. 75-18 at ¶ 16.

²⁴ 45 C.F.R. § 147.130(a)(1)(ii); *see Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 16 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

²⁵ *Advisory Committee on Immunization Practices: Work Groups: Standard Operating Procedures (August 2018)*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

1. The May 2025 Action

On May 27, 2025, the Secretary posted a video on his X social media account in which he, FDA Commissioner Marty Makary, and the Director of the National Institutes of Health, Jay Bhattacharya, appeared. In the video, the Secretary announced that he was directing the CDC to remove from its schedules the recommendation that “healthy children” and “healthy pregnant women” receive the Covid vaccine.²⁶ That same day, the Secretary published a Directive, dated May 19, 2025, instructing the CDC to remove these vaccines from the Schedules.²⁷

The Directive does not match the science that was reported only weeks before. A week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Marty Makary published an article dated May 20, 2025 in The New England Journal of Medicine that he co-authored with Vinay Prasad, the Director of the Center for Biologics Evaluation and Research in the FDA, stating that “pregnancy and recent pregnancy” are factors which “increase a person’s risk of severe COVID-19.”²⁸ Thus, the Directive, announced one week later, shows that “‘they literally contradicted themselves over the course of a couple of days.’ . . . ‘It appears RFK Jr. reversed his own FDA’s decision.’”²⁹

At the April 15, 2025 public meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe

²⁶ See Robert F. Kennedy, Jr., @SecKennedy, X (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138> (attached as Ex. 2).

²⁷ See *Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025) (attached as Ex. 1).

²⁸ Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 NEJM 2484, 2485, fig. 2 (2025).

²⁹ Louis Jacobson, Amy Sherman, *RFK Jr. Ended COVID Vaccine Recommendation for Kids, Pregnant Women. What do Facts Show About Risk?* POLITIFACT (May 29, 2025), <https://www.politifact.com/article/2025/may/29/COVID-19-vaccine-RFK-children-pregnant/>.

illness from the Covid virus.³⁰ Dr. Panagiotakopoulos noted that pregnant individuals continued to face an increased risk of severe outcomes from contracting Covid.³¹ Not only does a Covid vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid vaccine administered during pregnancy.³² Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid on children in the United States in the past year. “She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, half were previously healthy, virtually none had been vaccinated, and 152 had died, most less than 4 years of age. The conclusion was clear; all children in the United States, whether they were previously healthy or not, should receive the primary series of Covid vaccines.”³³

Despite these findings, the CDC’s immunization schedules were changed the same day as the May 27 announcement. Although the Directive ordered the CDC “to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age,” the CDC, did not remove the recommendation that children be routinely vaccinated against Covid. Instead, on May 29, 2025, the CDC downgraded the designation for children to SCDM without explanation or supporting scientific evidence.³⁴

³⁰ See Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 15, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf>.

³¹ See *id.* at 11.

³² See *id.*

³³ Paul Offit, *This CDC Resignation Should Scare You*, SUBSTACK (July, 8, 2025) <https://pauloffit.substack.com/p/this-cdc-resignation-should-scare>.

³⁴ See *Child and Adolescent Immunization Schedule by Age*, CTRS. FOR DISEASE CONTROL & PREVENTION (May 29, 2025), <https://web.archive.org/web/20250530173732/https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html>.

2. The January 2026 Action

On January 5, 2026, Defendants announced that immunization recommendations for six diseases had been downgraded, effective immediately.

- Downgrade from Routine Recommendation to Certain High-Risk Groups or Populations only: Hepatitis A (“HepA”), HepB, Meningococcal ACWY (“MenACWY”), Respiratory Syncytial Virus (“RSV”)
- Downgrade from Routine Recommendation to SCDM: HepA, Influenza, MenACWY, Rotavirus

The January 2026 Action made other substantive changes to the Childhood Schedule:

- Prior to the January 2026 Action, the Human Papillomavirus (“HPV”) vaccine was routinely recommended in a two-dose or three-dose series, with the first dose recommended to be given as early as 9 years old. The January 2026 Action increases the minimum age for the first dose to 11 years old and removes recommendations for any subsequent doses.
- Prior to the January 2026 Action, the HepB vaccine was recommended on the basis of SCDM, including the birth dose. The January 2026 Action removes the option for a birth dose of HepB vaccine and instead increases the minimum age of the first dose to two months old.
- Prior to the January 2026 Action, Meningococcal B (“MenB”) vaccines were recommended on the basis of SCDM for adolescents aged 16-23 years old. The January 2026 Action changes the recommendation for the MenB vaccine to certain high-risk groups or populations aged 10-17 years old and limits the SCDM recommendation to adolescents aged 16-17 years old only.

For each of these newly downgraded immunizations, before FDA approval and subsequent ACIP recommendation on use, both the FDA and the ACIP thoroughly evaluated the evidence on the immunizations against the target diseases. All were rigorously evaluated before licensing and recommendation for use and have, since then, been carefully monitored. The Decision Memo announcing the January 2026 Action, however, does not cite any new data that calls into question the safety or efficacy of any of the downgraded immunizations.

Like the May 2025 Action, the January 2026 Action bypassed the ACIP Process to change the CDC’s Childhood Schedule.³⁵ Defendants have provided no explanation for why they bypassed the ACIP Process and instead resorted to relying on individuals who have no responsibility for determining how a vaccine is recommended for use and listed on a CDC schedule. The authors of the Decision Memo to O’Neill are Jay Bhattacharya, Director of the National Institutes of Health, Mehmet Oz, Administrator of the Centers for Medicare and Medicaid Services, and Marty Makary, FDA Commissioner. Neither the CMS Administrator, the FDA Commissioner, the NIH Director, nor the agencies they run have any responsibility for revising the CDC’s immunization schedules.

The Decision Memo articulates three bases for changing the Childhood Schedule:

- (a) O’Neill’s discussions of childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark;
- (b) O’Neill’s discussions with CDC and FDA officials with duties and responsibilities related to vaccine safety and efficacy; and
- (c) a document titled “Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries,” (the “Assessment”) authored by Hoeg and Martin Kulldorff, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation whom the Secretary appointed Chair of the ACIP in June, 2025.

The Decision Memo does not state what O’Neill discussed with health officials from Japan, Germany, and Denmark; nor does it state what O’Neill discussed with CDC and FDA officials. Neither the Decision Memo nor the Assessment state what “scientific evidence underlying [the] practices” of peer countries was evaluated, what conclusions were drawn from that evaluation, and what, if any, best practices of peer countries were superior to those of the United States, as the Presidential Memoranda instructed. Neither document discusses or cites new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. The Assessment is not

³⁵ The events leading up to the January 5 Action are set forth in the pending Fourth Amended Complaint, ¶¶ 38–57.

peer reviewed. Neither document states that Defendants considered important factors such as differences in health care systems and populations between countries, the impact on the U.S. health care system, or input from the public or independent experts. Despite the failure to consider these and many other factors, the Secretary proclaimed that an “exhaustive review of the evidence” had been conducted before changing the Childhood Schedule.³⁶

B. Votes Taken by the Current ACIP (The “ACIP Actions”)

The second category of final agency actions challenged in this case are the votes by the current ACIP and subsequently adopted by the CDC Director. Pertinent facts regarding the appointments of the current ACIP members are as follows. On June 9, 2025, the Secretary sent shockwaves through the U.S. health care system when he announced in a *Wall Street Journal* Opinion Commentary that he was “totally reconstituting the [ACIP]” and “retiring the 17 current members of the committee,” based on alleged “persistent conflicts of interest.”³⁷ Two days later, the Secretary announced the appointment of eight new members to the ACIP whom he claimed were “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.”³⁸ He has made two subsequent sets of appointments: four more members on September 11, 2025, and two on January 13, 2026.³⁹

³⁶ *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 5, 2026), <https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html>.

³⁷ Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

³⁸ *Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 14–15 (June 2022), <https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf> [<https://perma.cc/93ZW-2J68>].

³⁹ See Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), <https://x.com/SecKennedy/status/1932899858920120692?s=20>.

Although members of the ACIP should have expertise in “*vaccines and related agents for effective control of vaccine-preventable diseases*,”⁴⁰ the Secretary’s appointees to the ACIP include three obstetrician-gynecologists, one psychiatrist, one operations management professional, a cardiologist, and an emergency medical physician.⁴¹ Ten of the 14 ACIP members have publicly stated views on vaccines that align with the Secretary’s anti-vaccine views.⁴² At least four are members or otherwise affiliated with openly anti-vaccine organizations, including the Independent Medical Alliance, the National Vaccine Information Center, and Children’s Health Defense, which was founded by Robert F. Kennedy, Jr. himself.⁴³

The current ACIP members’ credentials pale in comparison to those of the ACIP members terminated on June 9, 2025, all of whom had relevant subject-matter expertise and credentials.⁴⁴ The Secretary’s termination of the ACIP and the ACIP Appointments are consistent with his publicly stated distrust of experts.⁴⁵

Accordingly, the votes taken by the current ACIP that Plaintiffs request that the Court set aside are as follows:

1. The June 2025 Thimerosal Action

At the first meeting of this ACIP in June 2025, Lyn Redwood, the former long-time President of Children’s Health Defense, gave a presentation on thimerosal that resuscitated the

⁴⁰ See *Advisory Committee on Immunization Practices Policies and Procedures*, CTRS. FOR DISEASE CONTROL & PREVENTION 1,4 (June 2022), <https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf>.

⁴¹ See Fourth Amended Complaint for Declaratory & Injunctive Relief, *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026), ECF 180-1, ¶ 77.

⁴² See *id.* at ¶ 78.

⁴³ See *id.*

⁴⁴ See *ACIP Committee Members July 1, 2024–June 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), <https://archive.cdc.gov/#/details?url=https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html>.

⁴⁵ Very recently (Jan. 13, 2026), the Secretary said on *The Katie Miller Podcast*: “we need to stop trusting the experts,” and “this idea that you should trust the experts. A good mother doesn’t do that.” *The Katie Miller Podcast, RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 16:52–17:17 (Jan. 13, 2026), https://www.youtube.com/watch?v=w_fzlwxJZAA&t=843s.

long-debunked, settled issue of whether thimerosal in vaccines caused autism—a theory that Children’s Health Defense has long-promoted and that was an impetus for its founding.⁴⁶ At that meeting, Redwood made that claim that thimerosal is not an effective preservative and was never adequately tested before widespread use. She said: “[th]ey also found evidence that thimerosal was no better than water in protecting mice from potential fatal streptococcal infections,” and the “FDA grandfathered in thimerosal without formal submission of any animal safety data.”⁴⁷ However, Redwood’s presentation on thimerosal was highly misleading:

Thimerosal was introduced after repeated outbreaks of fatal bacterial contamination associated with multi-dose vaccine vials in the early 20th century. Multiple studies demonstrated that thimerosal was highly effective at preventing bacterial and fungal growth, outperforming alternative preservatives available at the time and doing so at much lower concentrations. Following the introduction of thimerosal, contamination-related deaths linked to vaccination dramatically declined. Claims that it is “no better than water” selectively reference short-term vial-entry experiments while ignoring real-world evidence and decades of safe use in vaccines. No evidence shows higher contamination rates in thimerosal-containing vaccines compared with alternatives.

The claim that thimerosal was ‘grandfathered in’ without adequate testing misrepresents the regulatory and scientific history. Before widespread use, thimerosal underwent extensive animal testing. Following licensure, thimerosal-containing vaccines were among the most intensively studied products in vaccinology, with large epidemiologic studies conducted across multiple countries. Post-licensure surveillance and population-based studies consistently found no association between thimerosal-containing vaccines and neurologic, developmental, or systemic harms. Characterizing this as ‘insufficient testing’ ignores both preclinical toxicology and decades of real-world safety data.⁴⁸

⁴⁶ See *History of CHD*, CHILD.’S HEALTH DEF., <https://childrenshealthdefense.org/about-us/history-of-chd/> (last visited Jan. 25, 2026).

⁴⁷ Ctrs. for Disease Control & Prevention, *Advisory Committee on Immunization Practices (ACIP)–Day 2 of 2*, YOUTUBE, at 2:34:24, 2:32:38 (June 26, 2025), <https://www.youtube.com/watch?v=z-16fImZoEc>.

⁴⁸ Marisa Donnelly, et al., *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

Nonetheless, on June 26, 2025, the ACIP, whose members had been appointed only two weeks before, “passed three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults. There was no explanation for why three separate recommendations were voted on or when the end goal was to stop using the preservation in all flu vaccines brought to the U.S. market.”⁴⁹ No new data or study on the presence of thimerosal in vaccines was presented at the meeting.

2. The September 2025 Action

On September 19, 2025, the ACIP voted to change the Covid vaccine recommendation for adults from routine to SCDM, consistent with the May 2025 Directive. At that meeting, misleading information was presented that the Covid vaccine contained unacceptable amounts of DNA contaminant.⁵⁰ The ACIP did not apply the GRADE Approach or follow the EtR framework, and it did not consult with the Covid Work Group prior to the vote. The CDC Director adopted the September 19 vote on October 6, 2025.⁵¹ Unlike the four previous occasions that the ACIP voted to designate a vaccine as SCDM,⁵² the CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

⁴⁹ See Helen Branswell, *HHS Secretary RFK Jr. accepts recommendations to drop thimerosal from U.S. flu vaccines*, STAT (July 23, 2025), <https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/>.

⁵⁰ See *infra* Section III.C.

⁵¹ See *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 6, 2025), <https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html>.

⁵² See Lauren E. Roper, et al., *Use of Additional Doses of 2024-2025 COVID-19 Vaccine for Adults*, 73 MORBIDITY & MORTALITY WKLY REP. 1118, 1121, (Dec. 12, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a2-H.pdf>; Sarah Schillie, et al., *New Dosing Interval and Schedule for the Bexsero Men B-4C Vaccine: Updated Recommendations of the Advisory Committee on Immunization Practices—United States, October 2024*, 73 MORBIDITY & MORTALITY WKLY REP. 1124, 1124–1125 (Dec. 12, 2024), <https://www.cdc.gov/mmwr/volumes/73/wr/pdfs/mm7349a3-H.pdf>; Almea Matanock, et al., *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf>; Elissa Meites, et al., *Human Papillomavirus*

3. The December 2025 HepB Action

On December 4, 2025, a current member of the ACIP and two outside presenters presented on the HepB vaccine. The first outside presenter, Cynthia Nevison, a climate scientist, presented on the “Burden of Disease.” The second, Mark Blaxill, who has no medical training or professional experience, presented on the safety of the HepB vaccine.⁵³ None of the presenters on the HepB vaccine presented new safety concerns or effectiveness issues that would prompt reconsideration of the HepB vaccine birth dose. Instead, “panelists said the review was prompted by parents concerned about the shot, the fact that most European countries give the immunization a few months after birth, and the length of time since ACIP last reviewed the topic.”⁵⁴ No Work Group presented at this ACIP meeting on HepB (or on any other vaccine). No EtR analysis was conducted or presented at this meeting.

The next day, the ACIP voted “8 to 3 to recommend individual-based decision-making for parents deciding whether to give the HepB vaccine, including the birth dose, to infants born to women who test negative for the virus.”⁵⁵ The new recommendation is that parents discuss with their doctors whether to give the HepB vaccine at birth, or at all, and that those who choose to do so should wait to begin the vaccine series until their baby is at least two months old. This deviates from the recommendation (in place since 1991) that all babies receive a dose of the HepB vaccine within 24 hours of birth, including mothers who test negative for the HepB surface antigen

Vaccination for Adults, 68 MORBIDITY & MORTALITY WKLY REP. 698, 700 (Aug. 16, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf>.

⁵³ Nevison and Blaxill were co-authors of an article connecting autism to vaccines that the journal later retracted because of misrepresentations of data. See Mark Blaxill, Toby Rogers, & Cynthia Nevison, *Retraction Note: Autism: The Impact of Rising Prevalence on the Societal Cost of Autism in the United States*, 53 J. AUTISM DEV. DISORD. 3315 (2023).

⁵⁴ Helen Braswell, *CDC panel recommends delaying birth dose of hepatitis B vaccine*, STAT (Dec. 5, 2025), <https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturms-30-year-policy/>.

⁵⁵ *ACIP Recommends Individual Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>.

(HBsAg-negative).⁵⁶ No evidence or data was presented justifying the two-month age restriction for the first dose of the HepB vaccine.

C. Meetings of The Unlawfully Constituted ACIP

The current ACIP's public meetings have been filled with false and misleading statements on vaccines and infectious disease. The presentation on thimerosal at the June 2025 meeting discussed above is a case in point.

At the September 2025 ACIP meeting, more inaccurate and misleading statements were made. At least 50 falsehoods were stated at the September meeting on the MMRV (measles, mumps, rubella, varicella) vaccine, the HepB vaccine, the Covid vaccine, and other topics.⁵⁷ For example, a claim was made at the September meeting that Covid vaccines contain dangerous levels of DNA contaminant exceeding regulatory limits. The truth, however, is that "[m]anufacturing impurities, including DNA, are carefully monitored because the FDA requires that residual DNA in vaccines be below 10 ng per dose. The presence of DNA fragments used in the manufacturing process is expected, found at acceptable levels, and is accounted for in safety standards. Multiple independent analyses have confirmed that mRNA vaccines meet these stringent requirements. Claims of dangerous DNA contamination typically arise from studies that use inappropriate detection methods or misinterpret the significance of trace amounts that are orders of magnitude below safety thresholds. Moreover, the work that initially flagged the concern used inappropriate

⁵⁶ See Aliza Rosen, *Hepatitis B Vaccination is an Essential Safety Net for Newborns*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUB. HEALTH (Sept. 24, 2025), <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth/>; *Hepatitis B Perinatal Vaccine Information*, CTRS. FOR DISEASE CONTROL & PREVENTION (Aug. 27, 2025), <https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/vaccine-administration.html#:~:text=Birth%20dose,a%20parent%20with%20HBV%20infection.>

⁵⁷ See Marisa Donnelly, et al., *Sept ACIP Meeting Fact Checking (Days 1-2)*, THE EVIDENCE COLLECTIVE (Sept. 19, 2025), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/68cde5ebaf4b826126e40899/1758324203698/Sept+ACIP+days+1+and+2.pdf>.

methods. Despite this, they found that vaccine lots with DNA levels above regulatory limits had fewer VAERS reports than those below the limits.”⁵⁸

The December 2025 meeting was even worse. There, “ACIP members and presenters made at least 60 (we lost count after this) false, misleading, or unsupported claims about vaccine-preventable disease epidemiology, vaccine safety, and the rationale for universal vaccination.”⁵⁹ Many false claims were made that testing before licensing and marketing of the HepB vaccine was inadequate and that surveillance has been inadequate since listing on CDC schedules. In fact, however, more than 15 safety studies were conducted on HepB vaccines, including randomized control studies, and there has been continuous safety monitoring in millions of recipients post-marketing.⁶⁰ In addition, Nevison made the claim that “targeted measures” to vaccinate against Hepatitis B have been more effective than universal vaccination for Hepatitis B disease. Nevison either does not know or ignores the historical fact that:

“[a] targeted strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: ‘Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.’ ***This makes targeted approaches ineffective.*** Similarly, 35–65%<https://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm> of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. ***The 1991 switch to universal vaccination reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually)***.”⁶¹

⁵⁸ Marisa Donnelly, et al., *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf

⁵⁹ Marisa Donnelly, et al., *Debunk Briefing: December Meeting of the Advisory Committee on Immunization Practices (ACIP)*, THE EVIDENCE COLLECTIVE (Dec. 5, 2025), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/693347ab2b70aa78cc908df3/1764968363179/Dec+ACIP_TEC+Brief.pdf.

⁶⁰ See *id.*

⁶¹ Marisa Donnelly, et al., *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026), (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

ARGUMENT

I. Plaintiffs Meet the Elements for a Preliminary Injunction

A. Preliminary Injunction Standard

For the Court to grant a preliminary injunction, plaintiffs must show four elements: “(i) the movant’s likelihood of success on the merits of its claims; (ii) whether and to what extent the movant will suffer irreparable harm if the injunction is withheld; (iii) the balance of hardships as between the parties; and (iv) the effect, if any, that an injunction (or the withholding of one) may have on the public interest.” *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 9 (1st Cir. 2013). Where the Government opposes the preliminary injunction, the last two factors merge. *Nken v. Holder*, 556 U.S. 418, 435–36 (2009). The most important of the four elements is the likelihood of success on the merits. *See Massachusetts v. Nat’l Insts. of Health*, 770 F.Supp.3d 277, 295 (D. Mass. 2025) (“*NIH P*”).

B. Plaintiffs are Likely to Succeed on the Merits.

1. Plaintiffs Have Standing to Seek the Requested Injunctive Relief.

In its January 6, 2026 Memorandum and Order on Defendants’ Motion to Dismiss (ECF No. 168), this Court denied Defendants’ Motion to Dismiss the Third Amended Complaint that was premised largely on the argument that Plaintiffs did not have standing to continue with any of their claims.⁶² The Third Amended Complaint alleged that the following final agency actions violated the APA: (a) the May 2025 Action (one of the Non-ACIP Actions); (b) the September 2025 Action (one of the ACIP Actions); and (c) the ACIP Appointments for violations of FACA. In the Order on the Motion to Dismiss, this Court held that “there is no question that, but for the

⁶² The Court also denied Defendants’ Federal Rule of Civil Procedure 12(b)(6) motion on Plaintiffs’ FACA claim.

change in vaccine recommendations and ACIP appointments, AAP would not have expended the resources that it did.” Order on Defs.’ Mot. to Dismiss, at 13, ECF No. 168.

If the Court grants leave to file the Fourth Amended Complaint, the allegations in that complaint will likewise be sufficient to establish standing as to the additional challenged actions.⁶³ The additional Non-ACIP Actions and ACIP Actions continue and magnify the harm that the Plaintiffs identified in the Third Amended Complaint,⁶⁴ since they impacted the immunizations for several additional conditions, whereas the May 2025 Action and September 2025 Action changed the recommendation regarding the immunization for *one* condition.

And as to the ACIP Appointments, Defendants’ dismantling of Charter-mandated liaison groups, including AAP, deprived Plaintiffs of their legal right to participate in ACIP activities. *See NAACP Legal Defense Fund, Inc. v. Barr*, 496 F.Supp.3d 116 (D.D.C. 2020) (plaintiffs’ membership denial was sufficient to confer fair balance claim under FACA) (citing *Nat’l Anti-Hunger Coal. v. Exec. Comm. of President’s Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983) (denial of access to representation on an advisory committee is a sufficiently concrete harm to constitute an injury in fact)); *see, e.g., Nat. Res. Def. Council v. Dep’t of Interior*, 410 F. Supp. 3d 582, 601–02 (S.D.N.Y. 2019) (noting that “the weight of the caselaw” holds that parties with direct interests in an advisory committees work is denied membership, then the party has standing to challenge). Further compounding the harm is the fact that the current

⁶³ *See* Fourth Am. Compl., *Am. Acad. Of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶¶ 1–6, 35, 38–42, 44–45, 49, 52–71, 74–79, 82–119; *see also* Ex. 27 (Kressly Decl.), ¶¶ 13, 15–18, 26–31, 36, 39–42, 51; Ex. 34 (Racine Decl.), ¶¶ 11, 13–18, 20, 39–40; Ex. 42 (Pring Decl.), ¶¶ 10, 12, 14, 16, 19, 23–31, 39–40, 46–47; Ex. 43 (Bornstein Decl.), ¶¶ 9, 13, 15–17, 19, 22, 26, 33, 40 45, 50; Ex. 31 (Berman Decl.), ¶¶ 8–19; Ex. 40 (Nahass Decl.), ¶¶ 12–13, 15–17; Ex. 41 (Chen Decl.), ¶¶ 22, 24–25; Ex. 45 (Jaeger Decl.), ¶¶ 10–11, 13, 16, 26, 31, 33–34; Ex. 44 (Pavlos Decl.), ¶¶ 16–20, 22–24, 29–30, 32–33, 35–37; Ex. 25 (Benjamin Decl.), ¶¶ 20–27, 29–32; Ex. 39 (Martinello Decl.), ¶¶ 8–10, 12–13; Ex. 46 (Srinivas Decl.), ¶ 14; Ex. 28 (O’Shea Decl.), ¶¶ 19, 23–26; Ex. 38 (Wheeler Decl.), ¶ 17; Ex. 37 (Jhaveri Decl.): ¶¶ 25, 28; Ex. 49 (Jane Doe 3 Decl.) ¶¶ 24-25; Ex. 50 (Jane Doe, MD Decl.) ¶¶ 13-14, 20; Ex. 53 (Jane Doe 2 Decl.) ¶¶ 31–32.

⁶⁴ *See id.*, ¶¶ 120–45.

ACIP has continued to spread significant misinformation at their public meetings, which creates more confusion, uncertainty, and disruption to the operations of the Plaintiffs and causes them to divert more resources to address the increased confusion and misinformation.⁶⁵

In short, the key standing issues in this case regarding both a Non-ACIP Action and an ACIP Action, as well as the ACIP Appointments, have already been litigated and decided, so it is now the law of the case. *See U.S. v. Vigneau*, 337 F.3d 62, 67 (1st Cir. 2003) (noting that the law of the case doctrine “is a prudential principle that precludes relitigation of the legal issues presented in successive stages of a single case once those issues have been decided”).

2. The Challenged Actions are Final Agency Actions.

Each of the Challenged Actions in this case are final agency actions because they (1) “mark the consummation of the agency’s decision making process”; and (2) are those “by which rights or obligations have been determined, or from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997). As a preliminary matter, the Defendants have waived any contention that the Challenged Actions are not final agency actions: they did not argue in their Motion to Dismiss that any of the final agency actions identified in the Third Amended Complaint—which included a Non-ACIP Action, an ACIP Action, and the ACIP Appointments—were not final agency actions, and, consistent with that position, Defendants conceded the challenged actions were final agency actions at the January 12, 2026 status conference before the Court (“[Mr. Belfer] I think something to keep in mind is that this case is really almost four cases ripened into one. We’ve got many different final agency actions”/ “So that’s at least five different final agencies actions, each of which has its own record . . . we’re basically talking about five

⁶⁵ Ex. 27 (Kressly Decl.), ¶¶ 16, 26–31, 39; Ex. 25 (Benjamin Decl.), ¶ 31; Ex. 42 (Pring Decl.), ¶¶ 16, 23–24, 30, 46–47; Ex. 43 (Bornstein Decl.), ¶¶ 26, 45; Ex. 40 (Nahass Decl.), ¶¶ 12, 16, 17; Ex. 41 (Chen Decl.), ¶ 24; Ex. 45 (Jaeger Decl.), ¶ 31; Ex. 44 (Pavlos Decl.), ¶¶ 17–18, 22–24, 29, 33, 36–37; Ex. 34 (Racine Decl.), ¶¶ 13–18, 39.

different agency actions that are potentially being challenged.”⁶⁶ In addition, in the Joint Status Report filed on January 21, 2026, which was filed after Plaintiffs’ Motion for Leave to File a Fourth Amended Complaint, Defendants stated that, of the actions challenged in the Fourth Amended Complaint, they “may explain why ACIP’s June 26, 2025, and December 5, 2025, recommendations are not final agency actions,”⁶⁷ but were silent as to any other action. Joint Status Report, at 3 ECF No. 181. As such, any objection on this ground has been waived.

In any event, the Challenged Actions have imposed immediate and irreparable legal consequences on Plaintiffs, who are forced to grapple with the daily and long-term public health and economic effects that flow from (1) Defendants’ deliberate decision not to follow well-established vaccine policy and procedures, and (2) the improper ACIP Appointments. These actions are ripe for review by the court to determine “an actual or immediately threatened effect.” *See Greater Bos. Legal Servs. v. United States Dep’t of Homeland Sec.*, No. 21-CV-10083-DJC, 2023 WL 2540892, at *2 (D. Mass. Mar. 16, 2023) (citation modified); *see also Biden v. Texas*, 597 U.S. 785, 808–09 (2022) (holding agency memoranda were final agency action, noting they “bound” agency staff by preventing them from continuing certain programs); *Student Loan Marketing Ass’n v. Riley*, 104 F.3d 397 (D.C. Cir. 1997) (finding agency letter had all of the indicia of finality because (1) it was signed by the Acting General Counsel on behalf of the Secretary of Education; (2) it was based on full deliberation at the highest level and reflected the agency’s consideration of the contrary views expressed by the petitioner; and (3) the position was stated unequivocally).

⁶⁶ Transcript of Hearing at pp. 28:9–22:25; 29:5–13, *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 12, 2026) (ECF No. 178).

⁶⁷ For the purposes of this analysis under *Bennett*, these two ACIP Actions are indistinguishable from the ACIP Action referenced in the Third Amended Complaint—the September 2025 Action—that Defendants previously conceded are final agency actions.

3. Both the Non-ACIP Actions and the ACIP Actions Violate the APA Because They are Arbitrary and Capricious.

When determining whether an agency acted arbitrarily or capriciously, the court must conduct “a thorough, probing, in-depth review” through a “searching and careful inquiry into the record.” *Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 720 (1st Cir. 1999) (citation modified). An agency action is arbitrary and capricious under 5 U.S.C. § 706 (2)(A) if it “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *State Farm*, 463 U.S. at 43; *see also Dep’t of Homeland Security v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020). Agency action must be “founded on a reasoned evaluation of the relevant factors.” *See NIH I*, 770 F.Supp.3d at 304. At bottom, arbitrary and capricious review is a search for “a satisfactory explanation” for an agency’s action. *Ohio v. Env’t Prot. Agency*, 603 U.S. 279, 292 (2024) (quoting *State Farm*, 469 U.S. at 43); *see also Int’l Ladies’ Garment Workers’ Union v. Donovan*, 722 F.2d 795, 814 (D.C. Cir. 1983) (“[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.”).

Further, when an agency changes its policy, not only must it provide a reasoned explanation; it must also “be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.” *Dep’t of Homeland Sec.*, 591 U.S. 1 at 30 (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. at 222); *see Food & Drug Admin. v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 570 (2025); *Perez v. Mortg. Bankers Ass’n*, 575 U.S. 92, 106 (2015) (“[T]he APA requires an agency to provide more substantial justification when . . . its prior policy has engendered serious reliance interests that must be taken into account. It would be

arbitrary and capricious to ignore such matters.”). When a challenged action constitutes a change in policy, the question is: “Did [Defendants] display awareness that [they were] changing position and offer good reasons for the new policy?” *See Wages & White Lion Invs.*, 604 U.S. at 570.

First, both the Non-ACIP Actions and the ACIP Actions were arbitrary and capricious because the Defendants failed to engage in reasoned decision-making as required by the APA. In the context of immunization actions, the ACIP Process provides a framework for engaging in a “reasoned evaluation of the relevant factors” through the GRADE approach, the EtR framework, and consultation with ACIP Work Groups. *See NIH I*, 770 F.Supp.3d at 304. For decades, the CDC schedules have been governed by these processes, which provide a structured, transparent, evidence-based review process requiring the ACIP to evaluate disease burden, morbidity and mortality, vaccine effectiveness, safety, and population-level impact under established analytical frameworks before adopting or modifying a recommendation.

Before prior ACIPs voted to adopt the routine recommendations for each of the now-downgraded vaccines, those ACIPs conducted multi-stage, data-driven reviews over multiple meetings, with the evidentiary basis for each recommendation documented and transparently evaluated. The charts attached as Exhibits 23⁶⁸ and 24⁶⁹ detail these processes as to two of the downgraded vaccines to serve as exemplars: HepB and RSV, respectively.

⁶⁸ As demonstrated in Ex. 23, ACIP subjected HepB vaccines to a long and rigorous evidence-based process, beginning in 1981 with review of double-blind, placebo-controlled clinical trial data even before FDA licensure. Over the next decade, ACIP revisited HepB vaccination recommendations in more than 20 formal meetings, repeatedly evaluating factors including safety, immunogenicity, duration of protection, adverse event reports, cost-effectiveness, and real-world implementation data across infants, children, adolescents, and high-risk adults. This spanned roughly 10 years from first data review to the unanimous 1991 universal recommendation. Even after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations, expanding the recommendation to all unvaccinated children aged 0-18 years of age in 1997.

⁶⁹ As demonstrated in Ex. 24, RSV monoclonal antibodies were recommended only recently by ACIP, with the first recommendation coming from ACIP on August 3, 2023, and the most recent recommendation for a monoclonal antibody coming on June 25, 2025. The monoclonal antibodies went through rigorous review by ACIP, including through the EtR Framework. The ACIP Maternal & Pediatric RSV Work Group met regularly leading up to the August 3m, 2023 ACIP vote, with presentations beginning at ACIP meetings as early as February 23, 2022, well before the monoclonal antibody received FDA approval on July 17, 2023. At least 19 presentations on topics

The one time a routine vaccine was downgraded on a CDC schedule to SCDM—the Prevnar vaccine (“PCV13”), which treats pneumococcal pneumonia—the ACIP went through the same rigor and analysis it would go through for any newly issued recommendation.⁷⁰ PCV13 was recommended for routine use on June 20, 2012. By June 2015, ACIP was already revisiting that recommendation and considering rigorously constructed Work Group presentations and rationale on proposed changes to the PCV13 recommendation. The Work Group presented numerous times on not only the vaccine, but the disease it was designed to prevent, and the effects of the disease within particular age groups over the years since PCV13’s routine recommendation. ACIP voted to change the recommendation on June 26, 2019, after considering no less than 34 such presentations on PCV13 and pneumococcal pneumonia. These presentations covered topics including suggested intervals between vaccinations, changes in the epidemiology of pneumococcal pneumonia, policy considerations, safety and efficacy of PCV13, direct and indirect effects of PCV13, the incidence and burden of pneumococcal pneumonia amongst adults in the US, EtR framework analyses for differing adult age groups, economic analyses of the current and adjusted recommendations, and alternative recommendations. Further, as with every prior instance in which the ACIP adopted an SCDM designation, PCV13’s downgrade from routine to SCDM was accompanied by explanatory guidance published in the MMWR, describing both the evidentiary

including numerous presentations on clinical considerations of the immunization, safety and efficacy, economic analyses, the ability of the monoclonal antibody to prevent RSV in all infants, the feasibility of the product, implementation considerations, the interplay between maternal and infant immunization, numerous EtR Framework presentations, and regular presentations on analyses conducted by the ACIP Maternal & Pediatric RSV Work Group. This rigorous, years-long process ultimately culminated in a vote and recommendation for the regular use of the RSV monoclonal antibody in infants, which itself resulted in numerous follow-up research and real-world studies of the effects of the immunization.

⁷⁰ See Plaintiff’s FED. R. EVID. 1006 Summary Chart for Prevnar-13 (attached as Ex. 22)

basis for the designation and providing guidance on how SCDM should be applied in practice for that recommendation.⁷¹

Defendants have not offered a scintilla of explanation for why they bypassed the ACIP Process entirely as to the Non-ACIP Actions. Nor have they explained why they did not apply the GRADE approach, utilize the EtR framework, or consult with ACIP Work Groups to examine relevant data before adopting the ACIP Actions. This blatant disregard for the established process for methodically assessing and reviewing evidence-based data to adopt or modify immunization recommendations is exactly the kind of “unexplained inconsistency” that espouses arbitrary and capricious action. *See Encino Motorcars, LLC*, 579 U.S. at 222; *see also Data Marketing P’ship, LP v. U.S. Dep’t of Labor*, 45 F.4th 846, 857 (5th Cir. 2022) (holding that an advisory opinion that adopted a definition of “working owner” that was materially different from the definitions in prior opinions was arbitrary and capricious because of the unexplained inconsistency).

Second, regardless of this failure of process, Defendants have failed to otherwise provide a satisfactory explanation for their actions based on any sort of reasoned evaluation or rational connection between the facts found and choices made. In the May 27 video posted on X, the Secretary justified the May 2025 Action with the conclusory assertion that “healthy kids” and “healthy pregnant women” don’t need the Covid vaccine.⁷² This explanation “fails under the APA because it is merely conclusory.” *See Ass’n of Am. Univs. v. Dep’t of Defense*, 792 F.Supp.3d 143, 171 (D. Mass. 2025) (holding that the Department of Defense’s justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because its

⁷¹ See Almea Matanock, et al., *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults*, 68 MORBIDITY & MORTALITY WKLY REP. 1069, 1074 (Nov. 22, 2019), <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6846a5-H.pdf>.

⁷² Robert F. Kennedy, Jr. (@SecKennedy), X (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138>.

conclusory justification did not provide a reasoned basis for the change); *NIH I*, 770 F.Supp.3d at 305 (holding that NIH’s justification for a change to reimbursement rate policy related to university research was arbitrary and capricious because it was conclusory given that it did not “provide any reasoning, rationale, or justification at all”).

Moreover, at the ACIP meeting the month before, CDC subject-matter experts reported that healthy children and pregnant women were very much still at risk from Covid and presented a wealth of uncontroverted data on the safety and efficacy of Covid vaccines for these populations. Fourth Am. Compl., ¶ 98, ECF 180-1. Accordingly, the Secretary’s claim that there isn’t “any clinical data to support the repeat booster strategy in children”⁷³ lacks any foundation. As in *Department of Commerce v. New York*, 588 U.S. 752 (2019), “the evidence tells a story that does not match the explanation the Secretary gave for his decision.” 588 U.S. at 784 (holding pretextual the Secretary of Commerce’s explanation why he decided to reinstate a citizenship question on the census).

Nor is there any reasoned explanation for the January 2026 Action. As noted above, the changes to the Childhood Schedule identified in the January 2026 Action were based only on (a) discussions with health officials in Japan, Germany, and Denmark and with CDC and FDA officials⁷³; (b) a Decision Memo signed by Defendant O’Neill⁷⁴; and (c) an allegedly scientific Assessment drafted by two individuals who are not part of the CDC and who lack education and professional backgrounds in vaccine science.⁷⁵ None of the stated reasons for the January 2026

⁷³ See *Decision Making Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule*, U.S. DEPT OF HEALTH & HUMAN SERVS., 1 (Jan. 5, 2026), <https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedu/index.html> (attached as Ex. 18).

⁷⁴ See *Id.*

⁷⁵ See *Id.*

Action offer a reasoned evaluation or rational connection between the facts found and choices made.

As also noted above, the Decision Memo does not state what Acting Director O’Neill discussed with health officials from Japan, Germany, and Denmark, nor does it state what Acting Director O’Neill discussed with CDC and FDA officials. The Assessment cites no new data, evidence, or studies of any of the immunizations changed on the Childhood Schedule. Additionally, neither the Decision Memorandum nor the Assessment document—which were apparently created in only a few weeks—were peer-reviewed before they were used as the basis to significantly change the Childhood Schedule. They also fail to explain why Japan, Germany, and Denmark serve as good immunization models for the United States. Therefore, Defendants have failed to offer any satisfactory explanation for the January 2026 Action to suggest it was the product of reasoned decision-making. *See State Farm*, 463 U.S. at 51 (holding that the National Highway Traffic Safety Administration (“NHTSA”)’s decision to rescind the rule that new motor vehicles be equipped with automatic seatbelts or airbags was arbitrary and capricious because the agency was “too quick to dismiss the safety benefits of automatic seatbelts” for the court to conclude that the rescission was the product of reasoned decision-making); *see also NIH I*, 770 F.Supp.3d at 306 (holding that the failure to explain why bringing the federal government in line with private foundations in terms of funding indirect cost rates in the research grant context rendered the policy change arbitrary and capricious).

There is also no satisfactory explanation for the Defendants’ actions relative to the ACIP Actions. The process that the ACIP followed leading up to the June 2025 Thimerosal Action, the September 2025 Action, and the December 2025 HepB Action demonstrate additional failures to examine relevant data or to provide reasonable explanation for the Defendants’ actions. No new

data or studies were reviewed, considered, or identified to justify or provide any reasonable connection to the decisions on these three actions. Again, “the evidence tells a story that does not match the explanation the Secretary gave for his decision.” *Dep’t of Commerce*, 588 U.S. at 784.

Third, the Non-ACIP Actions and the ACIP Actions are arbitrary and capricious because they fail to consider important aspects of the problem the agency itself said it was trying to solve. For example, the purported problem the Defendants were trying to solve with the January 2026 Action was: to “restore trust in public health recommendations made by the CDC” that allegedly was lost because of governmental action during the pandemic.⁷⁶ In *New York v. Trump*, 769 F.Supp.3d 119, 141 (D.R.I. 2025), the court held that the defendants federal funding freeze was arbitrary and capricious because the defendants failed to provide “a rational reason for how their alleged goal of safeguarding taxpayer funds justified a de facto suspension of nearly all federal funding.” Likewise, here, the Non-ACIP and ACIP Actions are arbitrary and capricious because Defendants have failed to provide a rational reason for how their alleged goal of “restor[ing] trust in the public health” justifies dramatic changes to the CDC schedules. None of the documents or statements supposedly justifying the Non-ACIP Actions or the ACIP Actions—including the May 2025 Directive; the Decision Memo; the Assessment; and the presentations during the June, September and December ACIP meetings—cite to any surveys, studies, or data to support Defendants' assertion that their actions will “restore trust in public health.” Indeed, doctors who see patients every day report that the Non-ACIP Actions and ACIP Actions have made their patients *more* distrustful of the public health system, not less.⁷⁷

⁷⁶ Tracy Beth Høeg, MD, Ph.D and Martin Kulldorff, Ph.D., *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries*, U.S. DEP’T OF HEALTH & HUMAN SERVS. (Jan. 2, 2026), <https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf> (attached as Ex. 19).

⁷⁷ See Ex. 25 (Benjamin Decl.), ¶¶ 11, 15–16, 20, 31–32; Ex. 27 (Kressly Decl.) ¶¶ 13, 26; Ex. 40 (Nahass Decl.) ¶¶ 13–15; Ex. 41 (Chen Decl.) ¶¶ 22, 24–25; Ex. 43 (Borenstein Decl.) ¶¶ 9; Ex. 45 (Jaeger Decl.) ¶¶ 10, 33–34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 33.

Further, neither the Decision Memo nor the Assessment considered any of the following essential factors for evaluating immunization recommendation decisions: (1) epidemiological data comparing the incidence and prevalence of diseases on the schedule in the United States and other countries; (2) socioeconomic data demonstrating that the populations of the alleged peer nations are comparable; (3) data establishing that any of the vaccines on the schedule are harmful; (4) data on screening programs for diseases in other countries; (5) citations to peer-reviewed published research concluding that the vaccines administered under prior iterations of the schedule were ineffective in preventing disease or mitigating symptoms of disease or the need for hospitalization; (6) any evidence from the FDA that any of the vaccines are not safe and effective; (7) changes to practice guidelines published by Plaintiffs or other professional organizations; (8) evidence of consultations with professional organizations; (9) modeling of potential outbreaks if there is a reduction in vaccination rates or loss of herd immunity; (10) cited evidence of superior outcomes in other nations, (11) consideration of other variables in other nations such as widespread screening for diseases that confound nation to nation comparisons such as universal health access; and (12) data on the reductions of the incidence and prevalence of diseases following widespread vaccination.⁷⁸ The same is true for the May 2025 Directive and the presentations at the ACIP meetings that preceded the ACIP Actions.

The outright failure to address or even consider these important issues before undertaking dramatic changes to the CDC schedules renders the Defendants' actions arbitrary and capricious. In *State Farm*, the agency, NHTSA, did not “cast doubt” on the “efficacy of airbag technology” or on “the need for a passive restraint standard.” 463 U.S. at 47. Therefore, because of NHTSA's prior position that “airbags are an effective and cost-beneficial lifesaving technology,” the

⁷⁸ See Ex. 34 (Racine Decl.), ¶¶ 29–38; Ex. 27 (Kressly Decl.), ¶¶ 25, 30, 33.

Supreme Court held that it would be arbitrary and capricious to abandon the mandatory passive restraint rule “without any consideration whatsoever of an airbags-only requirement.” *See id.* at 51. Likewise here, because none of the stated justifications for the Non-ACIP Actions or the ACIP Actions included new data or evidence-based analysis casting doubt on the safety or efficacy of the subject immunizations and vaccine ingredient, and because the CDC’s prior position was that the immunizations and vaccine ingredient were safe and effective, the recommendation and use of the immunizations and vaccine ingredient cannot be modified without consideration of the relevant data, evidence, analyses, and public health impacts related to such decisions. *See id.* Put simply, Defendants provide no “reasoned analysis for the change[s].” *See id.* at 42.

Finally, with respect to both the Non-ACIP Actions and the ACIP Actions, Defendants failed to take into account serious reliance interests before unleashing devastating consequences on Plaintiffs, their members, and the U.S. public health system. These Actions set into motion a vaccine policy that disrupts multiple parts of the American health care ecosystem. These changes have wide-ranging effects far beyond when and to whom a vaccine may be administered. The complex landscape of federal and state laws that govern American health care rely on the CDC schedules to inform many aspects of operations. For example, VFC providers are only required to stock vaccines designated as “routine.”⁷⁹ The change in classification of multiple vaccines from “routine” to SCDM jeopardizes access to these vaccines for children in the VFC program,⁸⁰ and more broadly.⁸¹

⁷⁹ *See VFC Operations Guide*, CTRS. FOR DISEASE CONTROL & PREVENTION at 82 (July 1, 2024), https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/vfc-ops-guide_version-4.0_july-2024_low-res-508-rev-2.pdf.

⁸⁰ *See* Ex. 42 (Pring Decl.) ¶ 17 (describing the delay in children covered by the VFC program receiving access to the 2025–26 Covid vaccine).

⁸¹ *See, e.g.*, Ex. 34 (Racine Decl.) ¶ 17; Ex. 44 (Pavlos Decl.) ¶ 24.

Similarly, how immunizations are listed on the CDC schedules can affect health insurance coverage and cost-sharing obligations under the Affordable Care Act. Children and pregnant women who were previously able to receive the vaccine free of charge or without difficulty may now face potential out-of-pocket expenses or an outright inability to receive life-saving vaccinations because of the Defendants' actions. And perhaps most importantly, the public at large relies on the safety and efficacy of routine immunizations to protect our population from serious illness, hospitalization, and death.

The APA requires the Secretary to consider these reliance interests when changing its mind, but the Defendants failed to do so here. *See Dep't of Homeland Sec.*, 591 U.S. 1 at 30; *see also NIH I*, 770 F.Supp.3d at 308–11 (holding that the NIH's change from individually negotiated indirect cost rates to a flat indirect cost rate for grant awards related to biomedical research was arbitrary and capricious because the NIH's "conclusory" explanation "plainly failed to sufficiently consider the substantial reliance interests at stake" for grant recipients).

For these reasons, Plaintiffs are likely to succeed on their arbitrary and capricious claims regarding the Non-ACIP Actions and ACIP Actions.

4. The ACIP Appointments Violate the APA Because They Were Not Made in Accordance with FACA.

With a growing number of advisory committees appointed to guide national policy and decision making, concerns mounted that advisory committees' operations were not consistent or transparent across all committees. Congress responded by enacting FACA in 1972 to impose "administrative guidelines [] to justify the investment of time, effort and expense in the use of advisory groups as an instrument of Government."⁸² Congress recognized the value of having non-

⁸² *See The Federal Advisory Committee Act (FACA): Overview and Considerations for Congress*, Cong. Rsch. Servs., citing *Hearing on the Role and Effectiveness of Federal Advisory Committees Before the H. Comm. on Gov't Op.*, 91st Cong. (1970).

governmental individuals “furnish[] expert advice, ideas and diverse opinions to the Federal Government,” *Cummock v. Gore*, 180 F.3d 282, 284 (D.C. Cir. 1999), and, through FACA, implemented mandatory requirements to ensure committees did not go unchecked.⁸³ The APA provides a cause of action for review of agency decisions that violate federal law, including FACA. *See* 5 U.S.C. § 706(2)(A), (C) (authorizing review of and “set aside” relief for agency actions taken “not in accordance with law” or taken “in excess of statutory jurisdiction, authority, or limitations”); *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 19 (1st Cir. 2020); *see also Physicians for Soc. Resp. v. Wheeler*, 956 F.3d 634, 643 (D.C.C. 2020).⁸⁴

Not only do courts have the authority to review FACA violations, an advisory committee’s work product that resulted from FACA violations may be enjoined. *See, e.g., Alabama-Tombigbee Rivers Coal. v. Dep’t of Interior*, 26 F.3d 1103, 1107 (11th Cir. 1994) (“We find injunctive relief as the only vehicle that carries the sufficient remedial effect to ensure future compliance with FACA’s clear requirements. Anything less would be tantamount to nothing.”); *Cal. Forestry Ass’n v. U.S. Forest Serv.*, 102 F.3d 609, 614 (D.C.C. 1996) (injunctive relief is appropriate if the absence of a remedy renders FACA a nullity); *Western Org. of Resource Councils v. Bernhardt*, 412 F.Supp.3d 1227, 1243–44 (D. Mont. 2019) (“A use injunction [preventing the agency from relying on an advisory committee’s recommendations or work product] is the only way to achieve FACA’s purpose[] of enhancing public accountability . . .”).

⁸³ The APA provides a vehicle for reviewing agency decisions that violate federal law. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020) (citing *Cowels v. Fed. Bureau of Investigation*, 936 F. 3d 62, 66 (1st Cir. 2019) and other cases). Where, as here, plaintiffs allege that change to membership on an advisory committee alters the balance and role of special influence over that committee, courts rely on FACA to inform “what Congress intended the [Secretary] to consider,” and the “APA’s reasoned decision-making standards” inform the rationality of any changes to policy that the committee recommends. *Id.* at 20.

⁸⁴ The Court acknowledged this in denying the Defendants’ Motion to Dismiss the Third Amended Complaint. *See* Memorandum and Order on Defendant’s Motion to Dismiss, No. 25-11916-BEM (D. Mass. Jan. 6, 2026), ECF No. 168, at 20–22.

i. FACA and Its Regulations Require Safeguards Against Inappropriate Influence.

Just as the binding regulations require FACA committees to be fairly balanced, the agency head “must” safeguard against inappropriate influence by the agency or any special interest. 41 C.F.R. § 102-3.105(g). The word “must” denotes a nondiscretionary obligation. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 255 (1988). FACA requires federal agencies to make “appropriate provision[] 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.” 41 CFR § 102-3.105(g). Advisory committee members whose professional interests or job prospects are directly affected by the committee’s output raise a strong potential for inappropriate influence. *See Cargill, Inc. v. United States*, 173 F.3d 323, 339–340 (5th Cir. 1999) (expressing concern that committee members were negotiating job positions with agencies whose regulatory authority will be directly affected by the results of the committee’s study).

ii. The ACIP Appointments Have Resulted in an Unfairly Balanced Federal Advisory Committee in Violation of FACA.

The Secretary’s appointments to the ACIP contravene FACA in at least three different ways. The ACIP’s operative document on membership—the Membership Balance Plan (“MBP”)—implements written safeguards to ensure the committee operates in a fairly balanced manner.⁸⁵ The Secretary failed to follow the MBP’s Candidate Identification Process, which requires widespread solicitation and ACIP Steering Committee review of proposed ACIP members.⁸⁶ The Secretary failed “to ensure the committee is balanced” consistent with the MBP’s

⁸⁵ See U.S. DEP’T OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024).

⁸⁶ See *id.* at ¶ 6.

“Point of View” and “Other Balance Factors” requirements.⁸⁷ As a result, the Secretarial appointment process filled the ACIP with individuals publicly espousing similar (anti-vaccine) views and preconceived hypotheses that vaccines are categorically unsafe to the exclusion of vaccinologists, epidemiologists, and other expert specialists and clinicians who do not hold such views.

First, the Secretary failed to follow the Candidate Identification Process. The MBP provides a detailed candidate identification process that “describe[s] the process” for achieving and evaluating ACIP balance as well as “how [ACIP] vacancies, if any, will be handled by the agency.”⁸⁸ The Candidate Identification Process provides three methods through which the Secretary can solicit names for new ACIP members: (1) email solicitation “distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations [], academic centers, and other contacts in the field of vaccinology; (2) annual postings on the Federal Register; (3) announcements at ACIP meetings via a web link broadcast to all virtual attendees. Membership applications must be reviewed by the ACIP Steering Committee, which in turn, selects two candidates for each vacant position based on “the quality of the candidate’s technical expertise, balance of specialty areas[], and geographic distribution.”⁸⁹ The ACIP Steering Committee must “finalize[] a proposed nomination package annually during November or December.”

The Secretary’s appointments of new ACIP members has occurred completely outside this framework. On June 9, 2025, the Secretary announced to the Wall Street Journal that he was

⁸⁷ *Id.* at ¶¶ 4-5.

⁸⁸ *Id.* at ¶¶ 4-6.

⁸⁹ *Id.*

“totally reconstituting the [ACIP].”⁹⁰ Two days later, the Secretary appointed eight new members. Subsequent ACIP members were appointed on September 15, 2025, and January 13, 2026.⁹¹ For each set of appointments, no email solicitations were sent out, including not to liaison organizations, who were all terminated and cut off from participation by June 9, 2025. No notices were posted in the Federal Register. No applications were reviewed by the ACIP Steering Committee nor, upon information and belief, were two candidates identified for each vacancy before selecting one. Rather, the Secretary, upon information and belief, sought out individual members through a targeted campaign based on political affiliation and lack of public criticism of the President or Secretary.

This practice violates the core of the MBP whose purpose is to ensure fair balance across ACIP. The Secretary’s unequivocal failure to properly identify candidates consistent with the MBP’s objectives alone renders the resulting ACIP (the current ACIP membership) not fairly balanced.

Second, the Secretary failed to obtain fair point-of-view balance. The MBP’s “Points of View” section “describes the process that will be used to ensure the committee is balanced, and identify the categories (e.g. individual expertise or represented interests) from which candidates will be considered.”⁹² The MBP explicitly states that “ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the

⁹⁰ Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

⁹¹ *HHS, CDC Announce New ACIP Members*, U.S. DEP’T OF HEALTH & HUM. SERVS. (Sept. 15, 2025), <https://www.hhs.gov/press-room/hhs-cdc-announce-new-acip-members-sept-2025.html>; *Secretary Kennedy Appoints Two OB-GYNs to CDC’s Advisory Committee on Immunization Practices*, U.S. DEP’T OF HEALTH & HUM. SERVS. (Jan. 13, 2026), <https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-ob-gyns-cdc-advisory-committee-immunization-practices.html>.

⁹² U.S. DEP’T OF HEALTH AND HUM. SERVS., *FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN* (2024) at ¶ 4.

Committee’s objectives.”⁹³ The requisite expertise and experience is captured through the four-part criteria upon which members are selected: (1) expertise in the field of immunization practices;” (2) “multi-disciplinary expertise in public health;” (3) “expertise in the use of vaccines and immunologic agents;” (4) “knowledge of vaccine development, evaluation, safety and delivery;” or (5) “[in the case of a consumer representative] knowledge about consumer perspectives and/or social and community aspects of immunization programs.”⁹⁴

With one exception,⁹⁵ the remaining ACIP members appointed by the Secretary categorically do not meet the requirement in the MBP. The Secretary’s appointments to the ACIP lack the requisite expertise, background, and credentials: three are obstetrician-gynecologists, one is a psychiatrist, one is an operations management professor, one is a cardiologist, and one is an emergency medical physician. Five current members have never engaged in vaccine-related research or publication. Another member (Levi) has published only two papers in which vaccines are discussed, both in 2025, just months before his appointment. In fact, at least three members (Blackburn, Pagano, and Pollack) have no discernable vaccine related experience at all.⁹⁶ To appreciate the extent to which the current ACIP members fail to satisfy this requirement, one need only look to the credentials of the ACIP members whom the Secretary fired on June 9, 2025. Those 17 former ACIP members held a variety of positions in infectious diseases; epidemiology; vaccinology; immunology; and pediatrics, geriatrics, or maternal health.⁹⁷

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ H. Cody Meissner, M.D., is professor of pediatrics at the Geisel School of Medicine at Dartmouth College and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. Fourth Am. Compl., Am. Acad. Of Pediatrics v. Kennedy, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶ 77.

⁹⁶ *See id.*

⁹⁷ The positions of the former ACIP members included: (i) Professor of Pediatrics and Infectious Diseases Epidemiology, University of Colorado School of Medicine and Colorado School of Public Health, Jules Amer Chair in Community Pediatrics; (ii) The Gillings Distinguished Professor in Public Health, Department of Health Behavior, Gillings School of Public Health, University of North Carolina; (iii) The Chief Medical Officer at a

Finally, the ACIP Appointments fail to achieve the “Other Balance Factors” set forth in the MBP. A factor that the MBP “identifies as important in achieving a balanced [ACIP]” is a “balance of specialty areas.”⁹⁸ The specialty areas enumerated in the MBP that a balanced ACIP would have include: “pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, public health perspective, etc.”⁹⁹ Of the Secretary’s appointees, there is one expert in pediatric infectious disease who is operating in academia at Dartmouth College, but no practicing pediatricians or family medicine practitioners. There is one

community health center in Watts, CA; and formerly a clinical professor of pediatrics at the Charles R. Drew University of Medicine and Science and past-president of the California Immunization Coalition; (iv) Director, Mount Auburn Travel Medicine Center, Division of Infectious Diseases and Travel Medicine, Mount Auburn Hospital; Associate Professor of Medicine, Harvard Medical School; Lecturer, Massachusetts Institute of Technology; (v) Professor of Medicine, University of Washington School of Medicine; Professor of Epidemiology, University of Washington School of Public Health; Attending Physician, Harborview Medical Center; (vi) Associate Professor of Medicine, Pediatrics, and Medical Science (Clinical), The Warren Alpert Medical School of Brown University; Associate Program Director, Brown Combined Residency in Internal Medicine and Pediatrics; (vii) Attending Physician and Chief Medical Epidemiologist, Memorial Sloan Kettering Cancer Center; Professor of Medicine, Weill Cornell Medical College; (viii) Professor and Travelers Chair in Geriatrics and Gerontology; Director, UConn Center on Aging; Claude D. Pepper Older Americans Independence Center (OAIC), UConn Health; publisher of articles on vaccines for older adults and influenza vaccines; (ix) Vice President for Medical Affairs, Dean, Carver College of Medicine, University of Iowa, with significant scholarship on maternal health, vaccines and infectious diseases in pregnancy, and vaccine-preventable diseases such as influenza, Ebola, Zika, dengue, and COVID; (x) Owner of a family medicine practice in New York state and former liaison to the ACIP for the American Academy of Family Practitioners; (xi) Chief, Immunization Section, Illinois Department of Public Health, Division of Infectious Diseases; (xii) Senior Associate Dean for Faculty Development and Diversity, Taube Endowed Professor of Global Health and Infectious Diseases; Professor of Pediatrics and of Epidemiology and Population Health; Interim Chair, Department of Medicine, Stanford University School of Medicine; Medical Director, Infection Prevention and Control and Attending Physician, Lucile Packard Children's Hospital at Stanford, Department of Pediatrics; (xiii) Co-Director, Vaccine Education Center, Children's Hospital of Philadelphia; (xiv) Chief, Immunization Branch, California Department of Public Health; (xv) Professor of Medicine, Section of Infectious Diseases, Yale School of Medicine; (xvi) Professor of Medicine, Vanderbilt University, with significant scholarship in influenza and other viral respiratory infections, including studies of vaccine immunogenicity, safety, and effectiveness in older adults; clinical and molecular epidemiology of respiratory viruses; diagnostic testing and antiviral use; immunologic mechanisms of vaccine response and immunosenescence; and vaccine policy, evaluation, and prevention strategies for high-risk populations; (xvii) Adjunct Professor, Department of Community Health Sciences at SUNY Downstate School of Public Health, and former Assistant Commissioner for the Bureau of Immunization New York City Department of Health and Mental Hygiene; former Director of the Vaccine Operations Center for the NYC Health Department’s COVID’s response; former Epidemic Intelligence Service Officer in the Malaria Branch, Division of Parasitic Diseases, CDC; former Bureau of Immunization as Medical Director. *See ACIP Committee Members July 1, 2024–June 9, 2025*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 14, 2025), <https://archive.cdc.gov/#/details?url=https://www.cdc.gov/acip/membership/archive/members-2024-jul-2025-jun.html>.

⁹⁸ U.S. DEPT OF HEALTH AND HUM. SERVS., FEDERAL ADVISORY COMMITTEE (FAC) MEMBERSHIP BALANCE PLAN (2024) at ¶ 5.

⁹⁹ *See id.*

member trained in epidemiology, but not with prior focus on immunology. There are no representatives from state or local health departments, or from public health, or clinician pediatricians. Worse, as described above, there is a dearth of vaccine-related experience at all. The complete absence of experts in key areas critical to ACIP's mission underscores the manner in which FACA has been ignored. This is exactly the type of imbalance that FACA sought to prevent. *See NAACP Legal Defense Fund, Inc. v. Barr*, 496 F.Supp.3d at 136–137 (D.D.C. 2020) (finding advisory committee consisting only of law enforcement personnel was not fairly balanced as it related to its role in advising on policing policy changes.)

Additionally, Defendants have failed to avoid inappropriate influence through the ACIP Appointments. Rather, Defendants have created new channels of influence to the ACIP. The 1978 amendment to the ACIP Charter requiring the ACIP chair be appointed from within the committee rather than from a governmental agency (like the CDC, as had been the case) was a deliberate action to depoliticize the ACIP. The ACIP was intended to be an independent body of experts providing independent advice to the federal agencies they serve. But the Secretary's deliberate appointments of special interest-affiliated persons to the ACIP has undermined this important safeguard.

The ACIP Appointments fails to meet the minimum requirements set forth in the statute requiring the avoidance of special interest groups. *Id.* at 136–137 (and citations therein). Ten of the 14 ACIP members have publicly stated views on vaccines that align with the Secretary's anti-vaccine views. At least four are members or otherwise affiliated with openly anti-vaccine organizations. The new ACIP members include individuals who have stated that they will not allow their grandchildren to be vaccinated, several individuals who have a history of spreading patently false information about vaccines, and one member who boasted that she has "probably

been anti-vax longer than RFK has.”¹⁰⁰ These unambiguous facts cannot be squared with the requirement of a fair balance, and there is ample evidence that special interests are being favored by the Secretary’s influence.

These multiple instances where the intent of FACA and the directives in the statute and implementing regulations have been disregarded fit well within the scope of those cases where injunctive relief is necessary to prevent an advisory committee from turning FACA’s safeguards into a nullity. The composition of the current ACIP and the actions it has taken stand the intent of the law on its head and are no more than a rubber stamp for Defendants’ agenda to create and spread public health misinformation. Accordingly, Plaintiffs are likely to succeed on their FACA claim.

II. Plaintiffs Have Suffered and Will Continue to Suffer Irreparable Harm from the Challenged Actions

Plaintiffs have endured significant and irreversible harm from the beginning of Defendants’ targeted campaign to undermine vaccination protocols in the United States, beginning with the May 2025 Action. Those harms—which include the diversion of resources to combat misinformation, confusion, and distrust, as well as non-compensable economic harms and imminent threats to public health—have compounded and escalated with each Non-ACIP Action, ACIP Action, and ACIP meeting. Such harms will continue and compound if the Challenged Actions are not enjoined. *See New Hampshire Indonesian Cmty. Support v. Trump*, 157 F.4th 29, 35 (1st Cir. 2025) (citing *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22–23 (2008)).

A. Plaintiffs Have Suffered Harms from Having to Combat Misinformation, Confusion, and Distrust.

¹⁰⁰ *See* Fourth Am. Compl., *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916 (D. Mass. Jan. 19, 2026) ECF No. 180-1, ¶¶ 76–77.

Rule and policy changes that directly impact organizational “burdens, costs, and effectiveness” pose a “real and substantial threat of imminent harm.” *See Mass. Fair Housing Ctr. v. U.S. Dep’t of Hous. & Urban Dev.*, 496 F.Supp.3d 600 (D. Mass. 2020). Further, “[o]bstacles that unquestionably make it more difficult for the plaintiff to accomplish its primary mission provide injury for purposes of irreparable harm.” *NIH I*, 770 F.Supp.3d at 322 (quoting *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (holding that the degradation of vital infrastructure, loss of imperative staff, loss of human capital, and uncertainty around the ability to sustain future grant applications qualified as irreparable harms to the plaintiff institutions’ primary research missions)).

The Non-ACIP Actions, the ACIP Actions, and the misinformation spread by the unbalanced ACIP have caused mass confusion among health care providers and patients.¹⁰¹ The process to effectuate the Non-ACIP Actions and ACIP Actions departed in significant ways from the ACIP’s and Defendants’ typical practices of compiling and evaluating evidence in support of reasoned recommendations. Further, none of the Non-ACIP Actions or ACIP Actions were accompanied by an MMWR publication or comparable guidance explaining the scientific rationale or clearly defining core elements of vaccination practice, such as dosing, target populations, or the circumstances under which vaccination should be offered under SCDM.¹⁰² The Challenged

¹⁰¹ See Ex. 27 (Kressly Decl.), ¶¶ 15, 26; Ex. 34 (Racine Decl.), ¶¶ 11, 15, 20, 40; Ex. 42 (Pring Decl.), ¶¶ 12, 14, 19, 24, 31, 46; Ex. 43 (Borenstein Decl.), ¶¶ 9, 19, 26; Ex. 31 (Berman Decl.), ¶¶ 15–17; Ex. 40 (Nahass Decl.), ¶ 14; Ex. 41 (Chen Decl.), ¶¶ 22, 24; Ex. 45 (Jeager Decl.), ¶¶ 16, 31, 34; Ex. 44 (Pavlos Decl.), ¶¶ 18, 29, 32, 33, 35.

¹⁰² See Ex. 25 (Benjamin Decl.), ¶ 20; Ex. 34 (Racine Decl.) ¶ 15; Ex. 43 (Borenstein Decl.) ¶¶ 22, 26; Ex. 31 (Berman Decl.) ¶ 9, 14–15; Ex. 41 (Chen Decl.) ¶ 25; Ex. 49 (Jane Doe 3 Decl.) ¶¶ 15–16, 17 (child refused vaccine because of confusion caused by a schedule change); Ex. 50 (Jane Doe 1 Decl.) ¶¶ 1–5, 20 (required to navigate a fragmented public health landscape, spanning her providers, pharmacies, and online resources, rife with confusion following a schedule change); Ex. 52 (Jane Doe 2 Decl.) ¶¶ 14, 31–32.

Actions have resulted in the spread of significant misinformation regarding the safety, efficacy, and utility of vaccines, as well as the erosion of trust between patients and their providers.¹⁰³

As a result, Plaintiff Organizations and their members have been required to divert significant resources—including time, staff attention, and financial resources—from their core initiatives, primary missions, and patient care to engage in emergency mitigation work addressing the Non-ACIP Actions and ACIP Actions; to address the misinformation, confusion, and distrust resulting from the Challenged Actions; and to develop methods for navigating the implications of the same.¹⁰⁴ Such mitigation efforts include urgently working towards developing, revising, and distributing educational materials, guidance, websites, and publications to address the confusion created by the CDC schedule changes and responding to numerous member inquiries about the same.¹⁰⁵ It also includes having to re-examine voluminous clinical practice guidelines that were based on the assumption that children are routinely vaccinated to determine where additional decision points need to be added.¹⁰⁶ This work, which is already extraordinarily extensive, burdensome, and costly (of time, financial resources, and opportunity) is just beginning: Plaintiffs and their members must continue doing it—incurring substantially more and more harms in the process—absent an injunction.

Moreover, for both the Plaintiffs Organizations and their members, the mitigation efforts require diverting time and resources to combat the reputational harm and erosion of public trust in

¹⁰³ See Ex. 34 (Racine Decl.) ¶¶ 14, 40; Ex. 42 (Pring Decl.) ¶¶ 24, 46; Ex. 43 (Borenstein Decl.) ¶¶ 9, 15, 19, 26, 33, 45, 50; Ex. 27 (Kressly Decl.) ¶¶ 13, 26, 40; Ex. 31 (Berman Decl.) ¶¶ 12, 16, 18; Ex. 40 (Nahass Decl.) ¶¶ 12, 14; Ex. 41 (Chen Decl.) ¶¶ 22, 24, 25; Ex. 45 (Jaeger Decl.) ¶¶ 10, 16, 31, 33, 34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 24, 33, 36.

¹⁰⁴ See Ex. 27 (Kressly Decl.) ¶¶ 16, 26–31, 39; Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 42 (Pring Decl.) ¶¶ 16, 23–24, 30, 46–47; Ex. 43 (Borenstein Decl.) ¶¶ 26, 45; Ex. 40 (Nahass Decl.) ¶¶ 12, 16, 17; Ex. 41 (Chen Decl.) ¶ 24; Ex. 45 (Jaeger Decl.) ¶ 31; Ex. 44 (Pavlos Decl.) ¶¶ 17–18, 22–24, 29, 33, 36–37; Ex. 34 (Racine Decl.) ¶¶ 13–18, 39.

¹⁰⁵ See Ex. 27 (Kressly Decl.) ¶¶ 26–28; Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 42 (Pring Decl.) ¶¶ 23–30, 46; Ex. 44 (Pavlos Decl.) ¶¶ 23–24, 29–30, 35, 37; Ex. 31 (Berman Decl.) ¶¶ 14–15; Ex. 40 (Nahass Decl.) ¶¶ 15–17; Ex. 34 (Racine Decl.) ¶¶ 15, 18, 39.

¹⁰⁶ See Ex. 27 (Kressly Decl.) ¶ 31.

the organizations, in physicians, and in vaccines more generally due to the Challenged Actions.¹⁰⁷ This imposes significant burdens on physicians who are already burnt out and stretched thin, and it impairs their ability to provide safe, efficient, clear, evidence-based care to patients.¹⁰⁸ The CDC schedule changes also expose physicians to potential malpractice liability, regardless of whether they do or do not administer the vaccine. If they do not administer downgraded vaccines, then under current CDC recommendations, they can be subject to liability, *even if a parent refuses the vaccine*.¹⁰⁹ If they do administer downgraded vaccines, they can be subject to liability or disciplinary action by their applicable Board of Medicine for failing to follow the current CDC schedules.¹¹⁰ The environment resulting from the Challenged Actions is also causing safety concerns for physicians who are facing increasingly distrustful, hostile patients.¹¹¹

“There can be no do over and no redress” for the time and resources the Plaintiff Organizations and their members have had to divert—and will have to continue to divert absent an injunction—from their primary missions and patient care to address the confusion, misinformation, and distrust stemming from the Challenged Actions. *See NIH I*, 770 F.Supp.3d at 321 (quoting *League of Women Voters*, 838 F.3d at 9). And if the February ACIP meeting were to go forward, Plaintiff Organizations and their members anticipate even more confusion, misinformation, and distrust, which would have compounding effects on all of these harms.¹¹²

B. Plaintiffs Have Suffered Further Economic Harms that Cannot be Compensated.

¹⁰⁷ See Ex. 25 (Benjamin Decl.) ¶ 31; Ex. 27 (Kressly Decl.) ¶¶ 13, 26, 40; Ex. 43 (Borenstein Decl.) ¶ 9; Ex. 40 (Nahass Decl.) ¶ 16; Ex. 34 (Racine Decl.) ¶ 40; Ex. 41 (Chen Decl.) ¶¶ 22, 24; Ex. 45 (Jaeger Decl.) ¶¶ 10, 16, 33–34; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 20, 22, 32–33.

¹⁰⁸ See Ex. 27 (Kressly Decl.) ¶¶ 18, 42, 51; Ex. 42 (Pring Decl.) ¶ 31, Ex. 43 (Borenstein Decl.) ¶¶ 9, 13, 15, 19, 26, 33, 40, 45, 50; Ex. 31 (Berman Decl.) ¶¶ 8, 10, 12, 16, 17–19; Ex. 40 (Nahass Decl.) ¶¶ 13, 16; Ex. 45 (Jaeger Decl.) ¶¶ 10, 33; Ex. 34 (Racine Decl.) ¶ 20; Ex. 44 (Pavlos Decl.) ¶ 19.

¹⁰⁹ See Ex. 27 (Kressly Decl.) ¶¶ 17, 51; Ex. 43 (Borenstein Decl.) ¶¶ 15, 19.

¹¹⁰ See Ex. 43 (Borenstein Decl.) ¶ 19; Ex. 45 (Jaeger Decl.) ¶ 16; Ex. 44 (Pavlos Decl.) ¶ 19.

¹¹¹ See Ex. 31 (Berman Decl.) ¶ 18; Ex. 43 (Borenstein Decl.) ¶ 33; Ex. 45 (Jaeger Decl.) ¶ 33.

¹¹² See Ex. 27 (Kressly Decl.) ¶¶ 41–42; Ex. 42 (Pring Decl.) ¶¶ 46–47.

This court has recognized that “[t]he costs of complying with challenged regulations” may be irreparable, given the obstacle faced in pursuing monetary damages. *California v. Kennedy*, F.Supp.3d, 2025 WL 2807729, at *6 (D. Mass. Oct. 1, 2025) (citing *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003)). This is especially true in the APA context, where monetary damages are not available. *See id.* (citing *Kentucky v. Biden*, 23 F.4th 585, 611 (6th Cir. 2022)); *see also NIH I*, 770 F.Supp.3d at 319–20. Indeed, economic harm can be irreparable where it is not accurately measurable or adequately compensable, or where the losses are compounding and disruptive. *NIH I*, 770 F.Supp.3d at 325–26.

Plaintiffs Organizations’ members and medical providers more broadly are experiencing and will continue to experience various financial harms due to the Challenged Actions. These harms include extended, largely uncompensated time spent engaging in SCDM discussions with patients during appointments (which also limits the number of patients that can be seen in a day, thereby also reducing compensation from that which pre-dated the Challenged Actions) as well as expenditures related to hiring additional staff to keep up with the demands on provider time resulting from the CDC schedule changes.¹¹³

Providers will also continue to experience administrative and financial burdens related to stocking, ordering, and supplying childhood vaccines. Stocking vaccines imposes significant financial and operational burdens on providers because vaccines are expensive upfront purchases, carry inventory loss and spoilage risk, and require expensive, refrigerated storage.¹¹⁴ Several

¹¹³ *See* Ex. 43 (Borenstein Decl.) ¶¶ 9, 13, 15–17, 19, 22, 33; Ex. 27 (Kressly Decl.) ¶ 16; Ex. 42 (Pring Decl.) ¶ 19; Ex. 31 (Berman Decl.) ¶¶ 11, 13–14, 16–18; Ex. 25 (Benjamin Decl.) ¶¶ 30, 32; Ex. 40 (Nahass Decl.) ¶¶ 13, 15–16; Ex. 41 (Chen Decl.) ¶¶ 22, 24–25; Ex. 45 (Jaeger Decl.) ¶¶ 10, 11, 31, 33, 34; Ex. 51 (Hopkins) ¶¶ 26, 37, 41–43; *see also* Ex. 49 (Jane Doe 3) ¶ 25 (stating that schedule changes to shared clinical decision-making for her children can require a physician visit 45 minutes farther than her local pharmacy for her children’s flu and Covid-19 vaccinations, resulting in additional travel and electricity costs to charge her electric vehicle); Ex. 50 (Jane Doe 1) ¶¶ 13–14, 20 (diverting her work time to independently navigate vaccine access amid provider confusion)

¹¹⁴ *See* Ex. 25 (Benjamin Decl.) ¶ 26; Ex. 42 (Pring Decl.) ¶¶ 10, 39–40; Ex. 43 (Borenstein Decl.) ¶ 40.

childhood vaccines are available as combination vaccines, including (1) the diphtheria-tetanus-acellular pertussis (DTaP)-inactivated poliovirus (IPV)-HepB combination vaccine, (2) the DTaP-IPV-HepB-Haemophilus influenzae type B (Hib) combination vaccine, and (3) the DTaP-IPV-Hib combination vaccine. Previously, all vaccines included in these combination vaccines were routinely recommended. As a result of the new Childhood Schedule implemented on January 5, 2026, which changed the HepB dosing schedule without any consideration of downstream impacts, all HepB-containing combination vaccines are no longer part of routine recommendations.

Physician offices complete vaccine ordering months in advance and may not stock sufficient doses of combination vaccine options that do not contain HepB (*e.g.* Pentacel) or standalone vaccines for DTaP, IPV, and Hib to present as an alternative to parents and caregivers, so they will likely have to dispose of the now-unusable combination vaccines *and* incur additional costs to order more individual vaccines.¹¹⁵ Further, accommodating the stock for more individual vaccines will require ordering more expensive, medical-grade vaccine refrigerators and freezers.¹¹⁶ These economic costs of adapting to the Non-ACIP Actions and ACIP Actions are irreparable because they are compounding, disruptive, and not adequately compensable by a later injunction, and Plaintiffs have no means to obtain money damages from Defendants. *See NIHI*, 770 F.Supp.3d at 325 (finding harms irreparable because “[e]ven for those harms that can be measured in dollars and cents, the losses are compounding and will result in even greater disruption”); *see also California*, 802 F.Supp.3d at 283 (D. Mass. 2025).

C. The Challenged Actions Are Causing and Will Continue to Cause Imminent Public Health Harms.

¹¹⁵ *See* Ex. 27 (Kressly Decl.) ¶ 36; Ex. 42 (Pring Decl.) ¶¶ 39–40.

¹¹⁶ *See* Ex. 42 (Pring Decl.) ¶ 40.

“Threats to public health and safety constitute irreparable harm that will support an injunction.” *Cigar Masters Providence, Inc. v. Omni Rhode Island, LLC*, No. 16-471-WES, 2017 WL 4081899, at *14 (D.R.I. Sept. 14, 2017); *Sierra Club v. U.S. Dep’t of Agric., Rural Utils. Serv.*, 841 F.Supp.2d 349, 358 (D.D.C. 2012). Plaintiffs need not wait until there is a significant rise in the rates of infection and hospitalizations in order to seek relief; if anything, waiting until then would be too late. *See, e.g., Silva v. East Providence Housing Authority*, 390 F.Supp. 691, 695 (D.R.I. 1975).

The vaccines for diseases that have been downgraded from routine recommendations have a long track record of improving public health by reducing disease transmission, hospitalization, and vaccine-preventable deaths.¹¹⁷ Before a vaccine was introduced for rotavirus, there were an estimated 2.7 million rotavirus infections per year in the United States, and rotavirus caused more than 410,000 physician visits and 20–60 deaths annually.¹¹⁸ Since introduction, rotavirus vaccination prevents an estimated 40,000–50,000 hospitalizations per year among infants and young children and has decreased prevalence of rotavirus among older children and adults that are not vaccinated.¹¹⁹

RSV is the leading cause of hospitalization among infants, and nearly all infants contract RSV by age 2.^{120,121} Before RSV immunizations were introduced, RSV caused approximately

¹¹⁷ See Ex. 25 (Benjamin Decl.) ¶¶ 22–24; Ex. 27 (Kressly Decl.) ¶ 13.

¹¹⁸ See Margaret Cortese & Penina Haber, *Chapter 19: Rotavirus*, in *Ctrs. for Disease Control and Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 25, 2024).

¹¹⁹ *Rotavirus Vaccine Recommendations*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Jul. 15, 2024), <https://www.cdc.gov/rotavirus/hcp/vaccine-considerations/index.html>.

¹²⁰ See Danielle L. Moulia, et al., *Evidence to Recommendation Framework: Clesrovimab*, ADVISORY COMM. ON IMMUNIZATION PRACS. (Apr. 16, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf>.

¹²¹ See Danielle L. Moulia, et al., *Evidence to Recommendation Framework: Clesrovimab*, ADVISORY COMM. ON IMMUNIZATION PRACS. (Apr. 16, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/02-Moulia-maternal-peds-RSV-508.pdf>.

58,000–80,000 hospitalizations and 100–300 deaths in children under 5 each year.¹²² One modeling study estimated that 2.1 million children under 5 years of age with RSV infection required medical attention annually.¹²³ Following the introduction of RSV immunizations, the burden of disease declined: cumulative RSV-associated hospitalization rates among infants 0–7 months of age fell from an estimated 14.8–15.0 cases per 1,000 children in the 2018–2020 seasons to 8.5–10.7 cases per 1,000 children in the 2024–2025 season.¹²⁴ RSV immunization is also demonstrated to be cost-effective; an analysis estimated that if half the US birth cohort received nirsevimab, immunization would avert approximately 100,000+ outpatient visits and avert approximately 14,000+ hospitalizations per year, at a cost of \$153,517 per quality-adjusted life year (“QALY”) saved.¹²⁵

Similarly, influenza has a significant impact on children; estimates for the 2024–2025 respiratory season indicate that 14.6 million children contracted influenza and 56,000 were hospitalized.¹²⁶ During the same season, an estimated 17,400 pediatric hospitalizations were prevented due to vaccination.¹²⁷ While influenza causes a continued impact on hospital settings

¹²² See *Increased Respiratory Syncytial Virus (RSV) Activity in Parts of the Southeastern United States: New Prevention Tools Available to Protect Patients*, CTRS. FOR DISEASE CONTROL AND PREVENTION (Sept. 5, 2023), <https://www.cdc.gov/han/2023/han00498.html>.

¹²³ See Caroline Breese Hall, et al., *The Burden of Respiratory Syncytial Virus Infection in Young Children*, 360 NEJM 588 (2009), https://www.nejm.org/doi/10.1056/NEJMoa0804877?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%200www.ncbi.nlm.nih.gov.

¹²⁴ See Megan E. Patton, et al., *Interim Evaluation of Respiratory Syncytial Virus Hospitalization Rates Among Infants and Young Children After Introduction of Respiratory Syncytial Virus Prevention Products — United States, October 2024–February 2025*, 74 MORBIDITY & MORTALITY WKLY. REP. 421 (May 8, 2025), https://www.cdc.gov/mmwr/volumes/74/wr/mm7416a1.htm?s_cid=mm7416a1_w.

¹²⁵ See David W. Hutton, et al., *Cost-Effectiveness of Nirsevimab for Respiratory Syncytial Virus in Infants and Young Children*, 154 PEDIATRICS (Nov. 5, 2024).

¹²⁶ See Influenza Division, Ctrs. for Disease Control & Prevention, *Severity, Disease Burden, and Prevented Burden for the 2024-2025 Influenza Season*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 25, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-dugan-influenza-508.pdf>.

¹²⁷ See *id.*

and substantial disease burden, routine vaccination has historically been a proven strategy to reduce severe illness among pediatric populations.¹²⁸

HepA occurred in epidemics, the largest of which peaked in 1971 at nearly 60,000 cases.¹²⁹ Following the introduction of a vaccine, hospitalization rates declined by more than 68%, and ambulatory care visits declined by more than 40%.¹³⁰ Hand-in-hand with a reduction in disease and medical attention was a reduction in medical expenditures: from 1996 to 2004, medical costs associated with HepA dropped by 68%, from \$29.1 million to \$9.3 million.¹³¹

Meningococcal disease has high severity: between 10–15% of individuals who contract meningococcal disease die, and among survivors, 20% have permanent sequelae such as neurologic damage, hearing loss, or loss of a limb.¹³² Before the MenACWY vaccine was introduced in 2005, an estimated 1,400–2,800 cases of meningococcal disease occurred each year in the U.S.¹³³ By contrast, in 2024, there were 503 cases of meningococcal disease (this number represents the highest reported annually since 2013).¹³⁴

These public health successes are in jeopardy of being reversed quickly, which would in turn overwhelm the U.S. health care system.¹³⁵ Further, if the February ACIP meeting proceeds as scheduled, “it will immediately compound the harms already inflicted on . . . the public health

¹²⁸ See *id.*

¹²⁹ See *Hepatitis A*, in *Ctrs. for Disease Control & Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), <https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf>.

¹³⁰ See *id.*

¹³¹ See *id.*

¹³² See Sarah Mbaeyi, et al., *Chapter 14: Meningococcal Disease*, in *Ctrs. for Disease Control and Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (Apr. 25, 2024), <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-14-meningococcal-disease.html>.

¹³³ See *Hepatitis A*, in *Ctrs. for Disease Control & Prevention: Epidemiology and Prevention of Vaccine-Preventable Diseases*, THE PINK BOOK (last updated Apr. 2015), <https://www.vdh.virginia.gov/content/uploads/sites/114/2019/06/Attachment-1-Hepatitis-A-Chapter-Pink-Book.pdf>.

¹³⁴ See *Meningococcal Disease Surveillance and Trends*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 9, 2025), <https://www.cdc.gov/meningococcal/php/surveillance/index.html>.

¹³⁵ See Ex. 25 (Benjamin Decl.) ¶ 22.

system” by “amplifying confusion, deepening the erosion of trust on which coordinated public health depends, and further destabilizing a stressed public health system.”¹³⁶ Although an agenda has not been released for the February meeting, ACIP members have hinted at potential topics, including downgrading polio and measles vaccines from routine in favor of “freedom of choice” and removing Covid mRNA vaccines from the market.¹³⁷ Regardless of topics discussed, however, based on the documented events of this ACIP’s prior meetings, Plaintiffs’ reasonable fears that future meetings of this ACIP will disseminate further public health misinformation rise above the level of speculation and are sufficient to satisfy the standard for irreparable harm.

Even a modest erosion in vaccination rates could result in immediate increases in preventable illness, morbidity, and death.¹³⁸ And crucially, the arbitrary and capricious Non-ACIP Actions and ACIP Actions are negatively affecting trust and immunization rates for *all* vaccines, not just the downgraded vaccines.¹³⁹ Put simply, “[o]nce these systems fail and preventable disease spreads, no later remedy can restore the lives lost as a result.”¹⁴⁰ That kind of threat to human life is a “quintessentially irreparable” harm. *NIH I*, 770 F.Supp.3d at 321 (“The Court is hard pressed

¹³⁶ See *id.* ¶¶ 32–33.

¹³⁷ See Apoorva Mandavilli, *Rejecting Decades of Science, Vaccine Panel Chair Says Polio and Other Shots Should be Optional*, N.Y. TIMES, Jan. 23, 2026, <https://www.nytimes.com/2026/01/23/health/milhoan-vaccines-optional-polio.html>; see also End Tribalism in Politics (@EndTribalism), X (Jan. 21, 2026, 5:09 PM), <https://x.com/EndTribalism/status/2014098027074449438?s=20>. (video of ACIP member Dr. Robert Malone).

¹³⁸ See Katherine Wu, *Rotavirus Could Come Roaring Back—Very Soon*, THE ATLANTIC, Jan. 5 2026, <https://www.theatlantic.com/health/2026/01/childhood-vaccine-schedule-rotavirus-paul-offit/685513/>; see also Ex. 45 (Jaeger Decl.) ¶¶ 26 (“As vaccination rates begin to decline, herd immunity will erode, at which point outbreaks will occur more rapidly.”), 31 (“When vaccines are presented as SCDM rather than routine, parents are more likely to delay or decline. Delays increase the likelihood that future vaccines will also be delayed or missed entirely.”); Ex. 27 (Kressly Decl.) ¶¶ 13 (“The Directive removing the COVID-19 vaccine from the routine vaccination recommendations . . . has eroded some patients’ faith and trust in all vaccines, causing them to refuse a myriad of routine vaccinations and creating an even more imminent and severe risk of serious illness, hospitalization, and death.”).

¹³⁹ See Ex. 45 (Jaeger Decl.) ¶¶ 13, 26, 31; Ex. 27 (Kressly Decl.) ¶¶ 13, 40; Ex. 41 (Chen Decl.) ¶ 24; Ex. 34 (Racine Decl.) ¶ 20.

¹⁴⁰ See Ex. 25 (Benjamin Decl.) ¶ 31-33.

to think of a loss more irreparable than the loss of a life There is no question, there can be no do over and no redress.”).

III. The Balance of Equities and the Public Interest Strongly Favor Entry of a Preliminary Injunction.

When deciding whether to grant a preliminary injunction, courts must “balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.” *Winter v. Nat. Res. Def. Council, Inc.*, 129 S.Ct. 365, 367 (2008) (citation modified). Here, both the balance of equities and the public interest overwhelmingly favor Plaintiffs and compel preliminary injunctive relief.

A. The Balance of Hardships Favor Plaintiffs

The balance of hardships overwhelmingly favor Plaintiffs. Absent preliminary injunctive relief, Plaintiffs will continue to suffer immediate, irreparable, and escalating harms caused by Defendants’ unlawful vaccine policy actions. Those harms include the diversion of limited clinical and public-health resources from patient care and disease prevention; uncompensated time counseling patients and families confused by abrupt and inadequately explained vaccine recommendations; disruption of established vaccination practices and supply chains; and increased risk that children, pregnant individuals, and immunocompromised patients will forgo timely immunization. These harms are not speculative. They are occurring now and will continue to compound absent judicial intervention. Clinicians and public health organizations are already expending extraordinary time and resources to correct confusion, counter unsupported federal messaging, and mitigate declining vaccination confidence. This time and these resources cannot

be recovered and directly detract from the organizations’ core mission work of patient care and outbreak preparedness.¹⁴¹

By contrast, Defendants will suffer no cognizable hardship from entry of a preliminary injunction. Maintaining the status quo ante would not remove vaccines from the market, restrict access to vaccination, or interfere with routine clinical care. Nor would it prevent Defendants from revisiting vaccine policy through lawful, properly constituted, evidence-based processes. At most, Defendants would be temporarily restrained from implementing actions adopted without adherence to required legal and procedural safeguards. There is no equitable interest in the continued operation of unlawful agency action. *See League of Women Voters*, 838 F.3d at 12. Because Plaintiffs face immediate and irreparable harm from the continued operation of the Challenged Actions, while Defendants face no equitable hardship from a temporary pause on its unlawful conduct, the balance of hardships tips sharply in Plaintiffs favor.

B. The Public Interest Strongly Supports Preliminary Injunctive Relief

“Courts have consistently held there is a strong public interest in health and safety.” *NIH I*, 770 F.Supp.3d at 326 (citing *World Gym, Inc. v. Baker*, 474 F.Supp.3d 426, 434 (D. Mass. 2020)). More critically, there is “no public interest in the perpetuation of unlawful agency action,” and a strong public interest “in having governmental agencies abide by the federal laws.” *Newby*, 838 F.3d at 12; *see also Neighborhood Ass’n of the Back Bay, Inc. v. Fed. Transit Admin.*, 407

¹⁴¹ *See e.g.* Ex. 25 (Benjamin Decl.) ¶¶ 26, 30-31 (“APHA has been forced to divert staff and expert contributors to review its flagship publications, including the Control of Communicable Diseases Manual, because those works have utilized the evidence-based ACIP framework that the Defendants have abandoned.”); Ex. 27 (Kressly Decl.) ¶¶ 26-28, 31; Ex. 28 (O’Shea Decl.) ¶¶ 7-9, 15-16, 18-21 (“Based on the 2026 Schedule Change, our practice was forced to change our operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. These changes will impact how we see patients, our availability to patients, and ultimately will harm patient uptake of vaccines.”); Ex. 34 (Racine Decl.) ¶¶ 13-19, 39 (“[A] significant portion of the AAP’s efforts involves interpreting government recommendations and translating them into toolkits, guidance documents, and communications for pediatrics and the public . . . due to the confusion that the Vaccine Changes have caused.”); Ex. 36 (Pavia Decl.) ¶¶ 40, 41; Ex. 42 (Pring Decl.) ¶¶ 23–24, 45-46; Ex. 44 (Pavlos Decl.) ¶¶ 23, 24, 29, 35-36, 40; Ex. 46 (Srinivas Decl.) ¶¶ 17, 18, 25-26

F.Supp.2d 323, 343 (D. Mass. 2005); *Clarke v. Office of Fed. Hous. Enter. Oversight*, 355 F.Supp.2d 56, 66 (D.D.C. 2004) (noting a “substantial public interest” in ensuring that a federal agency “acts within the limits of its authority”).

That public interest is directly implicated here. Plaintiffs have demonstrated that the Defendants failure to follow the customary, evidence-based framework for vaccine recommendations has destabilized America’s public health infrastructure and forced Plaintiff Organizations, clinician-members, and patients into a state of confusion, uncertainty, and perpetual crisis-response mode.¹⁴² By altering the CDC immunization schedule without ACIP evidence-based review, or through an improperly constituted advisory committee, Defendants have replaced evidence-based recommendations with unexplained departures that have sown confusion and distrust among public health organizations, medical associations, providers, and patients alike.¹⁴³ Those disruptions materially increase the risk of outbreaks of vaccine-preventable diseases, including HepB and RSV. Such harms cannot be remedied after the fact.¹⁴⁴ The Defendants here are not preventing public-health harm, they are creating it. Where unlawful government action undermines disease-prevention systems and leaves public health professionals unable to anticipate or contain outbreaks, the public interest weighs decisively in favor of injunctive relief. *See Savino v. Souza*, 459 F.Supp.3d 317, 331–32 (D. Mass. 2020).

The public interest is therefore served by restoring lawful decision-making, preserving reliance on evidence-based immunization frameworks, and preventing further irreparable harm to public health while this case is adjudicated. *See NIH I*, 770 F.Supp.3d at 326. Accordingly, the public interest weighs decisively in favor of preliminary injunctive relief.

¹⁴² See Ex. 25 (Benjamin Decl.) ¶¶ 20–21, 31–32; Ex. 34 (Racine Decl.) ¶¶ 14–15, 40; Ex. 44 (Pavlos Decl.) ¶¶ 16–18, 32–33; Ex. 46 (Srinivas Decl.) ¶¶ 14–28; Ex. 48 (Moser Decl.) ¶ 25.

¹⁴³ See Ex. 27 (Kressly Decl.) ¶¶ 13, 40; Ex. 41 (Chen Decl.) ¶¶ 22–25; Ex. 31 (Berman Decl.) ¶¶ 16–17.

¹⁴⁴ See Ex. 25 (Benjamin Decl.) ¶¶ 22–25; Ex. 28 (O’Shea Decl.) ¶¶ 23–26; Ex. 26 (Lewis Decl.) ¶ 21.

IV. CONCLUSION

This Court should grant the relief requested in the Proposed Order attached hereto as Exhibit A.

Original Dated: January 26, 2026
Corrected Dated: February 9, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 26th day of January 2026 (Corrected version served on the 10th day of February 2026):

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capacity as Secretary of Health and
Human Services

Jim O'Neill, in his official capacity
as Acting Director Centers for
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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,
AMERICAN COLLEGE OF PHYSICIANS,
INC., AMERICAN PUBLIC HEALTH
ASSOCIATION, INFECTIOUS DISEASES
SOCIETY OF AMERICA, MASSACHUSETTS
PUBLIC HEALTH ASSOCIATION D/B/A
MASSACHUSETTS PUBLIC HEALTH
ALLIANCE, SOCIETY FOR MATERNAL-
FETAL MEDICINE, THE MASSACHUSETTS
CHAPTER OF THE AMERICAN ACADEMY
OF PEDIATRICS, JANE DOE 1, JANE DOE 2,
and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; JIM O'NEILL, in his official capacity
as Acting Director of Centers for Disease Control
and Prevention; CENTERS FOR DISEASE
CONTROL AND PREVENTION; and DOES 1–
50, inclusive,

Defendants.

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

**FOURTH AMENDED COMPLAINT
FOR DECLARATORY AND
INJUNCTIVE RELIEF**

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

**LEAVE TO FILE GRANTED ON
FEBRUARY 17, 2026**

INTRODUCTION

1. In this Fourth Amended Complaint, Plaintiffs now challenge four final agency actions, all related to vaccines, that Defendants, Robert F. Kennedy, Jr., Secretary of the United States Department of Health and Human Services (the “Secretary”), and Jim O’Neill, Acting Director of the Centers for Disease Control and Prevention (“O’Neill”), have taken during the Secretary’s ten months in office. When taking these four actions, Defendants failed to “examine the relevant data and articulate a satisfactory explanation for [their] action[s].” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983). Accordingly, the Court should hold unlawful and set aside all final agency actions challenged in this action under the Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (“APA”), declare that each final agency action is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” in contravention of the APA, and grant Plaintiffs’ requested injunctive relief.

2. The most expansive and far-reaching, and thus the most egregious, reckless, and dangerous of the actions Defendants have taken to date, is the one announced in a “Decision Memo” dated January 5, 2026 (the “January 5 Action”) that ordered the alignment of the Centers for Disease Control and Prevention’s (“CDC”) Recommended Immunization Schedule for Child and Adolescent Ages 18 Years or Younger (the “Childhood Schedule”) with that of Denmark’s. This action should be set aside, enjoined, and declared unlawful because Defendants failed to consider important factors such as whether the changes to the Childhood Schedule would lead to increases in serious illness and death due to vaccine-preventable illnesses, or increased burden on the American healthcare system, or increased financial burden on American families.

3. The Court should set aside and declare unlawful the Secretary’s appointments to the Advisory Committee on Immunization Practices (“ACIP”) and enjoin the ACIP as currently

constituted from meeting. Most immediately, Plaintiffs seek to enjoin the next public meeting of the ACIP scheduled for February 25-26, 2026, because of the overabundance of false and misleading misinformation disseminated at the three prior public meetings of the ACIP in June, September, and December, 2025, with December being the worst. The ACIP that conducted those meetings consists entirely of members appointed by the Secretary after he fired *en masse* the 17 prior members of the ACIP on June 9, 2025, for pretextual reasons. The current composition of the ACIP violates the Federal Advisory Committee Act, 5 U.S.C. § 1004(b)(2) (“FACA”), which requires federal advisory committees to be “fairly balanced” and not be “inappropriately influenced.”¹ The public meetings of this ACIP have served as a megaphone for spreading misinformation about immunization and infectious diseases that is directly harming the Plaintiffs and the American public. Further, this ACIP should be enjoined from conducting further public meetings.

4. The current ACIP has cast three votes, approved by the CDC, that should be set aside: (a) the December 5, 2025, vote to remove the recommendation that babies receive the hepatitis B vaccine within 24 hours of birth (the “hepatitis B birth dose”); (b) the September 19, 2025, vote to classify the Covid vaccine as “Shared Clinical Decision Making” (“SCDM”) for anyone under 65; and (c) the June 26 vote that manufacturers discontinue use of thimerosal as a

¹ Just a few days ago, on January 13, 2026, the Secretary announced the appointment of two new members to the ACIP, both of whom are obstetrician-gynecologists (“OB-GYN”), who have made public statements that align with the Secretary’s well-known anti-vaccine views. One of the appointees, an OB-GYN in St. Petersburg, Florida, has publicly stated that: “I was not anti-vaccine. I am now.” The other, an OB-GYN in the Boston area, has publicly stated that the “science is not ‘long-settled’ regarding vaccines” and that there are “too many vaccines.” These most recent additions only add to the imbalance of the current ACIP. See Lena H. Sun, *New RFK Jr. pick for vaccine panel: ‘I was not anti-vaccine. I am now.’*, THE WASH. POST (Jan. 13, 2026), <https://www.washingtonpost.com/health/2026/01/13/rfk-jr-acip-appointments-vaccine-criticism/>; see also Adam Urato, MD (@AdamUrato1), X (June 26, 2025, 3:45 PM), <https://x.com/AdamUrato1/status/1938322690185544005?s=20>.

preservative in influenza vaccines.

5. The other two final agency actions challenged in this Fourth Amended Complaint (previously asserted in the Third Amended Complaint) are (a) the ACIP’s vote at its September 18-19, 2025 public meeting to no longer classify the Covid-19 vaccine for anyone under 65 as routinely recommended, but instead to classify the Covid-19 vaccine as “Shared Clinical Decision Making” (“SCDM”) for those under 65; and (b) the Secretarial Directive dated May 19, 2025, and announced in a video posted on X on May 27 (the “May 19 Directive”), in which the Secretary instructed the CDC to remove the routine recommendation that children and pregnant women receive the Covid-19 vaccine from the CDC’s immunization schedules.² These actions, too, should be set aside and declared unlawful under the APA, and the Court should enjoin Defendants from implementing or effectuating them in any way.

6. Moreover, the final agency actions challenged in this case, taken together, demonstrate that Defendants have engaged in a pattern and practice of changing U.S. vaccine policy without consideration of the relevant factors or providing any reasoned explanation. Accordingly, all of these actions violate the APA and, therefore, must be set aside, declared unlawful, and enjoined.

JURISDICTION AND VENUE

7. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1346. This Court has further remedial authority under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 *et seq.* Pursuant to 5 U.S.C. § 702, sovereign immunity is waived for the United States.

8. Pursuant to 28 U.S.C. § 1391(c) and (e), venue properly lies within the District of Massachusetts.

² Plaintiffs initially filed this action on July 7, 2025, to challenge the May 19 Directive.

PARTIES

A. PLAINTIFFS

9. Plaintiff, the American Academy of Pediatrics (“AAP”), is the nation’s premier professional organization for pediatric medicine and serves as an independent forum for addressing children’s health. The AAP’s membership includes 67,000 pediatricians, with members in every state in the country, many of whom are currently providing direct care to infants, children, adolescents, and young adults in both hospital and outpatient settings.

10. Plaintiff, the American College of Physicians, Inc. (“ACP”), is a professional organization comprised of 161,000 internal medicine specialists in every state in the country, related subspecialists, and medical students who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults worldwide. The ACP’s mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

11. Plaintiff, the American Public Health Association (“APHA”), has promoted the health of all U.S. residents since its founding in 1872. APHA members include more than 23,000 individual public health professional members, state and local health departments, organizations interested in health, and health-related businesses. APHA members work in every discipline of public health, in every state, and in countries across the globe.

12. Plaintiff, the Infectious Diseases Society of America (“IDSA”), is a professional nonprofit society comprised of over 13,000 members in every state in the country, including practicing clinicians, scientists and researchers in the academic setting, public health officials, hospital epidemiologists, and infectious disease specialists working in a variety of settings nationwide. Many IDSA members are currently providing direct care to infants, children, and

pregnant women, in both hospital and outpatient settings. IDSA's mission is to bring together the curiosity, compassion, and knowledge of its members and strengthen the field of infectious diseases, advance science, and advocate for health equity.

13. Plaintiff, the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), is a nonprofit organization dedicated to advocating for health equity and strong public health systems across the Commonwealth of Massachusetts. MPHA's membership is comprised of both individual and organizational public health leaders, including members of local public health departments, physicians, nurses, community health center leaders, academic public health professionals, nonprofit executives, and other frontline practitioners.

14. Plaintiff, the Society for Maternal-Fetal Medicine ("SMFM"), is a professional organization with members in every state dedicated to advancing optimal and equitable perinatal outcomes for all people who desire or experience pregnancy. SMFM represents the interests of over 6,500 members comprised primarily of maternal-fetal medicine subspecialists, as well as physicians in related disciplines, scientists, nurses, genetic counselors, and ultrasound technicians. At its core, SMFM is committed to leading the evidence-based practice of high-risk pregnancy care to optimize maternal and fetal outcomes and assure medically appropriate treatment options are available to all patients.

15. Plaintiff, the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP"), is a member organization of over 1,600 pediatricians in Massachusetts who are committed to the attainment of optimal physical, mental, and social health for all Massachusetts infants, children, adolescents, and their families, and to supporting the medical professionals who care for them. The MCAAP is the leading voice for child health advocacy and high-value equitable care for all youth in the Commonwealth of Massachusetts.

16. Plaintiff, Jane Doe 1, is a physician working in a hospital where she puts herself at risk of infectious diseases every day to care for patients and save lives. Jane Doe 1 is also a new mother, having given birth to her first child Baby Doe 1 in October 2025. Although Jane Doe 1 was vaccinated against Covid-19 before becoming pregnant, early in her pregnancy, her doctors advised her to get another dose of the vaccine later in pregnancy to better protect herself and her developing baby from contracting this deadly disease. Pregnancy increases the risk of severe illness and complications from infectious disease, including preterm birth and stillbirth. However, the Directive created barriers to access to the vaccine, which led her obstetrician to advise her to consider getting an older version of the Covid-19 vaccine earlier in her pregnancy in addition to the 2025–2026 Covid-19 vaccine upon reaching 34 weeks gestation. Accordingly, Jane Doe 1 was forced to decide whether to risk getting an old Covid-19 vaccine early, possibly jeopardizing her access to a 2025–2026 vaccine at the optimal timing in her pregnancy, in order to ensure she could pass at least some immunity to Baby Doe 1 during the pregnancy. This decision weighed on Jane Doe 1, causing her headaches, sleep disturbances, and fatigue which negatively impacted her productivity at work.

17. Plaintiff, Jane Doe 2, is also a new mother, having given birth to her first child Baby Doe 2 in October 2025. Jane Doe 2, who lives in Massachusetts, tried to get the Covid-19 vaccine multiple times after the Secretary’s announcement on X, but was refused. Even though Jane Doe 2 had a prescription from her obstetrician after the Directive was issued, a pharmacist refused to give her the vaccine because the pharmacist feared losing her license by giving a vaccine contrary to the CDC immunization schedules. A nurse at her obstetrician’s office told her that their office’s policy was not to give the vaccine with the change federal guidance regarding pregnant women. Jane Doe 2 subsequently tried at another location to get the Covid-19 vaccine but again was refused

because of the Directive. Finally, a chain pharmacy location advised Jane Doe 2 that she could only receive the vaccine if she scheduled an appointment with the pharmacy's "flexible" pharmacist, who would be willing to risk their license to vaccinate her. Even then, the pharmacy required Jane Doe 2 to sign an attestation stating: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC." When she asked the pharmacist what this meant, he informed her that the CDC's guidelines are unclear, but he "personally chooses to follow the recommendations of OB and pediatric groups." Although Jane Doe 2 was ultimately successful in obtaining a Covid-19 vaccine during her pregnancy, she and Baby Doe 2 were exposed to Covid-19 over the Fourth of July before she could get vaccinated. The difficulty she faced in getting the Covid-19 vaccine while pregnant and her exposure to Covid-19 exacerbated Jane Doe 2's underlying anxiety and depression, causing her physical injuries including sleep disturbances, and tooth grinding that required a dental intervention. Jane Doe 2 still suffers with the physical manifestations of stress as a result of the uncertainty of being able to get the Covid-19 vaccine while pregnant.

18. Plaintiff, Jane Doe 3 and her two teenage boys live in the Seattle, Washington area. Jane Doe 3 has a Masters in Public Health with a focus on Epidemiology and is immunocompromised. Both of her children are neurodivergent and wanted to get the Covid-19 vaccine before they started school at the end of August, so she made an online appointment for both of them at a nearby location of a national pharmacy. She entered both of her sons' birthdates into the online appointment system and was able to make an appointment for both of them on August 14, 2025. Timmy Doe, who has attention deficit hyperactivity disorder ("ADHD"), anxiety, and a severe needle phobia, had a panic attack the night before his vaccine appointment. When she took her sons to the pharmacy for their vaccine appointments, Timmy Doe had another

bout of anxiety. The pharmacist first tried to dissuade her from giving her sons the Covid-19 vaccine because a new Covid-19 vaccine was allegedly coming out in September, to which Jane Doe 3 replied that she did not know that. The pharmacist then asked her why did her sons need the vaccine, and Jane Doe 3 replied that she wanted her children to be protected before school started, and because it takes up to two weeks to obtain the full effect of the Covid-19 vaccine, she wanted them to receive the vaccine now. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and told her that she could not give her sons the Covid-19 vaccine because they were not in the eligible age group. When Jane Doe 3 asked what the eligible age group is, the pharmacist replied either over 60 or 65 is the eligible age group. She was not sure whether it was 60 or over or 65 or over. The pharmacist then ended the conversation by stating that she would not vaccinate her sons because they are not in the eligible age group. Both of her sons were upset that they could not get the Covid-19 vaccine. They were fearful of catching the new Covid-19 strain's "razor-blade throat" themselves and were even more fearful of infecting Jane Doe 3 given her compromised immune system. Jane Doe 3 further demonstrates the harm that the Directive caused. Jane Doe 3 scheduled another appointment for Jimmy Doe and Timmy Doe to be vaccinated on September 12, 2025. Timmy Doe had another panic attack the night before that appointment, which he would not have had but for the first appointment being unsuccessful. The Directive has caused confusion amongst pharmacists; it has prevented those who want to get the Covid-19 vaccine from getting vaccinated, thereby increasing the risk that they and their family members, especially those who are immunocompromised, will get sick with Covid-19; and it has caused fear and anxiety in those who cannot get the vaccine.

B. DEFENDANTS

19. Defendant Robert F. Kennedy, Jr. is the Secretary of the United States Department

of Health and Human Services and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. § 300u. He is sued in his official capacity.

20. Defendant the United States Department of Health and Human Services ("HHS") is an agency of the United States.

21. Defendant Jim O'Neill is Acting Director of the CDC. He is sued in his official capacity.

22. Defendant CDC is an agency that is housed within HHS.

23. The names and capacities of defendants sued herein as Does 1 through 50, inclusive, are presently not known to Plaintiffs, who therefore sue these Defendants by such fictitious names. Plaintiffs will seek to amend this Complaint and include these Doe Defendants' names and capacities when they are ascertained. Each of the fictitiously named Defendants is responsible in some manner for the conduct alleged here and for the injuries suffered by Plaintiffs.

FACTUAL ALLEGATIONS AND LEGAL BACKGROUND

A. THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES AND THE VACCINATION RECOMMENDATION PROCESS IN THE UNITED STATES

24. For more than 25 years before the ACIP came into existence, the main body that made recommendations on vaccine use in the United States was the AAP's Committee on Infectious Diseases ("COID")—called the Committee on Immunization Procedures at the time of its inception.³

25. "By the early 1960s, with the licensure of additional new vaccines (monovalent oral poliovirus vaccine, 1961; trivalent oral poliovirus vaccine, 1963; and measles vaccine, 1963) and

³ L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 405 (Jan. 2015), <https://pubmed.ncbi.nlm.nih.gov/25446820/>.

increased federal investment of resources in vaccines and immunization programs, it was evident that decision making on use of vaccines required a greater degree of continuity of expert technical advice rather than formation of ad hoc committees to address national immunization policy.” Therefore, the Surgeon General established ACIP in March 1964. The committee was “charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control.” That mission has remained essentially unchanged since the ACIP’s inception.⁴

26. In 1972, the ACIP was designated a federal advisory committee under the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et. seq.*, which sets forth legal requirements for operations of federal advisory committees such as the ACIP.

27. HHS oversees the process by which vaccines are approved and recommended. To harmonize this process, it has entrusted the FDA and the CDC to support aspects of vaccine review and recommendation relevant to their respective areas of expertise. Since their inception, vaccines have undergone a rigorous and continued safety and efficacy review in the United States. Initially, the FDA reviews Biologics License Applications (“BLA”) submitted by manufacturers for authorization to market new vaccines for use in the United States. 42 U.S.C. § 262(2). A BLA is a comprehensive submission that is submitted to the FDA. It includes preclinical and clinical data and information, as well as details of the manufacturing process and facilities. Before a vaccine manufacturer even submits a BLA to the FDA, the manufacturer will have conducted trials, including placebo-controlled randomized trials, of the vaccine on human subjects. The data from these trials is submitted with the BLA.

⁴ Jean Clare Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 955, 955 (Oct. 24, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm>.

28. While the BLA is under review at the FDA, which can take several years, an ACIP Work Group also thoroughly reviews all available scientific information about the vaccine, including the data submitted with the BLA, so that the Work Group will be prepared to present information to the ACIP about the vaccine as soon as it is licensed. At this point, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers.⁵ The ACIP is required by the 21st Century Cures Act to take up consideration of a newly-FDA-approved vaccine at the next public ACIP meeting after FDA authorization is announced.⁶

29. The ACIP is responsible for examining the evidence and recommending how the vaccine will be used to control disease in the United States. In 2010, the ACIP adopted a best practice call the “GRADE” framework—Grading of Recommendations, Assessment, Development, and Evaluation—for assessing the quality of evidence and developing evidence-based recommendations.⁷ The GRADE approach provides a framework for assessing the certainty (*i.e.*, quality or confidence) of the evidence and moving from evidence to decision making (*i.e.*, recommendations).⁸

30. In 2018, the ACIP by unanimous vote adopted another best practice, the Evidence to Recommendation (“EtR”) framework. As explained in the ACIP Evidence to Recommendation User’s Guide, the “ACIP has continued to follow and build upon the methodological advances in the GRADE approach and, as a result, has developed a modified Evidence to Recommendation

⁵ *Role of the Advisory Committee on Immunization Practices in CDC’s Vaccine Recommendations*, (Sept. 17, 2024), <https://restoredcdc.org/www.cdc.gov/acip/about/role-in-vaccine-recommendations.html>.

⁶ 21 U.S.C. § 360bbb-4 note (“Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the ‘Advisory Committee’) shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting”).

⁷ CDC, *Introduction in ACIP GRADE HANDBOOK* (2024) <https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.html>.

⁸ *Id.*

(EtR) framework tailored to the needs of ACIP (Appendix 1). The purpose of the EtR framework is to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.”⁹

31. The engines that power the ACIP recommendation process are the Work Groups.

As stated in the Work Groups Standard Operating Procedures manual:

The role of the Advisory Committee on Immunization Practices (ACIP) is to assist the Centers for Disease Control and Prevention (CDC) and the Department of Health and Human Services (HHS) in development of public policy related to immunization of the civilian population in the United States. ACIP utilizes subgroups of the Committee, known as work groups (WGs), to review relevant published and unpublished data and develop recommendation options for presentation to the ACIP. ACIP WGs are intended to augment the effectiveness of ACIP. ...

ACIP WGs are responsible for collection, analysis, and preparation of information for presentation, discussion, deliberation, and vote by the ACIP in an open public forum. WGs review specific topics in detail and elucidate issues in a manner that facilitates informed and efficient decision making by ACIP voting members.¹⁰

32. Each Work Group puts in hours of study and analysis of the evidence using the GRADE approach and EtR framework before a vaccine is presented for a vote at a public meeting of the ACIP. For example, the COVID-19 Vaccines Work Group, created in mid-2020:

would have weekly, robust discussions regarding scientific data about the developing COVID-19 vaccines. I attended and participated in each of the COVID-19 Vaccines Work Group. These discussions included the creation of the vaccines, how the vaccines were manufactured, and how clinical trials were conducted. We also discussed the triage plan, the distribution plan, and how this critical resource should be allocated. The COVID-19 Vaccines Work Group thoroughly reviewed published works

⁹ CDC, ACIP EVIDENCE TO RECOMMENDATION USER’S GUIDE 1, 3 (2020), https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide_october-1-2020.pdf.

¹⁰ ACIP PRACTICES SECRETARIAT & CDC, ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES WORK GROUPS STANDARD OPERATING PROCEDURES 1, 2 (2018), <https://www.cdc.gov/acip/downloads/Work-Group-Guidance-508.pdf>.

from all over the world, including independent research from various institutions and data from other countries.

Each week, the COVID-19 Vaccines Work Group would have an agenda. We would build upon and adapt our discussions as more data were gathered. As it got closer to each ACIP meeting, each work group, including the COVID-19 Work Group, would use the Evidence-to-Recommendation (EtR) framework to craft our recommendations to the ACIP. The EtR looks at benefits and harms, feasibility, acceptability, health equity, and other similar domains. Each expert in the work group would be polled on each of the domains to reach a recommendation.

Once the COVID-19 Vaccines Work Group came to a consensus on a proposed recommendation to the ACIP, we would put together a presentation that detailed the benefits and harms, feasibility, acceptability, comparators, and other domains to analyze each anticipated question from ACIP.

Next, the COVID-19 Vaccines Work Group would come up with a specific set of recommendation language to present to the ACIP committee. This proposed recommendation, along with our analyses from the evidence gathered, would be presented to the full ACIP committee summarizing this discussion and data. ...

At the April 15-16, 2025 ACIP meeting, which I attended in my capacity as a Liaison for ACP, the COVID-19 Vaccines Work Group members presented five different presentations regarding the COVID-19 vaccines and ended with the Work Group's considerations for use of the 2025-2026 COVID-19 vaccines. *See* Ex. A; Ex. B, *Use of 2025-2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025). ...

There was no vote scheduled at the April 15-16, 2025 ACIP meeting regarding COVID-19 vaccine recommendations, meaning that ACIP committee members did not vote on changing the COVID-19 vaccine schedule for pregnant persons or children at that meeting. In[stead], the vote on the 2025-2026 COVID-19 vaccine recommendations was slated for the June 25-26, 2025 ACIP meeting. *See* Ex. C, CDC ACIP Meeting Agenda, April 15-16, 2025; Ex. B at 3.¹¹

33. Once the ACIP votes on a recommended use of the vaccine, the CDC Director has the authority to adopt ACIP recommendations, and, once approved, the CDC publishes all ACIP

¹¹ Decl. of Jason M. Goldman, ECF No. 75-18 at ¶ 16.

recommendations on its website and in the Morbidity and Mortality Weekly Report (“MMWR”), finalizing the agency action.

34. The safety of a vaccine is rigorously tested before receiving FDA authorization. Work Groups of the ACIP thoroughly examine the safety data before the ACIP votes on a vaccine’s recommended use. The safety of a vaccine is continually monitored after listed on a CDC schedule.¹²

35. In a podcast released on January 13, 2026, the Secretary talked about “resetting the vaccine schedule. ... there was not good science behind the vaccine schedule. ... we know very little about the risk profile of those products because vaccines are the only medical ... intervention or pharmaceutical product that’s exempted from pre-licensing safety trials. So none of the vaccines on the schedule with the exception of the COVID vaccine, *none of them had ever been safety tested in a placebo controlled trial pre-licensure.*”¹³ Later in the interview, the Secretary elaborated on this false statement, stating: “we have no idea what the risk profile is of these products.”¹⁴

36. The truth, however, is that “[c]linical trials for vaccines, including Phase I, II, and III, typically span 5 – 10 years with thousands to tens of thousands of participants *before FDA approval.*”¹⁵

37. The FDA website has a tutorial on “How Vaccines are Developed and Approved

¹² See *supra* ¶ 88.

¹³ The Katie Miller Podcast, *RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 5:04–6:03 (Jan. 13, 2026) (emphasis added), https://www.youtube.com/watch?v=w_fzlwXJZAA&t=843s.

¹⁴ *Id.* at 8:57 – 9:01.

¹⁵ Marisa Donnelly, Annicka Evans, David Higgins, Katelyn Jetelina, Elisabeth Marnik, Edward Nirenberg, Emily Smith, Jessica Steir, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

for Use.”¹⁶ The section titled “Testing the vaccine” states:

Testing the vaccine

Next, the vaccine enters a clinical development stage, which is also called a clinical trial. To do this, researchers submit an Investigational New Drug (IND) application to FDA, which includes data from animal studies, information on manufacturing technology, and the quality of the vaccine. Vaccine quality is important because it affects how well it will work to provide long- and short-term protection against disease.

The clinical development stage is a three-phase process, which may include a fourth phase if the vaccine is approved by FDA.

Phase 1

Small groups of people (20 to 100) receive the trial vaccine. During this phase, researchers gather information on how safe the vaccine is in people. This includes learning about and identifying side effects, and studying how well the vaccine works to cause an immune response.

Phase 2

The clinical trial expands to hundreds (100-300) of trial participants who have characteristics (such as age and physical health) similar to the intended recipients for the vaccine. They can also include groups of people from diverse backgrounds to ensure representation across different populations.

This phase provides additional safety information on side effects and risks, and more information on how well the vaccine works to cause an immune response.

Phase 3

The clinical trial expands to thousands (1,000–3,000) of people. In this phase, researchers confirm how well the vaccine works, monitor common and less common side effects, and collect information to support safe use in people.

Phase 4 (after FDA approval)

After FDA approves (also known as “licenses”) a vaccine for use in the general population, it might advance to an additional clinical trial phase

¹⁶ *How Vaccines are Developed and Approved for Use*, CDC (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html#cdc_generic_section_4-testing-the-vaccine.

with thousands of participants. Phase 4 is a formal, ongoing study to evaluate the new vaccine's safety and effectiveness over a longer period of time.¹⁷

B. THE JANUARY 5 ACTION

38. The events in the public record leading up to the January 5 Action demonstrate an orchestrated plan to unilaterally change the U.S. Childhood Schedule without examining the relevant data or providing a reasonable explanation.

39. On Monday, November 17, 2025, the Secretary stated the following at a public meeting at George Washington University: "I know how to change things, and I'm not scared to disrupt things and these agencies need to be disrupted. They need to change their direction."

40. The ACIP met on December 4-5, 2025. On December 4, two outside presenters spoke on the Hepatitis B vaccine. The first, Cynthia Nevison, a climate scientist, presented on the "Burden of Disease." The second, Mark Blaxill, who has an MBA and no medical background, presented on the safety of the Hepatitis B vaccine.

41. The next day, December 5, Aaron Siri, a prominent anti-vaccine lawyer who has been identified as the Secretary's personal attorney and continues to be a key legal adviser to the Secretary, presented on the "Childhood/Adolescent Immunization Schedule," where he compared the U.S. Childhood Schedule to "other Developed Countries."¹⁸

42. A lunch break was taken after Siri presented. Three voting members of the ACIP attended the December 4-5 meeting remotely by Zoom: Chair Kirk Milhoan and voting members Cody Meissner and Joseph Hibbeln. Dr. Jason Goldman, current president of the American College of Physicians, serves as the ACP's liaison representative to the ACIP and attended both

¹⁷ *Id.*

¹⁸ CDC, *Meeting of the Advisory Committee on Immunization Practices (ACIP) Agenda*, <https://www.cdc.gov/acip/downloads/agendas/final-posted-2025-12-04-508.pdf> (last visited Jan. 19, 2026).

days by Zoom. At the beginning of the morning and afternoon sessions, an announcement was made on Zoom that the meeting was being recorded. Goldman has been participating in ACIP meetings as an ACIP Covid-19 Work Group member and ACP liaison representative for over five years. Whenever he participates in an ACIP meeting by Zoom and the announcement is made that the meeting is being recorded, he turns on the Zoom close-captioning and transcription functions and prints out the transcript to make sure he does not miss anything. At the end of the lunch break on December 5, the Zoom link was reactivated for the voting members and liaison representatives who were appearing remotely. Before the in-person meeting resumed, Milhoan and Meissner began conversing with each other over Zoom after the Zoom link had been reactivated. Goldman and others who were appearing by Zoom could hear what they said to each other. At one point in their conversation, Milhoan said: “You know, I feel like, you know, it’s sort of like we feel like a puppet on a string as opposed to really being [an] independent advisory panel.”¹⁹

43. The only presenter in the afternoon of December 5 was Tracy Beth Høeg (“Høeg”), whose medical degree is in sports medicine, who presented a comparison between the U.S. Childhood Schedule and the Danish Vaccine Schedule.

44. A few hours after the conclusion of the meeting on December 5, President Trump posted on X that he had “just signed a Presidential Memorandum directing the Department of Health and Human Services to ‘FAST TRACK’ a comprehensive evaluation of Vaccine Schedules from other Countries around the World, and better align the U.S. Vaccine Schedule, so it is finally rooted in the Gold Standard of Science and COMMON SENSE! I am fully confident Secretary Robert F. Kennedy, Jr., and the CDC, will get this done, quickly and correctly for our Nation’s Children.” The Secretary responded to the President’s post with: “Thank you, Mr. President.

¹⁹ Supp. Decl. of Jason Goldman, ECF No. 162 at ¶ 8.

We're on it."



45. Vice-Chair of the ACIP, Robert Malone, who ran the ACIP meeting in-person on December 4-5, replied that evening to the Secretary's "We're on it" post with the following two-word post: "Mission accomplished."



46. The December 5 Presidential Memoranda instructed the Defendants as follows:

I hereby direct 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 – vaccines recommended for children – and the scientific evidence that informs those best practices, and, if they determine that those best practices are superior to current domestic recommendations, 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.

47. Two days later, on December 7, Malone posted the following:



48. On the morning of December 18, 2025, the HHS press office issued the following Media Advisory:

App. 375

Health Secretary Robert F. Kennedy Jr. came within hours of publicly promoting Denmark’s childhood vaccine schedule as an option for American parents — before legal and political concerns got in the way. A senior HHS official told POLITICO that a press conference set for Friday was canceled at the last minute after the HHS Office of the General Counsel said it would invite a lawsuit the administration could lose.

A second senior official at the Department of Health and Human Services confirmed the press conference, which HHS had publicly announced, was to be about the Danish schedule. The second official said it was canceled because it was deemed politically risky.²²

52. In the morning of January 5, 2026, the Secretary, O’Neill, and others, held an off-the-record press conference in which they informed the reporters that HHS would be releasing an announcement at 2 p.m. ET that afternoon about the U.S. Childhood Schedule. The Secretary himself answered questions during that press conference.

53. At 2 p.m. ET that afternoon, the HHS Press Office issued a press release titled “CDC Acts on Presidential Memorandum to Updated Childhood Immunization Schedule,” that stated:

WASHINGTON, D.C. — JANUARY 5, 2026 — Deputy Secretary of Health and Human Services Jim O’Neill, in his role as Acting Director of the Centers for Disease Control and Prevention (CDC), today signed a [decision memorandum* \[PDF, 894 KB\] </sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf>](#) accepting recommendations from a [comprehensive scientific assessment \[PDF, 1.05 MB\] </sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf>](#) of U.S. childhood immunization practices, following a directive from President Trump to review international best practices from peer, developed countries. On December 5, 2025, via a [Presidential Memorandum <https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/>](#), President Trump directed the Secretary of HHS and the Acting Director of CDC to examine how peer, developed nations structure their childhood vaccination schedules and to

²² Tim Rohn, *RFK Jr. wanted to endorse the Danish vaccine schedule. He was forced to pull back*, POLITICO (Dec. 20, 2025), <https://www.politico.com/news/2025/12/20/rfk-kennedy-danish-vaccine-schedule-denmark-00701999>.

evaluate the scientific evidence underlying those practices. He instructed them to update the U.S. childhood vaccine schedule if superior approaches exist abroad while preserving access to vaccine currently available to Americans.

After consulting with health ministries of peer nations, considering the assessment's findings, and reviewing the decision memo presented by National Institutes of Health Director **Dr. Jay Bhattacharya**, Food and Drug Commissioner **Dr. Marty Makary**, and CMS Administrator **Dr. Mehmet Oz**, Acting Director O'Neill formally accepted the recommendations and directed the CDC to move forward with implementation.

'President Trump directed us to examine how other developed nations protect their children and to take action if they are doing better,' **Secretary Robert F. Kennedy Jr. said**. "After an exhaustive review of the evidence, we are aligning the U.S. childhood vaccine schedule with international consensus while strengthening transparency and informed consent. This decision protects children, respects families, and rebuilds trust in public health.' ...

The scientific assessment compared U.S. childhood immunization recommendations with those of peer nations, analyzed vaccine uptake and public trust, evaluated clinical and epidemiological evidence and knowledge gaps, examined vaccine mandates, and identified next steps. The assessment reviewed 20 peer, developed nations and found that the U.S. is a global outlier among developed nations in both the number of diseases addressed in its routine childhood vaccination schedule and the total number of recommended doses but does not have higher vaccination rates than such countries. In fact, many peer nations that recommend fewer routine vaccines achieve strong child health outcomes and maintain high vaccination rates through public trust and education rather than mandates. For example, in 2024, the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations. At the lower end is Denmark, which immunizes children against 10 diseases compared to a total number of 18 diseases for which protection was provided in 2024 in the U.S.

54. The Decision Memo linked in the press release begins as follows:

Public Health Service

Decision Memo

PURPOSE

RECOMMENDATION AND ACTION REQUESTED

App. 378

and Meningococcal disease are classified as SCDM.

C. DEFENDANTS' EXPLANATIONS FOR THE JANUARY 5 ACTION

58. The Decision Memo states that O'Neill relied on three things in deciding to approve the recommendation to revise the Childhood Schedule: (a) discussions with health officials from Japan, Germany, and Denmark; (b) discussions "with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy;" and (c) "the data and recommendations contained in TAB 1, 'Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries,'" a document authored by Høeg and Kulldorff, which argues that the U.S. is an outlier with respect to how many immunizations children receive.

Explanation # 1: Discussions with Health Officials from Denmark, Germany, and Japan

59. The Decision Memo fails to state what officials from Japan, Germany, and Denmark discussed with O'Neill. The Decision Memo fails to state whether officials from these countries agreed, disagreed, or had no opinion with aligning the U.S. Childhood Schedule with peer countries' childhood schedules.

60. The December 5 Presidential Memoranda directs the Defendants to "review best practices from peer, developed countries for core childhood vaccination recommendations – vaccines recommended for children – and the scientific evidence that informs those best practices." Neither the Decision Memo nor the Assessment discuss what other country's best practices are or the scientific evidence that informs those best practices.

61. A National Immunization Technical Advisory Group ("NITAG") is a multidisciplinary body of experts that provides evidence-based immunization recommendations to policymakers in their respective countries. NITAGs systematically evaluate evidence together with

the local epidemiological and social context to inform decision-making on vaccine use at the national level.²³ The ACIP is a NITAG. While the Secretary asserted in the January 5 press release that Defendants had done an “exhaustive review” of the best practices of peer countries, neither the Decision Memo nor Assessment mention that they consulted with the NITAG of Denmark, Germany, Japan, or any other so-called “peer” country.

62. After news of Defendants aligning the U.S. Childhood Schedule with that of Denmark’s broke, a Danish health official, Dr. Anders Hviid, who leads research on vaccine safety at Denmark’s equivalent of the CDC, commented: “‘It’s not at all fair to say look at Denmark unless you can match the other characteristics of Denmark.’”²⁴ He stated further that, in the United States, “‘it turns out to get crazier and crazier in public health from month to month. It is surreal, and it is difficult, from a Danish perspective, to understand what’s going on,’”²⁵ and “[y]ou cannot adopt the public health policies of another country unless the population, health care system and prevalence of infectious diseases match.”²⁶

63. Denmark’s health care system purchases vaccines for its citizens and omits shots from some diseases from the childhood schedule because they do not pose enough of a problem there to make the vaccines cost-effective, not because of concerns about safety.²⁷

64. Dr. Reinhard Berner, a pediatric infectious diseases expert in Germany and chair of STIKO, the independent committee that recommends vaccines for Germans, said the decisions in his country on not including certain vaccines on Germany’s schedules were not based on safety

²³ *National Immunization Technical Advisory Groups (NITAGs)*, WHO (2026)

[https://www.who.int/europe/groups/national-immunization-technical-advisory-groups-\(nitags\)](https://www.who.int/europe/groups/national-immunization-technical-advisory-groups-(nitags)).

²⁴ Apoorva Mandavilli, *RFK Jr. Likely to Swap U.S. Childhood Vaccine Schedule for Denmark’s*, THE N.Y. TIMES (Dec. 19, 2025), <https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html?searchResultPosition=1>.

²⁵ *Id.*

²⁶ Helen Branswell, *When it comes to vaccines schedules, the U.S. is now the outlier*, STAT (Jan. 9, 2026), <https://www.statnews.com/2026/01/09/childhood-vaccination-fact-check-denmark-not-america-is-the-outlier/>.

²⁷ *Id.*

concerns about the vaccines, but on the prevalence of diseases there.²⁸ German’s NITAG does “not have any concerns about the content of aluminum, and we do not have any concerns about the application of different vaccines at the same time.”²⁹

**Explanation # 2:
Discussions with CDC and FDA Officials**

65. The Decision Memo fails to state what CDC and Food and Drug Administration officials discussed with O’Neill and whether they agreed or disagreed with aligning the US Childhood Schedule with the Danish schedule.

66. In fact, vaccine experts at the CDC were blindsided by the release of the Decision Memo.³⁰ The decision to change the U.S. Childhood Schedule “contradicted guidance from career scientists who prepared a presentation outlining how the U.S. vaccine policy is not an international outlier, according to a copy of the presentation obtained by The Washington Post. Five career scientists and researchers, who spoke on the condition of anonymity for fear of retaliation, said that they are angered by the bypassing of expertise in Monday’s decision. That process to alter vaccine recommendations, they and several former health officials said, did not include extensive consultation with the agency’s subject matter experts or the CDC’s vaccine advisory panel that is usually done.”³¹

**Explanation # 3:
The Assessment**

67. While the Assessment purports to be a “scientific, evidence-based, data-driven” assessment, neither the Assessment nor the Decision Memo indicate that Defendants considered

²⁸ Apoorva Mandavilli, *RFK Jr. Likely to Swap U.S. Childhood Vaccine Schedule for Denmark’s*, THE N.Y. TIMES (Dec. 19, 2025), <https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html?searchResultPosition=1>.

²⁹ *Id.*

³⁰ Lena H. Sun, *CDC staff ‘blindsided’ as child vaccine schedule unilaterally overhauled*, THE WASH. POST (Jan. 7, 2026), <https://www.washingtonpost.com/health/2026/01/07/cdc-vaccine-recommendations-schedule-revisions/>.

³¹ *Id.*

evidence on the following factors:³²

- (a) the impact that the schedule changes would have on illnesses, hospitalizations, deaths, and disabilities;
- (b) input from the public;
- (c) input from independent experts;
- (d) the financial impact on families, such as paying a co-pay each time that an appointment with a doctor is made to engage in SCDM about a vaccination; missing work and school because the patient now must consult with a doctor each time s/he is considering a vaccination;
- (e) the ability that the 27 million uninsured in this country have to engage in SCDM if they have no doctor;
- (f) the impact on clinicians, such as higher stress levels, more fatigue and burnout, more doctors leaving the practice of medicine, all while reducing patient access with less available time to manage other clinically significant issues of their patient population;
- (g) the burden on hospitals, *e.g.*, more uninsured patients showing up in the emergency room because they could not engage in SCDM with a doctor to get vaccinated and became seriously ill with a vaccine-preventable disease; more patients being hospitalized from vaccine-preventable diseases and the concomitant burden on staff and capacity;
- (h) the differences between Denmark (or any other so-called “peer” country) and the U.S., including Denmark’s universal healthcare system, better disease screening, paid

³² See Marisa Donnelly, PhD; David Higgins, MD, MPH; Katelyn Jetelina, MPH, PhD; Christina M. Madison, PharmD, FCCP, AAHIVP; Elisabeth Marnik, PhD; Edward Nirenberg; Jessica Steier, DrPH, *In Response: Routine Childhood Vaccination Schedule Change*, p.1, THE EVIDENCE COLLECTIVE (Jan. 5, 2026), <https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/6967fdef24a3a6a4d791fb2/1768422895176/Childhood+vaccine+change.pdf>.

parental leave, national coverage monitoring, near-universal prenatal screening, centralized medical records from birth to death, and a more homogeneous population.

68. The Assessment concludes that the “U.S. is a global outlier among peer nations in the number of target diseases included in its childhood vaccination schedule and in the total number of recommended vaccine doses” and recommends that the U.S. Childhood Schedule be brought “in line with the consensus of peer nations.” However, Denmark is the actual outlier, with the fewest number of vaccines, as compared to Canada, Australia, Ireland, New Zealand, France, Italy, and Spain, who all have routine childhood vaccination schedules similar to the U.S.’s.³³

69. The comparison of the U.S. schedule to so-called peer nations is a false, unreasonable, irrational comparison.³⁴

70. The Assessment discusses no new evidence or data on the safety or efficacy of any of the vaccines on the Childhood Schedule.

D. CURRENT ACIP MEMBERS

Qualifications for ACIP Membership

71. While 42 U.S.C. § 217a gives the Secretary the authority to “appoint such advisory councils or committees (in addition to those authorized to be established under other provisions of law), for such periods of time, as he deems desirable ... for the purpose of advising him in connection with any of his functions,” he does not have unbridled discretion in doing so. First, by law, the Secretary is forbidden from considering political affiliation in making appointments to advisory committees. 42 U.S.C. § 217a–1. (“Advisory committees; prohibition of consideration of

³³ *Id.*

³⁴ See, e.g., Martin Kulldorff, *Study Designs for the Safety Evaluation of Different Childhood Immunization Schedules*, in INST. OF MED. & THE NAT’L ACAD. OF MED. THE CHILDHOOD IMMUNIZATION SCHEDULE AND SAFETY: STAKEHOLDER CONCERNS, SCIENTIFIC EVIDENCE, AND FUTURE STUDIES, app. at 161 (2013)(comparing different countries’ vaccine schedules “is very difficult to do well and generally not recommended”) https://www.ncbi.nlm.nih.gov/books/NBK206948/pdf/Bookshelf_NBK206948.pdf.

political affiliations. All appointments to advisory committees established to assist in implementing the Public Health Service Act [42 U.S.C. 201 et seq.] ... *shall be made without regard to political affiliation.*”).³⁵ Second, the ACIP Charter provides that “[m]embers shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.”³⁶ Third, by virtue of Congress incorporating ACIP recommendations within at least 13 federal statutes, and the adoption of nearly 600 statutes and regulations across 49 states, three territories, and Washington D.C., policy makers at all levels of government and healthcare providers, among others, have developed a very strong, deep reliance interest in the selection of ACIP members being done in good faith, without regard to political affiliation, based on qualifications and experience set forth in the ACIP Charter and regulation.³⁷

The Secretary Fires The ACIP on June 9, 2025

72. During his confirmation process, the Secretary promised Congress that he would “maintain the Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices without changes.”³⁸

³⁵ This statute was passed because “[a]t a time when public confidence in Government is at an all time low, and the need for high performance by the Government is at an all time high, the area of science and health should not be brought into pork barrel politics.” 121 CONG. REC. 39987 (1975).

³⁶ *ACIP Charter*, CDC, at 4 (Apr. 1, 2024), <https://www.cdc.gov/acip/about/acip-charter.html>.

³⁷ *Id.* (requiring that members “be knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.”); *see also* 41 CFR § 102-3.60(b)(3)(i) (“Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.”).

³⁸ KFF Health News, *Sen. Cassidy Says RFK Jr. Promised Key Vaccine Safety Commitments*, at 2:02. YOUTUBE (Feb. 4, 2025), <https://www.youtube.com/watch?v=QrJcBtkfwvQ>.

73. It did not take long for the Secretary to break his promise. On June 9, 2025, at exactly 4 p.m. Eastern Time, an Opinion Commentary written by the Secretary appeared in the online version of the *Wall Street Journal*. In the column, the Secretary announced he was “totally reconstituting the Advisory Committee for Immunization Practices (ACIP)” and “retiring the 17 current members of the committee.”³⁹

74. The 17 members of the ACIP first learned of their terminations from a *Wall Street Journal* column. A few hours after the column appeared online, each of the 17 members received an email that stated:

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

75. The Secretary’s June 9, 2025 column made a host of false accusations against the 17 ACIP members, including that they had “been plagued with persistent conflicts of interest,” had “become little more than a rubber stamp for any vaccine,” were corrupt,” and were “directly work[ing] for the vaccine industry.” These justifications were pretextual, as the following demonstrates:

(a) The Secretary justified the terminations by referencing reports from 1997, 2000, and 2009 on ACIP conflicts of interest, years in which none of the 17 terminated members were on the ACIP.

(b) Research from the USC Schaeffer Center for Health Policy & Economics finds that “reported conflicts on that Centers for Disease Control and Prevention panel had been *at historic*

³⁹ Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL STREET JOURNAL (June 9, 2025, 4:00 PM), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

lows for years before Kennedy’s abrupt dismissal. Furthermore, *the type of conflict typically considered the most concerning—income from vaccine makers—had been virtually eliminated among members of the CDC panel, known as the Advisory Committee on Immunization Practices (ACIP).*”⁴⁰ “Since 2016, an average of 6.2% of ACIP members and 1.9% of VRBAC members have reported a financial conflict of interest at any given meeting. During that time, *less than 1% of reported conflicts on both committees were related to personal income from vaccine makers, which includes consulting fees, stock, royalties or ownership.*”⁴¹

(c) The Secretary has failed to fulfill his promise to release both the Confidential Financial Disclosure Report (for Special Government Employees) and the OGE Form 450s⁴² for those he has appointed to the ACIP. Shortly before the Secretary’s new ACIP met in June of this year, an HHS spokesperson stated: “[b]efore starting work on ACIP, the new members’ ethics agreements *will be made public*. Every ACIP member will be vetted in accordance with their ethics agreement before they are permitted to participate in each meeting agenda item,” and further, that “both the ethics agreement and the OGE 450s will be disclosed.”⁴³ Nothing has been disclosed, even though new ACIP member Robert W. Malone, MD, posted on X on June 12, 2025, that “[sic] have already completed three months of ethics vetting and COI training by the appropriate

⁴⁰ *Conflicts of Interest on CDC Vaccine Panel Were at Historic Lows Before RFK Jr. Dismissal*, UNIV. OF SOUTHERN CAL. SCHAEFFER CTR. (Aug. 18, 2025), <https://schaeffer.usc.edu/research/cdc-acip-vaccine-conflicts-rfk-jr/>.

⁴¹ *Id.* (emphasis added).

⁴² See 5 CFR. § 2634.901 Policies of confidential financial disclosure reporting (“High-level officials in the executive branch are required to report certain financial interests publicly to ensure that every citizen can have confidence in the integrity of the Federal Government. It is equally important in order to guarantee the efficient and honest operation of the Government that other, less senior, executive branch employees, whose Government duties involve the exercise of significant discretion in certain sensitive areas, report their financial interests and outside business activities to their employing agencies, to facilitate the review of possible conflicts of interest.”).

⁴³ Isabella Cueto, *HHS backtracks on pledge to disclose new vaccine advisers’ conflict of interest*, STAT (July 9, 2025), <https://www.statnews.com/2025/07/09/kennedy-conflict-of-interest-radical-transparency-acip-vaccine-experts/#:~:text=WASHINGTON%20%E2%80%94%20The%20Department%20of%20Health,make%20key%20disclosure%20documents%20public.>

HHS officials.”

(d) The Secretary has not followed the Advisory Committee on Immunization Practices Policies and Procedures manual that provides: “[u]pon appointment, each voting member is required to file an Office of Government Ethics 450 form ... and a Confidential Financial Disclosure Report.”⁴⁴

(e) The Secretary, contrary to law, and upon information and belief, required candidates for membership on the ACIP to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary.

The Secretary’s Appointments To The ACIP

76. On June 11, 2025, two days after he fired the previous ACIP members, the Secretary announced the appointment of eight new members to the ACIP. When announcing his picks, the Secretary asserted that his selections were “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.”⁴⁵ On or about September 11, 2025, the Secretary announced four more appointments to the ACIP. On January 13, 2026, the Secretary announced two more appointments to the ACIP.

77. With one exception, the Secretary’s appointments to the ACIP do not possess the requisite expertise, background, and credentials to sit on the federal advisory committee that votes on how vaccines are listed on the CDC’s immunization schedules:

(a) **Kimberly Biss**, MD, an OB-GYN in St. Petersburg, Florida, is a Fellow of the Independent Medical Alliance, a physician group aligned with the Secretary, who has publicly

⁴⁴ *Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 14-15 (June 2022), <https://www.cdc.gov/acip/downloads/policies-procedures-508.pdf>.

⁴⁵ Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), <https://x.com/SecKennedy/status/1932899858920120692>.

stated: “I was not anti-vaccine. I am now,” and “My grandchildren will not get any shots if I can help it. The vaccine industry is disgusting.”

(b) **Adam Urato**, MD, an OB-GYN in Boston, who has stated: “The science is not ‘long-settled’ regarding vaccines,” and “My patients often ask: ‘How do we know that all these vaccines won’t have adverse effects on my baby and me?’ The answer is ‘we don’t.’”

(c) **Hillary Blackburn**, who holds a PharmD from the University of Mississippi and was the Director of Medication Access and Affordability at AscensionRx when appointed to the ACIP. Upon information and belief, she has not published any articles or participated in any studies or performed any research on vaccines, immunizations, or infectious diseases. At the September 2025 ACIP meeting she speculated that the Covid-19 vaccine could be connected to her mother’s lung cancer diagnosis.⁴⁶

(d) **Evelyn Griffin**, whom the CDC’s website lists as being an Obstetrician and Gynecologist at Baton Rouge General Hospital and states that she is “board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine.”⁴⁷ With 15 years of clinical practice, she was among the first robotic-assisted gynecologic surgeons in the U.S. and has led efforts to reduce maternal morbidity and mortality.”⁴⁸ The Baton Rouge General Hospital lists an **Ewelina Griffin**, MD, Obstetrics & Gynecology, Gynecology, Hospitalist, but provides no information on where she went to medical school or college. Upon information and belief, Evelyn or Ewelina Griffin, assuming that they are the same person, has not engaged in any vaccine-related research, vaccine administration, or worked in a relevant public health policy position. Dr. Griffin spoke at

⁴⁶ CDC, *Meeting of the Advisory Committee on Immunization Practices (ACIP) September 18-19, 2025 Meeting Summary*, at 78 <https://www.cdc.gov/acip/downloads/minutes/summary-2025-9-18-19-508.pdf> (last visited Jan. 19, 2026).

⁴⁷ *ACIP Membership Roster*, CDC (Jan. 14, 2026), https://www.cdc.gov/acip/membership/roster.html#cdc_generic_section_5-evelyn-griffin-m-d.

⁴⁸ *Id.*

a 2024 Louisiana “Health Freedom Day” event promoting efforts to repeal vaccine mandates, where she was introduced as being harassed for her coronavirus opinions and having lost her job with a health care system for refusing to get a coronavirus vaccine. In her speech, she said physicians “blindly believed” in the coronavirus vaccines because they were taught in medical school that vaccines were harmless. ‘When you are faced with this vaccination schedule, you are just taught, “Just memorize it at this point. Trust us, it’s safe,”’ she said, also adding that ‘Big Pharma’ influences medical school curriculums.’⁴⁹

(e) **Joseph Hibbeln, MD.** The CDC’s website describes Hibbeln as a Psychiatrist, Neuroscientist, and former Chief of Section on Nutritional Neurosciences, National Institutes of Health where he led “research on immune regulation, neurodevelopment, and mental health. His work has informed U.S. public health guidelines, particularly in maternal and child health.” Upon information and belief, Dr. Hibbeln has not studied, researched, or published on vaccines, immunizations, infectious disease, or epidemiology. He has, however, been vocal at ACIP meetings about how the ACIP meetings that he has attended have been conducted.

(f) **Martin Kulldorff, PhD,** was appointed chair of the ACIP shortly after the Secretary fired the previous ACIP. Kulldorff “previously served as a professor of medicine at Harvard University” according to the CDC’s website but lost his position at Harvard (and at Brigham and Women’s Hospital) when he refused to get vaccinated with the Covid-19 vaccine. He also is a co-author of “The Great Barrington Declaration” (dated October 4, 2020, after Operation Warp Speed began but before Covid-19 vaccines were authorized for use in the United States) that promoted “natural immunity” over public health measures and opposed vaccination in children against Covid-19, masking, lockdowns, and vaccine mandates. On December 1, 2025,

⁴⁹ Lena H. Sun & Lauren Weber, *RFK Jr. weighs adding critics of coronavirus shots to key vaccine panel*, THE WASH. POST (Sept. 8, 2025), <https://www.washingtonpost.com/health/2025/09/08/rfk-jr-new-vaccine-advisers/>.

only a few days before the ACIP public meeting on December 4, 2025, HHS announced Kulldorff's appointment as chief science officer for the Office of the Assistant Secretary for Planning and Evaluation.⁵⁰

(g) **Retsef Levi**, has a PhD in Operations Research from Cornell University and, according to his bio on the Massachusetts Institute of Technology website, has an impressive background in *operations management*. Noticeably absent from his MIT bio, however, is any mention of *vaccines*.⁵¹ The CDC's website, however, states that Dr. Levi is "a leading expert in healthcare analytics, supply chain and manufacturing analytics, risk management, and biologics and *vaccine safety*" and that he has "co-authored studies examining the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes."⁵² Upon information and belief, Dr. Levi has co-authored only two articles on the association between mRNA COVID-19 vaccines and adverse health outcomes, neither were peer reviewed, and both were published in 2025.⁵³ Before he co-authored these articles, Levi is on record stating that: "The evidence is mounting and indisputable that mRNA vaccines cause serious harm including death, especially among young people. We have to stop giving them

⁵⁰ *Renowned Epidemiologist and Biostatistician Martin Kulldorff Appointed to Senior HHS Role*, HHS (Dec. 1, 2025), <https://www.hhs.gov/press-room/renowned-epidemiologist-and-biostatistician-martin-kulldorff-appointed-to-senior-hhs-role.html>.

⁵¹ Levi's bio notes that he is "the J. Spencer Standish (1945) Professor of Operations Management at the MIT Sloan School of Management. He is a member of the Operations Management Group at MIT Sloan and affiliated with the MIT Operations Research Center. Levi also serves as the faculty leader for Food Chain Supply Analytics. ... *Levi's current research is focused on the design of analytical data-driven decision support models and tools addressing complex business and system design decisions under uncertainty in areas such as health and healthcare management, supply chain, procurement and inventory management, revenue management, pricing optimization and logistics*. He is interested in the theory underlying these models and algorithms, as well as their computational and organizational applicability in practical settings." *Retsef Levi*, MASS. INST. OF TECH., <https://mitsloan.mit.edu/faculty/directory/retsef-levi> (last visited Nov. 2, 2025).

⁵² *ACIP Membership Roster*, CDC (Sept. 16, 2025), https://www.cdc.gov/acip/membership/roster.html#cdc_generic_section_5-evelyn-griffin-m-d (emphasis added).

⁵³ Retsef Levi, et al., *Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida*, MEDRxIV (Apr. 29, 2025), <https://www.medrxiv.org/content/10.1101/2025.04.25.25326460v1>; Josh Guetzkow, et al., *Observed-to-Expected Fetal Losses Following mRNA COVID-19 Vaccination in Early Pregnancy*, MEDRxIV (June 20, 2025), <https://www.medrxiv.org/content/10.1101/2025.06.18.25329352v1.full-text>.

immediately!”⁵⁴ Both of Levi’s studies were published online by medRxiv, which warns that: “This article is a preprint and has not been peer reviewed. It reports new medical research that has yet to be evaluated and so should *not* be used to guide clinical practice.” The publisher further warns that “authors use the medRxiv service to make their manuscripts available as ‘preprints’ before certification by peer review, allowing other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on medRxiv have not been finalized by authors, *might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community.* We also urge journalists and other individuals who report on medical research to the general public to consider this when discussing work that appears on medRxiv preprints and *emphasize it has yet to be evaluated by the medical community and the information presented may be erroneous.*”⁵⁵ A co-author of one of these articles was Dr. Joseph Lapado, the current Surgeon General of the State of Florida, who has vowed to eliminate all vaccine mandates in the State of Florida and has compared vaccine mandates to slavery.⁵⁶ On the other article, a co-author was Tracy Beth Høeg, a surprise hire as a “special assistant” at the FDA in April 2025, who is a former sports medicine doctor who has promoted incorrect information and misinterpreted data about vaccines.^{57,58}

(h) **Robert W. Malone** has an MS in Biology from UC San Diego, an MD from Northwestern University, did one year of post-doctoral work at Harvard University, and was involved in early research on mRNA technology in the 1980s and 1990s. Malone claimed to be

⁵⁴ Retsef Levi (@RetsefL), X (Jan. 30, 2025, 1:28 AM), <https://x.com/RetsefL/status/1619945525670981632>.

⁵⁵ *Frequently Asked Questions (FAQ)*, MEDRXIV, <https://www.medrxiv.org/about/FAQ#unrefereed> (last visited Nov. 4, 2025) (emphasis added).

⁵⁶ Kayla Epstein, *The Florida surgeon general who likens vaccine mandates to slavery*, BBC NEWS (Sept. 4, 2025), <https://www.bbc.com/news/articles/c62q41qm9pvo>.

⁵⁷ Sarah Karlin-Smith, *‘Highly Problematic’: Acting FDA Commissioner Paused Planned OK Of Novavax Shot*, CITELINE (Apr. 4, 2025), <https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/highly-problematic-acting-fda-commissioner-paused-planned-ok-of-novavax-shot-GUT6LR4X6ZALRMMZAEXYZHY36Y/>.

⁵⁸ *Id.*

the inventor of mRNA vaccines, but “[w]hile he was involved in some early research into the technology, his role in its creation was minimal at best”, according to half a dozen Covid experts and researchers, including three who worked closely with Dr. Malone.⁵⁹ Malone spread so much misinformation and disinformation about the COVID-19 vaccine that he was permanently suspended from Twitter for repeated violations of Twitter’s COVID-19 misinformation policy.⁶⁰ Malone claimed on The Joe Rogan Experience podcast in late 2021 that “mass formation psychosis” was developing in American society in its reaction to COVID-19 just as during the rise of Nazi Germany⁶¹ and has spoken at anti-vaccine rallies.⁶²

(i) **Cody Meissner** is “a Professor of Pediatrics at the Geisel School of Medicine at Dartmouth and a nationally recognized expert in pediatric infectious disease epidemiology, vaccine development, and immunization safety. He previously served as Chief of the Division of Pediatric Infectious Disease at Tufts-New England Medical Center and on the CDC's Advisory Committee on Immunization Practices and the FDA's Vaccine and Related Biologic Products Advisory Committee.”⁶³

(j) **Kirk Milhoan** has an MD from Jefferson Medical College and a Ph.D. in the mechanisms of myocardial inflammation from University of California, San Diego. He is a Senior Fellow at the Independent Medical Alliance, which advocates for mRNA-based Covid-19

⁵⁹ Davey Alba, *The Latest Covid Misinformation Star Says He Invited the Vaccines*, NEW YORK TIMES (Apr. 3, 2022), <https://www.nytimes.com/2022/04/03/technology/robert-malone-covid.html>.

⁶⁰ Sophie Mellor, *Science Vs podcast takes on the Joe Rogan Experience and others, vowing to fact-check what Spotify won't*, FORTUNE (Feb. 1, 2022), <https://fortune.com/2022/02/01/science-vs-podcast-drops-show-focus-fact-checking-joe-rogan-experience-spotify-slap-in-the-face/>.

⁶¹ Timothy Bella, *A vaccine scientist's discredited claims have bolstered a movement of misinformation*, THE WASH. POST (Jan. 24, 2022), <https://www.washingtonpost.com/health/2022/01/24/robert-malone-vaccine-misinformation-rogan-mandates/>.

⁶² *Id.*

⁶³ *ACIP Membership Roster*, CDC (Sept. 16, 2025), <https://www.cdc.gov/acip/membership/roster.html>.

vaccines to be withdrawn from the market.⁶⁴ The Secretary appointed Milhoan Chair of the ACIP upon Kulldorff's transfer to another office inside HHS.⁶⁵

(k) **James Pagano**, according to the CDC's website, "is a board-certified emergency medicine physician with more than 40 years of clinical experience. He has worked in diverse emergency settings, from Level 1 trauma centers to small community hospitals, caring for patients across all age groups including infants, pregnant women, and the elderly. Dr. Pagano has served on multiple hospital committees, including utilization review, critical care, and medical executive boards."⁶⁶ He has no discernable expertise in vaccines or immunology.

(l) **Vicky Pebsworth**, who has a Ph.D in Health Services Organization and Policy from University of Michigan, is currently the Director of Research & Patient Safety at the National Vaccine Information Center, a known anti-vaccine organization and has "'probably been anti-vax longer than RFK has."⁶⁷

(m) **Catherine Stein**, who has a Ph.D. in Epidemiology and Biostatistics from Case Western Reserve University, is a "COVID-19 truther" who claimed that Covid-19 was "not the scary killer the media and government portray it to be," and claimed that Ohio's Department of Health was misconstruing the data.⁶⁸ Stein has ties to Health Freedom Ohio, which is linked to Children's Health Defense, the anti-vaccine organization founded by the Secretary.⁶⁹ Dr. Stein has testified in support of different versions of legislation written to allow lawmakers to vote down

⁶⁴ Stephanie Armour, *mRNA Vaccines, Once a Trump Boast, Now Face Attacks from Some in GOP*, KFF HEALTH NEWS (Mar. 10, 2025), <https://kffhealthnews.org/news/article/mrna-vaccines-trump-boast-under-gop-attacks-legislation/>

⁶⁵ See *supra* text accompanying note 50.

⁶⁶ *ACIP Membership Roster*, CDC (Sept. 16, 2025), <https://www.cdc.gov/acip/membership/roster.html>.

⁶⁷ *Nurse on new CDC Vaccine Panel said to have been 'anti-vax longer than RFK,'* THE GUARDIAN (July 5, 2025) <https://www.theguardian.com/us-news/2025/jul/05/vicky-pebsworth-vaccine-experts-rfk-jr>

⁶⁸ Jake Zuckerman, *She's a public health professor by day; a COVID-19 truther by night*, THE OHIO CAPITAL JOURNAL (Feb. 22, 2021), <https://ohiocapitaljournal.com/2021/02/22/shes-a-public-health-professor-by-day-a-covid-19-truther-by-night/>.

⁶⁹ Sara Moniuszko, *New CDC advisory panel members include more COVID vaccine critics*, CBS NEWS (Sept. 16, 2025), <https://www.cbsnews.com/news/new-cdc-acip-members-covid-vaccine-critics/>.

public health orders. She has spoken in support of the bills alongside affiliates of Health Freedom Ohio and the Ohio Advocates for Medical Freedom, another anti-vaccine group. Dr. Stein also testified in support of a “Truth in Covid Statistics” bill, which essentially would force the Ohio Department of Health to publish certain data points about Covid-19 — most of which the department already publishes. She also has spread misinformation equating Covid-19 disease severity with influenza.

(n) **Raymond Pollack** is the Chief of Liver Transplantation and Director of Multiorgan Transplant Programs at the University of Illinois and has held leadership roles with the United Network for Organ Sharing and the American Society of Transplant Surgeons. He lacks expertise regarding vaccines and infectious disease.

78. With the recent appointments of two more anti-vaxxers, ten out of the 14 current ACIP members have publicly stated views on vaccines that align with the Secretary’s. Seven lack the relevant expertise and credentials required by the ACIP Charter. Only one (Cody Meissner) has legitimate credentials and expertise comparable to those whom the Secretary fired from the ACIP.

79. None of the new ACIP members were required to follow the rigorous application process to become an ACIP member.⁷⁰ Historically, the application process to become a voting ACIP member has taken up to two years.

80. The Secretary’s appointments of non-experts to the ACIP reflect his well-documented distrust of experts. In an interview with Tucker Carlson on June 30, 2025, he stated:

You know, my opinion, I always tell people is irrelevant. Um, we, you know, people, *we need to stop trusting the experts, right?* We were told at the beginning of Covid don’t look at any data yourself. Don’t do any

⁷⁰ *Id.*; *Apply for ACIP Membership*, CDC (Dec. 20, 2024), <https://www.cdc.gov/acip/apply-for-membership/>; Edwin J. Asturias, MD, et al., *Advisory Committee on Immunization Practices at a Crossroads*, 334 JAMA NETWORK (2025), <https://jamanetwork.com/journals/jama/article-abstract/2835626>.

investigation yourself. Just trust the experts. And trusting the experts is not a feature of science. It's not a feature of democracy. It's a feature of religion and it's a feature of totalitarianism. In democracies, we have the obligation, and it's one of the burdens of citizenship, to do our own research and make our own determinations about things.⁷¹

81. In a recent appearance on a podcast, the Secretary repeated his distrust of experts, when asked the question “what would you currently recommend that I give my child upon birth?” His response was:

We've made our recommendations and as an agency, I don't give medical advice to individuals because I'm not a doctor and I'm not competent to do that. And but what I would say to people is do your own research that, you know, um *this idea that you should trust the experts. A good mother doesn't do that. Good, good mother.*⁷²

82. On July 31, 2025, an email from acip@cdc.gov was sent to members of ACIP Liaison organizations, which include members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups like the Covid-19 Work Group. The pretextual reason given in the email was that “[l]iaison organizations are special interest groups and therefore are expected to have a ‘bias’ based on their constituency and/or population they represent. It is important that the ACIP Workgroup activities remain free of influence from any special interest groups so ACIP workgroups will no longer include Liaison organizations.” While Liaison members do not vote at ACIP public meetings on vaccine recommendations, they have “historically done important work undertaking detailed evidence reviews of the safety and effectiveness of vaccines that helps to inform the group’s votes.”⁷³

83. The ACIP Charter, however, states that: “There also *shall* be non-voting liaison representatives from ... American Academy of Pediatrics; ... the American College of Physicians;

⁷¹ The Katie Miller Podcast, *RFK Jr. on Dietary Guidelines, Vaccines & Trump*, at 13:52–14:35 (Jan. 13, 2026) (emphasis added), https://www.youtube.com/watch?v=w_fzlwXJZAA&t=843s.

⁷² *Id.* at 16:52–17:17.

⁷³ Brenda Goodman, *HHS further constrains certain vaccine advisors to the CDC, limiting their input in evidence reviews*, CNN (Aug. 1, 2025), <https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc>.

... Infectious Diseases Society of America; ...” The Secretary’s termination of liaison representatives from participation in ACIP work groups violates the ACIP Charter.

E. THE THREE MEETINGS OF THIS ACIP

The December 4-5, 2025 Meeting

84. This ACIP held three public meetings in 2025: June 25-26, September 18-19, and December 4-5. At each meeting of this ACIP, current ACIP members and invited speakers made claims “that were inaccurate, misleading, or not supported by the best available evidence.”⁷⁴

85. At the December 4-5 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
Pre-licensure trials for hepatitis B vaccines had no control groups and only days of safety follow-up.	<u>Aaron Siri</u>, Dec. 5, at 3:17:13 (“the two current standalone hepatitis B vaccines, Engerix B and Recombivax HB... were licensed for children based on an uncontrolled trial. So there was no control group.”)⁷⁵ <u>Mark Blaxill</u>, Dec. 4, at 1:12:24 (“there were basically no randomized or placebo-controlled trials ... the cited trials had very short follow-up periods”).⁷⁶	There have been more than 15 studies of Hep B vaccines, including randomized control studies and extensive US “real-world” analyses (VSD, VAERS). Follow-up periods ranged from 21 days to 24 months. Four studies directly compared birth dose to delayed first dose and found no increased risk of any short- or long-term adverse events. ⁷⁸

⁷⁴ Marisa Donnelly, *et al.*, Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁷⁵ Advisory Committee on Immunization Practices (ACIP) – December 5, 2025 – Day 2 of 2, CDC, at 3:17:13 (Dec. 5, 2025) <https://www.youtube.com/live/kUgXRUpKaI4>.

⁷⁶ Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2, CDC, at 1:12:24 (Dec. 4, 2025) <https://www.youtube.com/watch?v=LpthhPBFAGI>.

⁷⁸ Marisa Donnelly, *et al.*, Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
	<u>Evelyn Griffin</u> , Dec. 4, at 2:38:08 (“These two products for birth dose were set for four and five days of testing, and without a placebo trial.”). ⁷⁷	
Hepatitis B vaccine is associated with Sudden Infant Death Syndrome (“SIDS”)	<u>Mark Blaxill</u> , Day 1, 1:25:02 (“There were eight cases of SIDS and that was the single largest cause of death in the vaccinated group ... There were zero cases of SIDS in the unvaccinated group. That was a potential signal that the authors discounted.”) ⁷⁹	Multiple studies have found no association between vaccines and SIDS, including at least one focused explicitly on the Hepatitis B vaccine. The study referred to “did not withstand statistical scrutiny ... The total number of unexpected infant deaths from any cause was not statistically different between the vaccinated and unvaccinated groups. The unvaccinated group had zero SIDS deaths but higher rates of other causes of death, suggesting infants in this group were more medically fragile, making them a poor comparison group for this study. When the authors calculated SIDS rates using the full population, 240,717 vaccinated infants (8 SIDS deaths, 3.3 per 100,000) and 120,979 unvaccinated infants (4 SIDS deaths, also 3.3 per 100,000), the rates were identical. The apparent imbalance found in this single study reflects confounding, not a real signal. The study found no causal or temporal link

⁷⁷ *Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2*, CDC, at 2:38:08 (Dec. 4, 2025) <https://www.youtube.com/watch?v=LpthhPBFAGI>.

⁷⁹ *Id.* at 1:25:02.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
		between vaccination and death.” ⁸⁰
“Targeted measures” have been more effective than universal vaccination for Hepatitis B disease.	Cynthia Nevison, Dec. 4, at 39:01 (“it’s the more targeted measures that have had the biggest effect in bringing down cases of Hepatitis B”); and 41:12 (“selective vaccination of persons with identified risk factors has not lowered the incidence of Hepatitis B, but that is not true according to this graphs because the cases were already down 33 percent by 1991”). ⁸¹	“A targeted strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: ‘Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.’ This makes targeted approaches ineffective. Similarly, 35–65% of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. The 1991 switch to universal vaccination reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually). The pre-1991 declines in hepatitis B cases that Nevison cited were in adult populations due to blood screening. This cannot be used as evidence for targeted infant vaccination.”⁸²

⁸⁰ Marisa Donnelly, *et al.*, Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁸¹ *Advisory Committee on Immunization Practices (ACIP) – December 4, 2025 – Day 1 of 2*, CDC, at 39:01, 41:12 (Dec. 4, 2025) <https://www.youtube.com/watch?v=LpthhPBFAGI>.

⁸² Marisa Donnelly *et al.*, Summary Of 2025 ACIP Meetings, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

86. **The hepatitis B vote:** at the December 5, 2025, meeting, the ACIP voted “8 to 3 to recommend individual-based 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.”⁸³ The new recommendation is that parents discuss with their doctors whether to give the hepatitis B vaccine at birth, or at all, and that those who choose to do so should wait to begin the vaccine series until their baby is at least two months old.

(a) Since 1991, the United States has recommended that all babies receive a dose of hepatitis B vaccine within 24 hours of birth, including mothers who test negative for the hepatitis B surface antigen (HBsAg-negative).⁸⁴ The second dose is given at 1 to 2 months and a third dose at 6 to 18 months.

(b) The presenters on the hepatitis B vaccine the morning of the December 4, 2025 ACIP meeting (Pebsworth, Nevison, Blaxill) presented no fresh safety concerns or effectiveness issues that would prompt reconsideration of the hepatitis B vaccine birth dose. Instead, “panelists said the review was prompted by parents concerned about the shot, the fact that most European countries give the immunization a few months after birth, and the length of time since ACIP last reviewed the topic.”⁸⁵

(c) Before the 1991 universal birth dose recommendation, the United States had tried a targeted approach like the one the ACIP voted to recommend on December 5. “A targeted

⁸³ *ACIP Recommends Individual Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CDC (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html>.

⁸⁴ Aliza Rosen, *Hepatitis B Vaccination is an Essential Safety Net for Newborns*, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH (Sept. 24, 2025) <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth>; see also *Hepatitis B Perinatal Vaccine Information*, CDC (Aug. 27, 2025), <https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/vaccine-administration.html#:~:text=Birth%20dose,a%20parent%20with%20HBV%20infection>.

⁸⁵ Helen Braswell, *CDC panel recommends delaying birth dose of hepatitis B vaccine*, STAT (Dec. 5, 2025), <https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturms-30-year-policy/>.

strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: ‘Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.’ This makes targeted approaches ineffective. Similarly, 35–65% of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. The 1991 switch to universal vaccination *reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually).*⁸⁶

(d) Before he joined the Senate, Senator Bill Cassidy (R-La.) was a liver doctor. He posted the following on social media after the December 5 vote: “As a liver doctor who has treated patients with hepatitis B for decades, this change to the vaccine schedule is a mistake. This makes America sicker.”⁸⁷

(e) A modeling study on the impact of removing the universal birth dose of hepatitis B was posted online shortly before the December 4-5 ACIP meeting.⁸⁸ The results of the study were:

Results All delayed vaccination scenarios resulted in more infections, worse health outcomes, and higher costs than the current universal birth dose recommendation. Under perfect adherence, delaying HepB vaccination by 2 months for infants of HBsAg-negative parents led to an additional 90 acute infections, 75 chronic infections, 29 HBV-related deaths, with \$16.4 million in added costs for infants born during one year. Delaying to 12 years resulted in an additional 190 acute infections, 50 deaths, and nearly \$30 million in added costs. Delaying HepB vaccination to 12 years for infants of both HBsAg-negative and HBsAg-unknown parents resulted in an additional 2,351 acute infections, 744 deaths, and

⁸⁶ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁸⁷ Helen Braswell, *CDC panel recommends delaying birth dose of hepatitis B vaccine*, STAT (Dec. 5, 2025), <https://www.statnews.com/2025/12/05/cdc-hepatitis-b-vaccination-acip-panel-overturms-30-year-policy/>.

⁸⁸ Eric W. Hall, *et al.*, *Economic evaluation of delaying the infant hepatitis B vaccination schedule*, MEDRxiv (Nov. 25, 2025) (Preprint), <https://www.medrxiv.org/content/10.1101/2025.11.24.25340907v1.full.pdf>.

\$368 million in excess costs. Imperfect adherence to the vaccination schedule amplified all negative outcomes substantially. Incorporating pre-vaccination serologic screening for delayed schedules markedly increased total costs.

Conclusions Even brief delays in HepB vaccine initiation substantially increase HBV infections, adverse health outcomes, and health system costs. Our results quantify and demonstrate the importance of the universal HepB birth dose in preventing perinatal and early childhood HBV transmission in the United States.

(f) On December 16, the CDC adopted the ACIP's December 5 vote on the hepatitis B immunization, thus making it a final agency action.⁸⁹

September 18-19, 2025 Meeting

87. At the September 18-19 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
Hep B vaccines are unsafe	Malone, September 19, at 25:22: "We have an IOM report indicating that they could not conclude statistically whether or not those [case reports] had merit. That does not mean that it is safe, which was the assertion." ⁹⁰	The Institute of Medicine found insufficient evidence to establish causation for extremely rare events (except anaphylaxis). Insufficient evidence "means there was not enough evidence to suggest that vaccines were causing these rare events. It does not mean that harm was found. Rare, coincidental events occur when vaccinating millions; causation requires large studies. It should also be noted that, because these events are so rare, our main source of evidence for them is case reports, which actually underscores that the vaccines

⁸⁹ *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for the Hepatitis B Virus*, CDC (Dec. 16, 2025), <https://www.hhs.gov/press-room/cdc-adopts-individual-based-decision-making-for-hepatitis-b-immunization-for-infants-born-to-women-who-test-negative-for-the-hepatitis-b-virus.html>.

⁹⁰ *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 25:22 (Sept. 19, 2025) <https://www.youtube.com/watch?v=9ChY9SpPIY>.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
Covid-19 vaccines contain dangerous levels of DNA contamination exceeding regulatory limits.	<u>El-Deiry and Kuperwasser</u>, September 19, at 2:12:06: “DNA impurities, both the Pfizer and Moderna vaccines have been found to contain DNA that exceeds the FDA limits. Importantly, the DNA impurity limits do not take into account lipid nanoparticles, which carry DNA into cells and nuclei. There are concerns due to known DNA integration and gene activation disruption by SV40 promoter/enhancer sequences.”⁹³	in question are safe for the vast majority of people.”^{91,92} “Manufacturing impurities, including DNA, are carefully monitored because the FDA requires that residual DNA in vaccines below 10 ng per dose. The presence of DNA fragments used in the manufacturing process is expected, found at acceptable levels, and is accounted for in safety standards. Multiple independent analyses have confirmed that mRNA vaccines meet these stringent requirements. Claims of dangerous DNA contamination typically arise from studies that use inappropriate detection methods or misinterpret the significance of trace amounts that are orders of magnitude below safety thresholds. Moreover, the work that initially flagged the concern used inappropriate methods. Despite this, they found that vaccine lots with DNA levels above regulatory limits had fewer VAERS reports than those below the limits. SV40 (simian virus 40) is a virus originally found in a monkey kidney cell line that was used in the production of polio vaccines. Some data

⁹¹ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added) https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁹² INST. OF MED. OF THE NAT’L ACADEMIES, *Hepatitis B Vaccines in ADVERSE EVENTS OF VACCINES: EVIDENCE AND CAUSALITY* 435, 435–91 (2012), <https://www.nationalacademies.org/read/13164/chapter/10#437>.

⁹³ *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 2:12:06 (Sept. 19, 2025) <https://www.youtube.com/watch?v=9ChY9SpPIY>.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
		suggest SV40 infection may be associated with cancer development. But these vaccine claims related to SV40 are false. COVID-19 vaccines do not contain the SV40 virus. The sequence in question is a small DNA piece from SV40 used during the manufacturing process of mRNA vaccines. This fragment cannot cause infection or cancer because it does not encode the full SV40 virus or any of its proteins. Moreover, during the manufacturing process, the vaccine undergoes treatments with enzymes that destroy DNA. This means the sequences remaining in the vaccines are short and uninformative. Even in the historical case where the SV40 virus contaminated some polio vaccines in the 1950s and 1960s, large U.S. studies found no increased cancer risk among people who received them, and subsequent data showing links were later shown to reflect reagent issues and laboratory contamination. The quoted section also describes integration—when a virus's genome (or parts of it) becomes part of the cell's genome, allowing it to persist. Integration has been observed in cells infected with SV40, but SV40 lacks the specific machinery some other viruses have for this. When it does happen, it's a random event: the cell's normal DNA repair

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
		processes accidentally incorporate nearby DNA. There's no evidence that the SV40 fragment in the vaccines plays any special role in making this happen.” ⁹⁴
CDC lacks proper safety evaluations of vaccines.	Levi, September 19, at 4:46:16: “Do we have a culture of safety? And what would it take for us to acknowledge that there is a problem...?” ⁹⁵	“CDC operates multiple robust safety monitoring systems, including VAERS, VSD, and V-safe, which have successfully identified even extremely rare side effects, such as myocarditis (occurring at approximately 1-17 per 100,000 doses in the highest-risk groups). These systems lead to immediate investigation and transparent communication about risks. They also led to the detection of vaccine-induced immune thrombotic thrombocytopenia (a rare but devastating clotting complication that can readily be fatal if not recognized quickly) after the Janssen vaccine, based on 6 cases out of 6.8 million doses given (this later led to more capture of cases, giving an overall rate of approximately 1 in 330,000 doses). This safety signal was first identified by the CDC and FDA on April 9, 2021, and triggered a nationwide “pause” announced on April 13, 2021, followed by an emergency ACIP meeting on April 14. The detection of

⁹⁴ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added)
https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁹⁵ *Advisory Committee on Immunization Practices (ACIP) – September 19, 2025 – Day 2 of 2*, CDC, at 4:46:16 (Sept. 19, 2025) <https://www.youtube.com/watch?v=9ChY9SpPIY>.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
		these rare events and swift action demonstrated that safety monitoring is prioritized and works as intended.” ⁹⁶

88. **The Covid Vote:** on September 19, the ACIP voted to change the Covid-19 vaccine recommendation for adults from routine to SCDM.

(a) Defendant O’Neill finalized this agency action on or about October 6 when he announced on X that he had adopted the September 19 vote of the ACIP on the Covid-19 vaccine recommendation for adults. In an October 6 post on X, O’Neill stated: “[i]nformed consent is back. CDC’s 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today.” Informed consent and SCDM are not the same thing. Doctors have always had discussions and obtained informed consent from patients before performing procedures, including administering a vaccine. In contrast, the CDC’s website states that, “[u]nlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.”⁹⁷

(b) The ACIP did not apply GRADE criteria or follow the EtR framework prior to voting to change the CDC’s immunization schedule in September, 2025 to designate the Covid-

⁹⁶ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added)
https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

⁹⁷ *ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025),
<https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html>.

19 vaccine as SCDM.

(c) The ACIP did not consult with the Covid-19 Work Group prior to voting to designate the Covid-19 vaccine as SCDM for adults.

(d) Unlike the four previous occasions that the ACIP voted to designate a vaccine as SCDM, the CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

June 25-26, 2025 Meeting

89. At the June 25-26 ACIP meeting, voting members and presenters made numerous false or misleading statements, including the following:

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
Emphasis on myocarditis risk from COVID vaccines without considering myocarditis risk from Covid-19 disease.	Høeg, June 25, at 4:13:08: “..concern about ongoing myocardial damage that was seen with late gadolinium enhancement or MRI imaging about a half a year after, about a half a year after vaccination with uncertain clinical significance. But because of that, we did, we did announce that there was a safety label change today to the mRNA vaccines.” ⁹⁸	“Covid-19 vaccination reduces the risk of myocarditis associated with SARS-CoV-2 infection. SARS-CoV-2 poses a much greater myocarditis risk than vaccines for nearly all demographics. Newer analyses have also shown that rates of vaccine-associated myocarditis have dropped to levels comparable to the background incidence (i.e., an increased risk is not observed), suggesting a role for dosing intervals in myocarditis risk. The evolution of the long-term prognosis of vaccine myocarditis is being actively monitored, but thus far, post-vaccination myocarditis outcomes are much better than post-infection outcomes.” ⁹⁹

⁹⁸ *Advisory Committee on Immunization Practices (ACIP) – Day 1 of 2* CDC, at 4:13:08 (June 25, 2025), https://www.youtube.com/watch?v=_9ChY9SpPIY.

⁹⁹ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
RSV monoclonal antibodies show concerning infant death signals.	Levi, June 26, at 6:42 “Now, if I look on the clinical trials of the product we are supposed to vote on today, this is the clesrovimab, again, a trial of two-to-one with healthy children. There is, again, imbalance on the deaths, seven to three,...So, when I look on all of this, I would like to hear maybe from our colleagues at the CDC, should we not be concerned that maybe there are some safety, potential safety signals?” ¹⁰⁰	“There were 3 deaths in the MELODY trial among the group that received nirsevimab (the name of the monoclonal antibodies). None were deemed related to nirsevimab (2 were from gastroenteritis with no medical encounter, and 1 in a child with failure to thrive and multiple comorbidities). Though two of these deaths both occurred at around 140 days, they had different causes, and the gastroenteritis cases did not cluster together in time. It is difficult to argue that the deaths could plausibly be related to nirsevimab. Levi also cited an imbalance of deaths in the phase 3 trials for clesrovimab (a second RSV monoclonal antibody — 7 deaths vs 3 for clesrovimab vs placebo). This is misleading, given that the trial used a 2:1 randomization ratio (clecivimab:placebo). With twice as many participants in the clesrovimab group, you would statistically expect approximately twice as many deaths in that group. These rates are too similar to be able to conclude that they aren’t more than random chance.” ¹⁰¹
Thimerosal is not an effective preservative and was never adequately safety tested before widespread use.	Redwood, June 26, at 2:34:24: “They also found evidence that thimerosal was no better than water	“Thimerosal was introduced after repeated outbreaks of fatal bacterial contamination associated with multi-dose

¹⁰⁰ *Advisory Committee on Immunization Practices (ACIP) – Day 2 of 2* CDC, at 6:24 (June 26, 2025), <https://www.youtube.com/watch?v=z-16fImZoEc>.

¹⁰¹ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
	in protecting mice from potential fatal streptococcal infections. Redwood at 2:32:38: “FDA grandfathered in thimerosal without formal submission of any animal safety data.”¹⁰²	vaccine vials in the early 20th century. Multiple studies demonstrated that thimerosal was highly effective at preventing bacterial and fungal growth, outperforming alternative preservatives available at the time and doing so at much lower concentrations. Following the introduction of thimerosal, contamination-related deaths linked to vaccination dramatically declined. Claims that it is “no better than water” selectively reference short-term vial-entry experiments while ignoring real-world evidence and decades of safe use in vaccines. No evidence shows higher contamination rates in thimerosal-containing vaccines compared with alternatives. The claim that thimerosal was ‘grandfathered in’ without adequate testing misrepresents the regulatory and scientific history. Before widespread use, thimerosal underwent extensive animal testing. Following licensure, thimerosal-containing vaccines were among the most intensively studied products in vaccinology, with large epidemiologic studies conducted across multiple countries. Post-licensure surveillance and population-based studies consistently found no association between thimerosal-containing vaccines

¹⁰² *Advisory Committee on Immunization Practices (ACIP) – Day 2 of 2* CDC, at 2:34:24, 2:32:38 (June 26, 2025), <https://www.youtube.com/watch?v=z-16fImZoEc>.

<u>Claim</u>	<u>Statements</u>	<u>Correction</u>
		and neurologic, developmental, or systemic harms. Characterizing this as ‘insufficient testing’ ignores both preclinical toxicology and decades of real-world safety data.” ¹⁰³

90. **The thimerosal vote:** on June 26, the brand new ACIP “passed three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults. There was no explanation for why three separate recommendations were voted on when the end goal was to stop using the preservation in all flu vaccines brought to the U.S. market.”¹⁰⁴

91. This vote was based on cherry-picked data and long-debunked junk science.

92. The Secretary adopted the ACIP’s vote on thimerosal on July 23, finalizing this agency action.

F. THE MAY 19 DIRECTIVE

93. The announcement that the Secretary made on May 27¹⁰⁵ instructing the CDC to remove the Covid-19 vaccine recommendation for pregnant women and children came as a surprise to officials at the CDC, who five hours after the video was posted on X, received the written May 19 Directive for the first time.¹⁰⁶

¹⁰³ Marisa Donnelly, *et al.*, *Summary Of 2025 ACIP Meetings*, THE EVIDENCE COLLECTIVE (Jan. 2026) (emphasis added), https://static1.squarespace.com/static/68435457c33bc03421c23ff7/t/696beaa8cb9b640a609a510f/1768680104162/2025+ACIP+Falsehoods+Recap_Highlights.pdf.

¹⁰⁴ Helen Branswell, *HHS Secretary RFK Jr. accepts recommendations to drop thimerosal from U.S. flu vaccines*, STAT (July 23, 2025), <https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/>.

¹⁰⁵ Robert F. Kennedy, Jr. (@SecKennedy), X (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138>

¹⁰⁶ Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASH. POST (May 28, 2025), <https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/>.

94. Just a week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Marty Makary published an article dated May 20, 2025 in The New England Journal of Medicine that he co-authored with Vinay Prasad, the Director of the Center for Biologics Evaluation and Research in the FDA, stating that “pregnancy and recent pregnancy” are factors which “increase a person’s risk of severe COVID-19.”¹⁰⁷ Thus, the Directive, announced one week later, shows that “‘they literally contradicted themselves over the course of a couple of days.’ ... ‘It appears RFK Jr. reversed his own FDA’s decision.’”¹⁰⁸

95. The CDC’s immunization schedules were changed the same day as the May 27 announcement. Although the Directive ordered the CDC “to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age,” the CDC, however, strangely did not entirely remove the recommendation that children be routinely vaccinated against Covid-19. Instead, on May 29, 2025, the CDC downgraded the designation to SCDM.

96. The Secretary did not consult with the ACIP before he signed the Directive.

97. The Secretary did not consult with the Covid-19 Work Group before he signed the Directive.

98. The Secretary did not consult with the CDC about the Directive. In fact, at the April 15, 2025 open meeting of the ACIP, Dr. Lakshmi Panagiotakopoulos, an epidemiologist at the CDC, presented recommendations on use of Covid-19 vaccines for 2025-2026 for different population groups for which there is conclusive evidence of a higher risk of severe illness from the Covid-19 virus.¹⁰⁹ Dr. Panagiotakopoulos noted that pregnant individuals continued to face an

¹⁰⁷ Vinay Prasad & Martin Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 THE NEW ENGLAND J. MED. 2484, 2485, fig. 2 (2025).

¹⁰⁸ Louis Jacobson, Amy Sherman, *RFK Jr. Ended COVID Vaccine Recommendation for Kids, Pregnant Women. What do Facts Show About Risk?* POLITIFACT (May 29, 2025), <https://www.politifact.com/article/2025/may/29/COVID-19-vaccine-RFK-children-pregnant/>.

¹⁰⁹ Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations* (Apr. 15, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf>.

increased risk of severe outcomes from contracting Covid-19.¹¹⁰ Not only does a Covid-19 vaccine protect the mother, but it also protects infants less than six months of age because infants less than six months old cannot receive the Covid-19 vaccine, but the mother can protect the infant by passing antibodies to the fetus from a Covid-19 vaccine administered during pregnancy.¹¹¹ Dr. Fiona Havers, also an epidemiologist at the CDC, presented findings at the April 25, 2025 ACIP meeting on the impact of Covid-19 on children in the United States in the past year. “She found that at least 7,000 children were hospitalized with Covid. About 20 percent of those hospitalized were admitted to the intensive care unit, half were previously healthy, virtually none had been vaccinated, and 152 had died, most less than 4 years of age. The conclusion was clear; all children in the United States, whether they were previously healthy or not, should receive the primary series of Covid vaccines.”¹¹²

99. The Secretary cited no emergency, let alone change in circumstances, to justify the Directive.

100. There is no indication that the Secretary engaged in any formal evidence review, applied the GRADE criteria to assure the quality of the evidence relied upon, or applied the EtR framework.

101. The Secretary signed the Directive only five days after he testified before Congress that: “what I would say is my opinions about vaccines are irrelevant,” and “I don’t think people should be taking medical advice from me.”¹¹³

102. The Directive is contrary to the wealth of data and peer-reviewed studies that

¹¹⁰ *Id.* at 11.

¹¹¹ *Id.*

¹¹² Paul Offit, This CDC Resignation Should Scare You, SUBSTACK (July, 8, 2025) <https://pauloffit.substack.com/p/this-cdc-resignation-should-scare>.

¹¹³ Sara Moniuszko, *RFK Jr. says people shouldn't take his medical advice when asked about vaccines at hearing*, CBS News (May 14, 2025), <https://www.cbsnews.com/news/rfk-jr-medical-advice-vaccine-question-hearing/>.

demonstrate the safety and efficacy of Covid-19 vaccines for children and pregnant women.

G. HARM

Harm To the Plaintiffs Since The Third Amended Complaint

103. Plaintiffs initiated this action on July 7, 2025, challenging the May 19 Directive. (ECF # 1). Within 21 days of filing and serving the original complaint, Plaintiffs amended the original complaint pursuant to Federal Rule of Civil Procedure 15(a)(1)(A) to add a Plaintiff Organization (the Massachusetts Chapter of the AAP) and Jane Doe 2 as Plaintiffs. (ECF # 63). Plaintiffs filed a Second Amended Complaint on September 3, 2025, to add Jane Doe 3 as a Plaintiff. (ECF # 99). Defendants moved to dismiss the Second Amended Complaint that same day. (ECF # 102). The government's reply brief in support of the motion to dismiss the Second Amended Complaint was due October 3, 2025, and a hearing on the Motion to Dismiss the Second Amended Complaint was scheduled for October 8. The U.S. government, however, shutdown on October 1, and the government's reply brief and the hearing on the motion to dismiss were stayed as a result. (ECF # 121, 122). Plaintiffs moved to lift the stay on this case on October 20 when there appeared to be no end in sight of the shutdown. (ECF # 127). This Court held a hearing on that motion on October 30 and lifted the stay that day. (ECF # 134). At the October 20 hearing, the parties conferred on a briefing schedule on a motion to dismiss a Third Amended Complaint that Plaintiffs informed Defendants and the Court that they intended to file to challenge the final agency action of October 6, 2025 that changed the classification of the Covid vaccine from routine to SCDM for everyone under 65. (*Id.*). Defendants did not object to the filing of a Third Amended Complaint, which was filed on November 5. (ECF # 139). Defendants, however, moved to dismiss the Third Amended Complaint on standing grounds on November 19 (ECF # 144), the Court held a hearing on the motion to dismiss on December 17, 2025 (ECF # 164), and in a January 6, 2026, Memorandum and Order, denied Defendants' Motion to Dismiss. (ECF # 168).

104. Plaintiffs originally filed this action because of the harm that the May 19 Directive caused them and the public. Since then, Defendants' actions with regard to vaccines have been increasingly egregious and have amplified the harm to the Plaintiffs and the public by many orders of magnitude.

105. The final agency actions challenged herein, particularly the December 5 ACIP vote on the hepatitis B vaccine and the January 5 changes to the Childhood Schedule, have forced AAP to divert substantial time, staff attention, and financial resources away from core child-health initiatives and toward emergency mitigation work. AAP is now revising, developing, and distributing materials specifically to address the confusion created by the January 5 Action to counteract the rapid spread of misinformation that the changes to the Childhood Schedule has triggered. The AAP is being asked, in real time, to advise its members on how to meet the needs of children in their communities when the system is not prepared for the sudden, drastic changes recently made to the Childhood Schedule, where the healthcare system was not given time to plan for the changes.

106. Instead of advancing children's health, AAP is now spending time trying to mitigate damage caused by Defendants' actions. For example, the January 5 Action is causing AAP to re-examine clinical practice guidelines that were developed with the assumption that children are routinely vaccinated. Many clinical decision pathways implicitly rely on vaccination status, even when not stated explicitly. For example, in acute otitis media, also known as an ear infection, which affects almost all children, widespread vaccination shifted the epidemiology toward viral causes, supporting guidance that it is often safe to have an observation period before starting antibiotics. If vaccination rates drop and bacterial disease becomes more common again, those assumptions may no longer be valid. That means re-examining the guidelines and changing them

if indicated. The AAP is in the process of inventorying its full catalog of clinical guidance to determine where vaccination assumptions are embedded or where decision points need to be added. This is extensive work that was unanticipated, brought on by the January 5 Action.

107. The January 5 Action has had an immediate impact on AAP member and pediatrician in Michigan who owns two practices outside of Detroit, **Dr. Molly O'Shea**. Within 24 hours of the announcement and adoption of the Schedule Change, she was forced to reorganize her practice. To do so, she had to carve out time away from other duties to meet and discuss how the Schedule Change would impact their practice and the operational changes that would be necessary to ensure compliance. This meeting would not have been necessary but for the announcement and immediate adoption of the Schedule Change, which required corresponding immediate action by our practice.

108. Based on the Schedule Change, her practice has been forced to change operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. Because previously routinely recommended vaccines are now subject to SCDM, her practice's protocol must be replaced with a new, revised protocol. Under the new, revised protocol, the time and professional input of a provider will now be required in order to satisfy and comply with the SCDM component of the Schedule Change. This means patients will be required to make an appointment to see a provider, who in turn must now dedicate time specifically to SCDM and vaccine administration. Operationalizing this new protocol will require her practice to set aside one dedicated provider every day who will be solely responsible for handling SCDM appointments. This dedicated provider will conduct 30-minute appointments for any vaccines that now fall under the SCDM category. This change to office operations will disrupt the workflow of her practice and that of the dedicated provider because at least two to three sick visits, or one to

two well child visits, which otherwise be conducted by that dedicated provider in that same time frame, will now be displaced by SCDM appointments. An increasing number of her patients are already requesting to be vaccinated on an alternate schedule. This trend, combined with the effects of the Schedule Change and the need to change the practice's operations, will make it more difficult to see or treat patients in the regular course and scope of her business.

109. An AAP member and pediatrician in a Massachusetts town about 30 miles east of Providence, **Dr. Aaron Bornstein**, has felt an immediate impact from the messaging about vaccines from Defendants spread through various channels, including livestreamed ACIP meetings. The publicity accompanying the January 5 Action has been plentiful. Since December 18, 2025, after reports began to circulate about the Schedule Change, and Dr. Robert Malone, vice chair of ACIP, published an article anticipating the Schedule Change, he and his colleagues have observed a noticeable increase in parent concerns regarding vaccination. These questions have arisen during visits unrelated to vaccination, such as behavioral health visits. Among parents who support vaccinating their children, many parents have expressed anxiety about potential loss of access to vaccines and concern that their children may no longer be recommended for or able to receive routine immunizations due to the January 5 Action. He has also seen many parents who were on the fence about vaccinating their children and are now choosing not to vaccinate, directly attributable to the January 5 Action and public messaging from HHS, CDC, and ACIP. When these questions and concerns arise, he and his colleagues have been required to spend time to address them, often without compensation. This time is time he and his colleagues now cannot spend seeing other patients for sick visits or well child visits.

110. One recent example involved a family with three children who were visiting his clinic for an initial, unpaid "meet-and-greet" consultation. The two older children were fully

immunized, but the parents were now considering delaying or declining vaccines for their youngest child. During that visit, the father brought up party affiliation, cited CDC language suggesting that there are “too many vaccines,” and asserted that the CDC no longer recommends certain immunizations. The doctor attempted to direct the conversation toward established medical recommendations, but the father was unwilling to engage. The encounter ended without resolution, and it remains unclear whether the family will ultimately transfer care to his practice. The practice was uncompensated for the extra time required to engage with the parents on vaccinations.

111. Visits with parents have become increasingly confrontational. After news about changes to the Childhood Schedule broke in December but before the January 5 Action, a teenage patient, accompanied by the father, was being seen by a young, female nurse practitioner. The nurse practitioner noted that the teenager was due for a second dose of a meningococcal vaccine. When she brought this up, the father became agitated and confrontational, accusing the clinician of recommending vaccines for financial reasons and refusing to allow the vaccine to be given. The interaction became sufficiently aggressive that the nurse practitioner focused on de-escalation rather than clinical counseling. The patient left without receiving the routinely recommended vaccine. An interaction like this would not have occurred but for the messaging on vaccines from Defendants.

112. APHA’s mission is to: “Build public health capacity and promote effective policy and practice.” APHA members include more than 23,000 individual public health professional members, as well as state and local health departments, organizations interested in health, and health-related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in every state, and in countries across the globe. Unless the February 2026 meetings of the ACIP and CDC pediatric

childhood immunization schedule changes announced on January 5, 2026, including the accompanying decision memorandum and assessment, are immediately enjoined, these actions will cause immediate harm to APHA, its members, and the public's health of the United States. The public health system that APHA and APHA members are dedicated to building and protecting is, quite literally, a house on fire, and the challenged actions pour gasoline on that fire. The system is an essential component of ensuring optimal health for all.

113. The Executive Director of the APHA, **Georges C. Benjamin, M.D.**, states that abrupt changes to the CDC childhood immunization schedule effects the overall public health messaging in the United States and completely harms how public health vaccination campaigns that are run by APHA and APHA members need to operate to protect the public's health nationwide. Public health messaging is based on consistency and process that has relied on the evidence-based GRADE and EtR frameworks that guide the decision making that resulted in the previous CDC immunization schedule recommendations. These recommendations have been in place for years and are embedded into every part of the public health guidance that APHA and APHA members use to ensure evidenced based protection of the public's health. The HHS Secretary and Acting CDC Directors approval of the abrupt change to the CDC childhood immunization schedule breaks this evidence-based process that APHA and APHA's members have trusted and invested their time, effort, and money in for years as they conduct the on-ground outreach and campaigns necessary to prevent or respond to, preventable infectious disease outbreaks across the United States. The January 5, 2026 change in the CDC childhood immunization schedule simultaneously downgraded multiple long-standing routine pediatric vaccine recommendations causing severe disruptions in the procedures, vaccine availability and usability as well as procedures used to provide lifesaving protections to children and adolescents

in the United States. The accompanying decision memorandum and alleged multinational policy review used to explain their decision making process is flawed. The scientific policy review document includes numerous factual errors, misquotes findings from referenced studies and cherry picks the research and other data used to inform this policy decision. The supporting documentation is incomplete and fails to answer many questions essential to making such a radical policy recommendation change. This immediately forces APHA and APHA members to divert resources to explain and address the immediate policy, operational and program changes proposed by this abrupt, action by HHS leadership and the CDC. This change has nationwide impact.

114. APHA members report that APHA members are immediately required to review and when needed, revise counseling practices, educational materials, and public-facing guidance to explain the conflicts with well accepted evidenced based guidance with the new flawed federal recommendations changing the CDC childhood immunization schedule. State and local health departments staffed by APHA members are now reallocating personnel away from outbreak surveillance, emergency preparedness, and seasonal respiratory-virus response to address confusion created by the revised schedule. These diversions are occurring during peak respiratory-virus season and amid ongoing measles, influenza, RSV, and pertussis outbreaks, leaving APHA members understaffed in areas where delays or lapses directly increase morbidity and mortality. Once herd-immunity thresholds are reduced and preventable outbreaks begin, those harms are costly and difficult to control.

115. APHA members who provide vaccinations are also experiencing immediate financial and logistical harm as a direct result of the January 5, 2026, childhood immunization schedule changes because it has disrupted vaccine procurement decisions already made months earlier in reliance on routine CDC recommendations. APHA members who are public-health

agencies and physician practices purchase pediatric vaccines, including combination vaccines, well in advance based on established schedules. APHA members report that the downgrade of component vaccines, including hepatitis B, has rendered previously purchased combination vaccines unusable when parents decline a single component, forcing agencies to discard doses purchased with federal and state funds. At the same time, the CDC's mid-season changes to influenza recommendations have destabilized influenza vaccination programs already in progress. APHA members had ordered vaccines, printed materials, scheduled clinics, and launched outreach campaigns encouraging vaccination. Changing federal guidance in January and February during the peak in the influenza season has required APHA members to alter clinics, train staff on the implications of the altered guidance and patient eligibility, and respond to public confusion, which are actions that increase the likelihood of reduced influenza vaccine uptake. Decreased vaccination rates results in higher hospitalization rates and potentially more deaths from influenza or influenza related complications. Increased influenza hospitalizations during peak season strain emergency departments, and hospital inpatient capacity, producing additional harms such as delayed treatment for other critical health conditions like strokes, heart attacks, serious trauma and other time-sensitive conditions.

116. The CDC's downgrade of rotavirus and meningococcal vaccinations has created particularly acute and irreversible harms for APHA members responsible for pediatric and adolescent disease prevention. Rotavirus vaccination is the primary means of preventing severe diarrheal disease in infants. It is a highly contagious infection causing severe diarrhea, vomiting and abdominal pain. It has not known antiviral therapy but is easily prevented through vaccination. APHA members report that the shift of rotavirus vaccination to shared clinical decision-making has already led parents to decline or delay vaccination. Because rotavirus vaccines must be

administered within a narrow age window, missed doses cannot be recovered, permanently increasing the risk of dehydration-related hospitalizations and preventable pediatric morbidity. APHA members are actively diverting staff and resources to prepare for rotavirus outbreaks now, rather than engaging in routine preventive care. Similarly, meningococcal disease progresses rapidly and carries a high fatality rate, with catastrophic consequences for survivors. APHA members have also long relied on routine meningococcal vaccination recommendations to protect adolescents and college-bound students in congregate housing. The January 5 schedule introduced confusion just as students return to dormitories nationwide, forcing APHA members to devote substantial time to addressing questions from parents, clinicians, and school administrators. Any delay or reduction in meningococcal vaccination during this period materially increases outbreak risk.

117. The CDC's actions have also inflicted immediate harm on APHA itself by compelling the organization to abandon planned mission-critical work and operate in a constant crisis-response mode. APHA leadership, scientific staff, and communications teams are now spending hours each day responding to misinformation, correcting federal pronouncements, and briefing members on the internally inconsistent CDC materials. APHA has been forced to divert staff and expert contributors to review its flagship publications, including the Control of Communicable Diseases Manual, because those works utilize the evidence-based ACIP framework that the CDC schedule change process abandoned here. At the same time, the CDC's unexplained departure from established scientific processes has damaged APHA's credibility as a reliable disseminator of evidence-based guidance, because of the confusion, misinformation and disinformation caused by the abrupt unscientific change in federal guidance. This is requiring APHA to expend additional resources to ensure trust with members, partners, and the public. Loss

119. If the February 25-26, 2026 ACIP meeting proceeds as scheduled, this ACIP meeting will spread more misinformation and confusion throughout the United States, thereby causing more harm to the Plaintiff Organizations and their members. Each Plaintiff Organization represents frontline clinicians and public-health professionals who will be forced to divert substantial time, expertise, and organizational resources away from patient care, disease prevention, and core public-health functions to address confusion, misinformation, and erosion of trust caused by an illegitimate ACIP. Each additional meeting of this ACIP, and each vote this ACIP takes, compound the injury: clinicians must counsel patients amid uncertainty created by unstable federal guidance; clinicians must spend additional uncompensated time counseling patients and explaining ACIP changes to the CDC immunization schedule that fail to follow the established GRADE and EtR evidence framework; public-health agencies and practitioners must respond to and prepare guidance, outreach, and communication materials that have relied on the CDC immunization schedule and EtR framework to prevent the spread of infectious diseases across the country; and Plaintiff organizations must redirect staff and funding to crisis response rather than their core missions. These harms occur the moment ACIP votes to endorse or ratify

changes to the CDC immunization schedule, which are immediately treated as authoritative federal guidance nationwide. Once such guidance issues, the resulting damage to vaccine confidence, clinical reliance, and coordinated public-health infrastructure cannot be fully reversed through later litigation or post-hoc agency reconsideration. Absent immediate injunctive relief, Plaintiff organizations and their members will remain trapped in perpetual crisis-response mode, sustaining ongoing injuries to their missions, their members, and the public health of the United States.

Harm Alleged In The Third Amended Complaint

120. Although this Court has found that the allegations of harm in Plaintiffs' Third Amended Complaint were sufficient to survive Defendants' Motion to Dismiss on standing grounds (ECF # 168), Plaintiffs repeat the allegations of harm set forth in their Third Amended Complaint below for the sake of completeness and because this Fourth Amended Complaint now becomes the operative complaint for this action.

121. The difficulties that the Directive created for Jane Doe 1, who was expecting her first child, to get the Covid-19 vaccine earlier this year caused her to lose sleep, suffer headaches, and endure fatigue. Jane Doe 1's headaches and fatigue negatively affected her productivity at work, which was already compromised by her need to redirect hours of time and energy to coordinate with her healthcare providers about their recommendations and logistics for obtaining a Covid-19 vaccine while pregnant.

122. When the Secretary announced on May 27 that he was ordering the CDC to remove the recommendation from the CDC's immunization schedule that pregnant women get the Covid-19 vaccine, Jane Doe 2 was also expecting her first child. From May 30 to July 23, 2025, Jane Doe 2 tried at least ten times (either by driving to or calling her doctor's office, urgent care, or pharmacies) to get the Covid-19 vaccine but could not because of the chaos and confusion that the

Directive injected into the healthcare system. At one of her trips to a pharmacy, the pharmacist told her that she could not administer the Covid-19 vaccine to a pregnant woman because of the change in CDC guidance. Jane Doe 2 suffered clinically-significant sleep disturbances as a result of the stress directly-attributable to the Directive. She required a dental intervention to address stress-induced tooth-grinding because she was so stressed about having access to the Covid-19 vaccine and being vulnerable to the disease personally and for her baby. She still suffers from anxiety, depression, and clinically-significant sleep disturbances as a result of being denied the Covid-19 vaccine between June 2025 and July 2025. She also was forced to incur gasoline expense because of the multiple different times she went to her doctor's office, urgent care, or to pharmacies to try, unsuccessfully, to get the vaccine.

123. Plaintiff Jane Doe 3 is the mother of two neurodivergent teenage boys, one of whom suffers anxiety attacks. When Jane Doe 3 took her sons to a pharmacy in August to get a Covid-19 booster before school resumed in September, the pharmacist refused to vaccinate them because, according to the pharmacist, they were not in the eligible age group. Jane Doe 3 scheduled another appointment for her sons to get vaccinated in September, and the night before that appointment, her son had an anxiety attack about getting a shot the next day. He would not have had that anxiety attack but for the confusion that the Directive created that forced a repeated attempt to get vaccinated.

124. Because the Plaintiff medical and public health organizations ("Plaintiff Organizations") do not trust the Secretary or his reconstituted ACIP,¹¹⁴ the Plaintiff Organizations

¹¹⁴ Nor do many state governments. For example, several Northeastern states, including Massachusetts, announced in September the formation of the Northeast Public Health Cooperative, which will issue joint vaccine recommendations, coordinate public-health efforts, and share data. Joseph Ax, *Northeast US states form health alliance in response to federal vaccine limits*, REUTERS (Sept. 18, 2025), <https://www.reuters.com/business/healthcare-pharmaceuticals/northeast-us-states-form-health-alliance-response-federal-vaccine-limits-2025-09-18/>. Similarly, the West Coast states of California, Oregon, and Washington formed the West Coast Health Alliance because of concerns the "CDC has become a political tool that increasingly peddles

have had to divert resources to develop new infrastructures, processes, and guidance to fulfill their mission to their members.¹¹⁵ For example, on August 19, 2025, the AAP “published an independent evidence-based immunization schedule for children and adolescents in the wake of federal officials undermining the rigorous scientific process for making recommendations. ... The biggest difference between the AAP and CDC schedules is around COVID-19 vaccination. The CDC no longer recommends routine vaccination for healthy children, although children can get vaccinated after a conversation with their doctor. In contrast, the AAP recommends all young children ages 6-23 months get vaccinated as well as children ages 2-18 years in certain risk groups. It also calls for children whose parent or guardian desire protection from COVID-19 to have access to the vaccine.”¹¹⁶ The same day that the AAP published its own immunization schedule, the Secretary made the following threat: “AAP today released its own list of corporate-friendly vaccine recommendations. ... AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC’s official list are not shielded from liability under the 1986 Vaccine Injury Act.”¹¹⁷

125. The Final Agency Actions have adversely affected the physician-patient relationship because, *inter alia*, they have injected mistrust, misinformation, uncertainty, and confusion into that relationship, putting physicians in the conflicting position of either advising

ideology instead of science, ideology that will lead to severe health consequences.”” Amelia Templeton and Michelle Wiley, *Oregon, Washington, California form health care alliance to protect vaccine access*, OREGON PUBLIC BROADCASTING (Sept. 3, 2025), <https://www.opb.org/article/2025/09/03/vaccines-oregon-washington-california-cdc/>.

¹¹⁵ See, e.g., Decl. of Mark Del Monte, ECF No. 118-9 at ¶5 (“Multiple different teams within AAP have had to divert their attention from other urgent matters related to child health to contend with the impact of the Directive, including staff at all levels on the Senior Leadership Team, the Pediatric Practice and Healthcare Delivery Team, the Quality Team, the Finance and Payment Strategy Team, the Public Affairs Team, the Communications Team, the Publishing Team, and the Information Technology Team.”).

¹¹⁶ Melissa Jenco, *AAP releases evidence-based immunization schedules; calls on payers to cover recommendations*, AAP NEWS (Aug. 19, 2025), <https://publications.aap.org/aapnews/news/32835>.

¹¹⁷ Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, 5:17 PM), <https://x.com/SecKennedy/status/1957914911415153107>.

patients on what they believe is the proper standard of care or adhering to inconsistent federal guidance. The Final Agency Actions will also result in decreased rates of vaccination, increased rates of transmission, long-lasting illness, and ultimately preventable deaths. The Final Agency Actions have and will put more stress on an already taxed healthcare system in this country at a time when many are uninsured, under-insured, or who may lose their health insurance coverage.

126. Dr. Robert H. Hopkins, Jr., is an Internal Medicine and Pediatrics physician in Arkansas. He is an active ACP member and current chair of the ACP Immunization Committee. He has served on several ACIP vaccine Work Groups. Early in July 2025, Dr. Hopkins saw a parent and child for a wellness visit for the child. The parent wanted the Covid-19 vaccine for the child, who was eligible for the VFC program. Dr. Hopkins, however, was unable to order the Covid-19 vaccine for the child through the VFC portal. He was able to find the vaccine through another source, but told the parent that the parent would have to pay out of pocket for the vaccine. The parent could not afford to pay, so the parent and child left without getting the vaccine. Further, because of the Final Agency Actions, Dr. Hopkins has been required to spend more time counseling patients regarding the safety of the Covid-19 vaccine. Approximately half of the patients he sees in a given day require counseling on Covid-19 vaccines. In such discussions, Dr. Hopkins has counseled patients that, based on the evidence, the Covid-19 vaccine is safe and beneficial. However, after these discussions, several patients, such as parents of young children, have decided to trust the Secretary's advice and refused to get the Covid-19 vaccine for their child. His relationship with these patients has deteriorated as a result of the Final Agency Actions.

127. Dr. Susan J. Kressly is the current President of the AAP. She learned from AAP members that, because of the Directive, AAP members experienced great frustration and new barriers in effectively counseling patients and their families regarding the Covid-19 vaccine. AAP

members believe that they are compromising the standard of care that they should be providing to their patients due to the confusion and distrust created by the Final Agency Actions, which have caused physician members to spend more time counseling patients regarding the effectiveness of the Covid-19 vaccines that, in turn, diverts time and resources from other patients. Due to the confusion and lack of evidence-based data supporting the Directive, the AAP ceased its endorsement of the CDC's current Child and Adolescent Schedule, and instead published and endorsed the CDC Child and Adolescent Immunization Schedule in effect in November 2024. The Final Agency Actions have put all AAP members (and, indeed, all other physicians in this country) in the untenable position of telling their patients that the country's top-ranking government health official's advice and recommendations from the new ACIP are wrong and that we are right. This erodes trust, which is the foundation of a healthy physician-patient relationship and vital to the success of AAP members' medical practices.

128. AAP member Dr. Mary Doherty-O'Shea Galluci is a pediatrician and owns two practices in Michigan. The Final Agency Actions have led to an increase in vaccine hesitancy in her patients. Parents are now questioning Dr. Galluci whether they should vaccinate their children against Covid-19, or worse, whether they can. Parents are now distressed and unsure about Covid-19 vaccines where they were not before. Dr. Galluci is especially concerned about pregnant patients and infants under 12 months old whom she sees at her clinics. During pregnancy, the immune system undergoes significant changes to protect the developing fetus. This puts pregnant women at high risk for severe Covid-19 complications, and the only way to protect their infants is through maternal vaccination and early-life immunization. Covid-19 infection in infants can be severe or fatal. Denying or delaying access to the Covid-19 vaccine in this population is medically dangerous and ethically indefensible. The Final Agency Actions are immediately and irreparably

endangering the lives of patients she is seeing right now at her clinics. The CDC's current emphasis on "shared decision-making" for the Covid-19 vaccine for children has put a chilling effect on her practice. Shared decision-making implies that the Covid-19 vaccine is optional or suspect, making it harder to hold Covid-19 vaccine clinics, limiting her practice's ability to order vaccines in bulk, and creating reimbursement challenges. Her billing team is spending excessive time navigating unclear insurance coverage rules. Parents also fear receiving unexpected co-pays for the Covid-19 vaccine due to the fluctuating, inconsistent messaging from the CDC. Access to Covid-19 vaccines is being reduced as a result of the Final Agency Actions. In addition to all of this, Dr. Galluci now must also confront and navigate the prospect of potential legal liability in light of the Secretary's post on his official X account in which he warned that "recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." Dr. Galluci understands this post to be as a threat to her and her colleagues who follow the AAP's, not the CDC's, immunization schedule. This prompted Dr. Galluci to consult her malpractice coverage, and she now worries whether her commitment to the standard of care she has followed for years will expose her to liability because of the contrary, conflicting messages that the Final Agency Actions send. Dr. Galluci is also being forced to perform uncompensated work in the face of increased SCDM she must now engage in with patients who previously trusted in routine vaccination. This is detracting from other aspects of her practice and results in loss of compensation. In short, the Final Agency Actions are interfering with her ability to provide the standard of care recommended by the AAP and interfering with her ability to comply with the oath she took as a doctor to do no harm.

129. Dr. Jason Goldman is the current President of the ACP and owns his own internal medicine practice in Florida. Since Covid-19 vaccines were first approved, physician members of

ACP have been routinely recommending and administering the Covid-19 vaccine. This routine administration of the vaccine has become the standard of care for physician members of the ACP. ACP physician members informed Dr. Goldman that the Directive placed them in an untenable situation of providing medical advice that some patients believe is inconsistent with federal guidance. ACP physicians face financial harm because some insurers do not cover vaccines that are designated SCDM on the CDC immunization schedules.

130. Dr. Georges C. Benjamin is the current Executive Director of the APHA. He has discovered that APHA members across the country face increasing difficulty because of the Final Agency Actions with providing the optimal standard of care that members have been following since the Covid-19 vaccines were approved. The Final Agency Actions have frustrated the ability of clinicians and other public health members to advise the communities that they serve regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and death, thus compromising APHA members' ability to practice consistent with their standard of care. The Final Agency Actions have increased vaccine hesitancy and diminished trust in sound medical advice, which has caused APHA members to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid-19 vaccines, thus diverting time and resources away from other important health care or public health duties.

131. J. Edward Johnson is the Assistant Health Commissioner for External Affairs at the Columbus Department of Public Health ("Columbus Public Health"), which is a member of APHA. Columbus Public Health's mission is to "Build public health capacity and promote effective policy and practice." In particular, Columbus Public Health endeavors to curb transmission of infectious diseases by operating an immunization clinic that offers several immunizations, including against Covid-19, through its Columbus Public Health Vaccine

Preventable Diseases Clinic and Program (the “CPH Clinic”). The Final Agency Actions frustrate this purpose and mission of Columbus Public Health because they are at odds with the mission, vision, and values of Columbus Public Health.

132. Dr. Andrew Pavia is an infectious disease doctor in Utah, has served as a Board member for IDSA, and is an active member of IDSA as Chair of the Avian Influenza Task Force and co-Chair of the IDSA Influenza Treatment Guidelines Committee. Consistent with ACIP recommendations before the Secretary took office this year, IDSA adopted ACIP’s recommendations on the Covid-19 vaccine, which had become the standard of care for IDSA physician members and which IDSA has adopted into its guidelines. The Directive, however, places IDSA members in an ethical quandary because they are now required to discuss recommendations from the current ACIP and CDC that are no longer evidence-based. The Final Agency Actions have increased the number of encounters with parents who express increasing concern and confusion about whether their infants and children should get the Covid-19 vaccine. The Final Agency Action’s creation of mistrust has damaged the cornerstone of the physician-patient relationship.

133. Dr. Ravi Jhaveri is an infectious disease expert, board certified in Pediatrics and Infectious diseases, and practices in Illinois. He is a member of both the Pediatric Infectious Disease Society (“PIDS”) and the IDSA. It is his clinical judgment to recommend routine Covid-19 vaccination for pediatric patients ages six months to 17 years, as he has seen that the vaccine protects children from getting the disease and/or from suffering the effects of long Covid. The Final Agency Actions have placed him in the untenable position of attempting to dispel the misinformation and disinformation coming out of the current ACIP and CDC when he sees his patients. The Final Agency Actions have damaged his practice and relationships with his patients.

134. Regina LaRocque, M.D., M.P.H., FIDSA, is a physician board certified in infectious diseases. She is a member of IDSA and presently treats patients, including pediatric patients and pregnant individuals, in a traveler's advice and immunization clinic. The Secretary's Directive disincentivized physicians from recommending Covid-19 vaccines for pregnant individuals and children ages 6 months through 17 years and created uncertainty about eligibility for and access to this vaccination. Based on her more than 20 years in the field of infectious disease, she asserts confidently and without qualification, that based on her professional experience, more patients of all ages will contract Covid-19 and experience severe symptoms, including death, due to the barriers to vaccination that the Final Agency Actions are erecting. The Final Agency Actions are disrupting her practice and compromising her ability to provide the highest level of care to her patients.

135. Carlene Pavlos is the Executive Director of the Massachusetts Public Health Alliance ("MPHA"), a nonprofit organization that advocates for health equality and strong public systems across the Commonwealth of Massachusetts. The Final Agency Actions irreparably harm MPHA members by frustrating the work they do to support maternal and child health, vaccine delivery, and pandemic response in Massachusetts. The Final Agency Actions undermine MPHA members' independent medical judgment and critically weaken the public health infrastructure MPHA members rely on to perform their jobs.

136. Dr. Sindhu K. Srinivas is a physician and board certified in Obstetrics and Gynecology and Maternal Fetal Medicine. She is the President of the Society of Maternal Fetal Medicine ("SMFM"). The Final Agency Actions have frustrated SMFM's members' ability to effectively counsel patients regarding the effectiveness of the Covid-19 vaccine at preventing serious illness and compromise the standard of care to which SMFM members adhere. The Final

Agency Actions harm SMFM members' practices by undermining and eroding the physician-patient relationship and requires SMFM members to divert resources to addressing confusion about the Covid-19 vaccine.

137. SMFM member Dr. Caroline Rouse is a board-certified maternal-fetal specialist in Indiana who treats high-risk pregnant patients. The Directive had harmful effects on her practice because it disrupted vaccination schedules for her patients and caused dangerous confusion for her clinical practice. Many of her current patients have an altered immune system, and they are now presenting at her practice as afraid, misinformed and at increased risk of preventable illness and death as a result of the Final Agency Actions. In short, the Final Agency Actions are endangering the health and lives of her patients as well as undermining the trust and confidence upon which the physician-patient relationship is built. The Final Agency Actions are disrupting her practice and compromising her ability to provide the highest level of care to her patients.

138. The Directive created an ethical and legal dilemma for an SMFM member who is a maternal-fetal specialist in Massachusetts. The day after the Directive was publicized, this SMFM member assisted in preparing a statement in response to requests from SMFM members requesting clarification of the appropriate standard of care in light of the Directive and seeking affirmation that SMFM still recommended the Covid-19 vaccine during pregnancy. That statement provides:

As the experts in high-risk pregnancy, the Society for Maternal-Fetal Medicine (SMFM) strongly reaffirms its recommendation that pregnant patients receive the COVID-19 vaccine. Pregnancy increases the risk of developing severe illness compared with nonpregnant patients. Maternal immunization remains the best way to reduce maternal, fetal, and infant complications from COVID-19 infection, and is safe to be given at any point during pregnancy. Maternal immunization is also associated with

improved infant outcomes and decreased complications, including maternal and infant hospitalizations.

SMFM recommends that all people who are considering pregnancy, pregnant, recently pregnant, or breastfeeding receive vaccination against COVID-19. Surveillance data collected since the beginning of the COVID-19 pandemic, which started in 2020, clearly demonstrates the safety and efficacy of mRNA vaccines in pregnancy.

All physicians and other health care partners, along with health insurers, should continue recommending COVID-19 vaccination to pregnant patients. Maternal immunization is proven to protect patients and their infants against severe illness and death from infectious diseases.¹¹⁸

139. An SMFM member who is a maternal-fetal specialist in Texas and treats high-risk pregnancies has experienced an undermining of trust, disruption of immunization schedules for his patients, and dangerous confusion in the clinical setting. He is being forced to spend more time in counseling on the Covid-19 and other vaccines, which diverts time from seeing other patients.

140. Dr. Margie Andreae, another AAP member, is a board-certified pediatrician who practices at the Pediatric Clinic of the Canton Health Center in Canton, Michigan. Over her more than three decades of experience, Dr. Andreae has trusted the ACIP and its recommendations because she trusted that the appointments to the ACIP were made in good faith and that ACIP members had legitimate, relevant qualifications. The Final Agency Actions have changed that. She and her colleagues must now spend more time counseling patients over the safety and effectiveness of the Covid-19 vaccine. While routine counseling is part of a physician's job, the time spent engaging in SCDM has increased the counseling aspect of her job due to the confusion and distrust it has fomented over the Covid-19 vaccine. She, however, is not able to bill for the additional time

¹¹⁸ *SMFM Continues to Recommend Influenza, COVID-19, and RSV Vaccine During Pregnancy*, SOC'Y FOR MATERNAL-FETAL MED. (June 25, 2025), <https://www.smfm.org/news/smfm-continues-to-recommend-influenza-covid-19-and-rsv-vaccine-during-pregnancy>.

that she spends in SCDM with her patients. The Secretary's actions deprive her of income and force her to perform uncompensated work.

141. Mary-Cassie Shaw, M.D., F.A.A.P., is a practicing pediatrician in Raleigh, North Carolina. Dr. Shaw has experienced increased chaos and confusion in her practice due to the Final Agency Actions. The chaos and confusion have resulted in she and her colleagues spending more time than before calling drug stores, local health departments, and other providers to determine the availability of the Covid-19 vaccine. The Final Agency Actions now require her to engage in more in-depth conversations with parents about the safety and efficacy of the Covid-19 vaccine, conversations that were not occurring before the changed to SCDM. None of this time has been compensable. Dr. Shaw has also seen patient numbers drop, which she attributes to the mistrust that the Final Agency Actions have sown. This loss in patients has caused her financial harm.

142. Dr. Suzanne Berman is another board-certified pediatrician and AAP member who has seen more and more parents unwilling to vaccinate their children with the Covid-19 vaccine since the issuance of the Directive. This has caused financial harm to her practice, harm that is compounded by the SCDM counseling that she must now engage in, time which often is not reimbursable. She now expects to be left with unused vaccines that she cannot return, further deepening her financial harms as co-owner of her clinical practice.

143. James Lewis, M.D., M.P.H., is a board-certified physician in internal medicine, infectious diseases, and preventative medicine. In addition to his role as an adjunct professor at the University of Washington's Division of Allergy and Infectious Diseases. Dr. Lewis also serves as the Health Officer for the Snohomish County Health Department in the State of Washington. He is also a member of APHA. Like the other physicians mentioned here, the Secretary's action have concretely harmed Dr. Lewis. Because of the Directive, Dr. Lewis now reallocates his time

to projects that otherwise would not be necessary. These include efforts to change local and state laws and Snohomish County policies that tie vaccine recommendations to ACIP and CDC guidance. Dr. Lewis and his colleagues undertake this work because he can no longer trust in the integrity or judgment of the new ACIP, its recommendations, or CDC guidance.

144. Thomas Boyce, M.D., is a physician board certified in infectious diseases and pediatrics. Like Dr. Jhaveri, Dr. Boyce is a member of both IDSA and PIDS. Dr. Boyce treats patients in a large, rural healthcare system in Wisconsin that serves approximately 310,000 patients, of whom 46,500 are children. As a pediatric infectious disease physician, Dr. Boyce's primary duty is to consult with providers and patients about infectious diseases. Over his more than 30 years in practice, Dr. Boyce trusted in the process that ACIP followed that resulted in vaccines being listed on the CDC immunization schedules. He had confidence in the nonpartisan and apolitical nature of the important work federal public health agencies undertake. The Final Agency Actions have changed that. Now, because of the change to SCDM for both children and adults, and the misinformation and disinformation that the Secretary and his reconstituted ACIP have spread on vaccines, Dr. Boyce is required to engage in much lengthier discussions as to the benefits and risks of the Covid-19 vaccine, a discussion he struggles with because the Secretary and his reconstituted ACIP have identified no new data on either safety or efficacy justifying the changes they have made to the CDC's immunization schedules. The increased time spent in counseling is work for which he is not compensated because he is unable to bill or code for this SCDM time. Dr. Boyce estimate that he spends an average of 1.5 hours per day in uncompensated time engaging in SCDM over the Covid-19 vaccine that diverts him from other, more urgent and pressing work.

145. David A. Wheeler, M.D., is a practicing physician in Northern Virginia with an

emphasis in infectious diseases and internal medicine. He is a fellow of the ACP and the IDSA. Since the designation of the Covid-19 vaccine as SCDM for adults under 65, Dr. Wheeler has seen an increase in calls from primary care physicians asking him for guidance on how to conduct SCDM for healthy adults under 65. As the infectious disease expert in his community, these primary care physicians and other practitioners increasingly turn to him for advice on questions about how to counsel patients. One primary care physician went so far as to ask Dr. Wheeler to write a prescription for the Covid-19 vaccine. Dr. Wheeler, however, cannot bill for any of this time spent counseling fellow practitioners on the risks and benefits of the Covid-19 vaccine. Thus, the Directive and the designation of the Covid-19 vaccine for adults as SCDM have forced Dr. Wheeler to perform work without compensation.

CAUSES OF ACTION

COUNT I

Violation of the Administrative Procedure Act – The Childhood Schedule

146. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

147. The APA authorizes courts to “hold unlawful and set aside agency action, findings, and conclusions found to be” “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law or that are taken “without observance of procedure required by law[.]” 5 U.S.C. § 706(2)(A). An agency action is arbitrary and capricious if the agency has “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983).

Under the APA, Defendants must “examine the relevant data and articulate a satisfactory explanation for [their] action[s].” *Id.*

148. The January 5 Action was a final agency action.

149. With respect to the January 5 Action, the agency “relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983).

150. When undertaking the January 5 Action, Defendants failed to “examine the relevant data and articulate a satisfactory explanation for [their] action[s].” *Id.*

151. The January 5 Action was a final agency action that caused and continues to cause harm to the Plaintiffs.

152. The January 5 Action was unlawful and must be set aside.

153. Plaintiffs are entitled to a declaratory judgment that the January 5 Action was unlawful.

154. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing or otherwise giving effect to the January 5 Action.

155. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count I, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT II
Violation of the Administrative Procedure Act – The ACIP

156. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

157. Under FACA, the ACIP must be fairly balanced and not subject to inappropriate influence. Violations of FACA are justiciable under the APA.

158. The Secretary's appointments to this ACIP have resulted in an unfairly balanced ACIP.

159. The Secretary has inappropriately influenced this ACIP.

160. The Secretary's appointments to this ACIP are arbitrary, capricious, and not in accordance law.

161. The public meetings of this ACIP have harmed and continue to harm the Plaintiffs and the public.

162. Future public meetings of this ACIP will cause additional harm to the Plaintiffs and the public.

163. The Secretary's appointments to the ACIP are unlawful and must be set aside.

164. Plaintiffs are entitled to a declaratory judgment that that this ACIP is unfairly balanced and has been inappropriately influenced in violation of FACA and the APA.

165. Plaintiffs are entitled to a declaratory judgment that public meetings of this ACIP have harmed the Plaintiffs and the public.

166. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining future meetings of this ACIP.

167. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from giving effect to the Secretary's vacating the Secretary's appointments to this ACIP on June 11, 2025, September 11, 2025, and January 13, 2026.

168. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count II, that they have suffered and will suffer irreparable harm, that the

balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT III

**Violation of the Administrative Procedure Act –
The ACIP’s December 5, 2025 Hepatitis B Vote, September 19, 2025 Vote
On The Covid Vaccine, and the June 26, 2025 Vote on Thimerosal**

169. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

170. The CDC adopted the ACIP’s December 5, 2025 vote on the hepatitis B birth dose on December 16, 2025; adopted the ACIP’s September 19 vote on the Covid vaccine on October 6, 2025; and adopted the June 26, 2025 vote on thimerosal on July 23, 2025, thus making all of these votes final agency actions.

171. In taking these final agency action, Defendants “relied on factors which Congress has not intended it to consider, entirely failed to consider [] important aspect[s] of the problem, offered [] explanations for its decision that run[] counter to the evidence before the agency, [and provided explanations] so implausible that [they] could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983).

172. These final agency actions were arbitrary and capricious and not in accordance with law because, inter alia, the ACIP and the Defendants failed to “examine the relevant data and articulate a satisfactory explanation for [their] action[s].” *Id.*

173. These three final agency action caused and continue to cause harm to the Plaintiffs and the public.

174. Plaintiffs are entitled to a declaratory judgment that these three final agency actions were unlawful under the APA.

175. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing and otherwise giving effect to the December 5, 2025, September

19, 2025, and June 26, 2025 votes of the ACIP.

176. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count III, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

COUNT IV
Violation of the Administrative Procedure Act – the May 19 Directive

177. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

178. The May 19 Directive failed to consider relevant evidence.

179. Defendants have failed to articulate reasonable explanation for the May 19 Directive.

180. The May 19 Directive has injured and will continue to injure the Plaintiffs.

181. Plaintiffs are entitled to a declaratory judgment that the May 19 Directive was unlawful.

182. Plaintiffs are entitled to preliminary and permanent injunctive relief enjoining Defendants from implementing and otherwise giving effect to the May 19 Directive.

183. The facts pled herein demonstrate that Plaintiffs are likely to succeed and will succeed on the merits of Count IV, that they have suffered and will suffer irreparable harm, that the balance of equities are in their favor, and that injunctive relief would be in the public interest.

PRAYER FOR RELIEF

184. Plaintiffs respectfully request that this Court enter judgment in their favor and that the Court:

185. **As to Count I:**

(a) Declare that the January 5 Action violated the APA because it was arbitrary and

capricious, not in accordance with law, and failed to consider important aspects of the problem.

- (b) Set aside the January 5 Action.
- (c) Grant preliminary and permanent injunctive relief enjoining the Defendants from implementing and otherwise giving effect to the January 5 Action.

186. **As to Count II:**

- (a) Declare that appointment of this ACIP's members violated FACA, the APA, and the ACIP Charter.
- (b) Set aside the appointments of members to this ACIP.
- (c) Grant preliminary and permanent injunctive relief enjoining Defendants from implementing and giving effect to the appointments to the ACIP of any and all current members of this ACIP.
- (d) Grant preliminary and injunctive relief enjoining the current ACIP from holding any future meetings, including the meeting currently scheduled for February 25-26, 2026.

187. **As to Count III:**

- (a) Declare that the December 5, September 19, and June 26, 2025 votes that became final agency actions violated the APA because they were arbitrary and capricious, not in accordance with law, and failed to consider important aspects of the problem.
- (b) Set aside the December 5, September 19, and June 26 votes of the ACIP that were adopted by the CDC.
- (c) Grant preliminary and permanent injunctive relief enjoining Defendants from

implementing and otherwise giving effect to these votes.

188. **As to Count IV:**

- (a) Declare the May 19 Directive violated the APA because it was arbitrary and capricious, not in accordance with law, and failed to consider important aspects of the problem.
- (b) Set aside the May 19 Secretarial Directive.
- (c) Grant preliminary and permanent injunctive relief enjoining the Secretary from implementing and otherwise giving effect to the May 19 Secretarial Directive.

189. **As to all Counts:**

- (a) Award to Plaintiffs reasonable attorney's fees and costs incurred in pursuing this action; and
- (b) Grant all such other and further relief as this Court deems just and appropriate.

Dated: February 17, 2026

Respectfully submitted,

By: James J. Oh

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by via email on this 17th day of February 2026:

Robert F. Kennedy, Jr., in his official capacity
as Secretary of Health and Human Services

Jim O'Neill, in his official capacity as Acting
Director of the Centers for Disease Control
and Prevention

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/s/ James J. Oh
James J. Oh

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF	)	
PEDIATRICS, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	No. 1:25-cv-11916-BEM
v.	)	
	)	
ROBERT F. KENNEDY, JR.,	)	
ET AL.,	)	
	)	
Defendants.	)	

BEFORE THE HONORABLE BRIAN E. MURPHY
UNITED STATES DISTRICT JUDGE

Motion hearing

February 13, 2026
9:04 a.m. - 4:46 p.m.

John Joseph Moakley United States Courthouse
Courtroom No. 12
1 Courthouse Way
Boston, Massachusetts 02210

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P R O C E E D I N G S

THE CLERK: All rise.

(The Honorable Court entered.)

THE CLERK: This Honorable Court is now in session.
Judge Brian Murphy is presiding. Please be seated.

Civil Action Number 25-11916, American Academy of
Pediatrics, et al. versus Kennedy, et al.

If counsel can please identify yourselves for the
record.

MR. OH: Good morning, Your Honor. James Oh on behalf
of the plaintiffs.

THE COURT: Good morning, Mr. Oh.

MR. OH: And if you don't mind, my team would also
like to enter their appearances.

THE COURT: Sure.

MS. MCEVOY: Good morning, Your Honor. Elizabeth
McEvoy on behalf of the plaintiffs.

THE COURT: Good morning, Ms. McEvoy.

MR. HUGHES: Good morning, Your Honor. Richard Hughes
on behalf of the plaintiffs.

THE COURT: Good morning, Mr. Hughes.

MS. BARRETT: Good morning, Your Honor. Kathleen
Barrett on behalf of the plaintiffs.

THE COURT: Good morning, Ms. Barrett.

1 MS. LEE: Good morning, Your Honor. Daniella Lee on
2 behalf of the plaintiffs.

3 THE COURT: Good morning, Ms. Lee.

4 MR. WANERMAN: Good morning, Your Honor. Robert
5 Wanerman on behalf of the plaintiffs.

6 THE COURT: And good morning, Mr. Wanerman.

7 MR. BELFER: Good morning, Your Honor. Isaac Belfer
8 for the Department of Justice for the government.

9 THE COURT: Good morning, Mr. Belfer.

10 MR. BELFER: I'm joined by James Harlow for the
11 Department of Justice and also Katrina Hodges from the
12 Department of Health and Human Services.

13 THE COURT: And good morning to you both. Thank you,
14 everyone, for being here.

15 MR. OH: Your Honor, also, there are some members of
16 the plaintiff organizations here. I thought I'd introduce them
17 before we get started.

18 THE COURT: Sure. That's fine.

19 MR. OH: So, as you know, there are seven
20 organizations. And representing the American Academy of
21 Pediatrics is Dr. Andrew Racine.

22 DR. RACINE: Good morning, Your Honor.

23 THE COURT: Good morning.

24 MR. OH: Representing the American College of
25 Physicians is Dr. Daniel Kuritzkes, K-U-R-I-T-Z-K-E-S.

1 DR. KURITZKES: Good morning, Your Honor.

2 THE COURT: Good morning, Doctor.

3 MR. OH: Representing both the American Public Health
4 Association and the Massachusetts Public Health Association,
5 Carlene Pavlos.

6 MS. PAVLOS: Good morning, Your Honor.

7 THE COURT: Good morning.

8 MR. OH: Representing the Infectious Diseases Society
9 of America, Dr. Sandra Nelson.

10 DR. NELSON: Good morning, Your Honor.

11 THE COURT: Good morning, Doctor.

12 MR. OH: Representing the Society for Maternal-Fetal
13 Medicine, Dr. Malavika Prabhu, Malavika, M-A-L-L-A-V-I-K-A
14 (sic), Prabhu is P-R-A-B-H-U.

15 DR. PRABHU: Good morning, Your Honor.

16 THE COURT: Good morning, Doctor.

17 MR. OH: And representing the Massachusetts Chapter of
18 the American Academy of Pediatrics, Dr. Brenda Pring.

19 THE COURT: Good morning, Doctor.

20 MR. OH: And I would have liked to bring the Jane Does
21 in. As you know, we have three Jane Does, but if we -- maybe
22 if we get to a trial on the merits, I will -- that will happen.

23 THE COURT: Thank you, Mr. Oh.

24 MR. OH: Thank you.

25 THE COURT: I appreciate it.

1 So we're dealing with three things. I'd like to
2 tackle them, I think, in order of difficulty. The first is the
3 motion to supplement that was filed this morning -- the motion
4 for leave to file a supplemental declaration.

5 Mr. Belfer, I saw this only this morning. Have you
6 seen what he filed on the attached declarations?

7 MR. BELFER: I saw it last night, Your Honor.

8 THE COURT: Mr. Oh, I'll hear you as to the motion for
9 the leave to file the additional declarations.

10 MR. OH: I'm sorry?

11 THE COURT: I'll hear you as to the motion for leave
12 to file the additional declarations.

13 MR. OH: Yes, Your Honor.

14 One of the amazing things about this case has been how
15 there are so many people who have come had forward wanting to
16 help, and it was just recently that Dr. Diana Zuckerman who
17 runs a not-for-profit in D.C. reached out to us to let us know
18 that she had been vetted for the ACIP back in June by a partner
19 at Siri & Glimstad, and so we got the declaration on file as
20 soon as we could or move for leave to file it as soon as we
21 could.

22 And then the other two declarations are to maybe
23 complete the record up to as close to possible as this moment
24 from Dr. Kressly, who is the -- was the president of the
25 American Academy of Pediatrics up through the end of last year,

1 and Dr. Suzanne Berman, who is a pediatrician in Tennessee, and
2 they are both -- those declarations speak to the compounding
3 harm coming out of the January 5, 2026, childhood schedule
4 change, and how they have to plan now for what they anticipate
5 is going to happen at the February 25 through 27 ACIP meeting.

6 Dr. Malone, who is the vice chair, posted on his
7 Substack that at the next ACIP meeting the ACIP would have to
8 vote to align the childhood schedule with the Vaccines for
9 Children Program list.

10 And if there's anything we've learned from the
11 secretary's department is that they forecast what they're going
12 to do and then they do it.

13 And so my clients have had to start planning now and
14 divert resources now in the event that they're -- they do what
15 they say they're going to do, which we, kind of, have no doubt
16 that they're going to do, so that is why we got these
17 declarations in as soon as possible.

18 And, as you know, we thank you for expediting this,
19 and, you know, we filed the amended complaint and then the PI
20 motion, and then the government got their two weeks to respond,
21 and it was just this past Monday.

22 So this hearing today is kind of like our reply brief
23 on both our motion for leave and on our motion for preliminary
24 injunction, and so we've felt like we should try to supplement
25 the record to make it as current as possible.

1 THE COURT: Thank you, Mr. Oh.

2 Mr. Belfer, I understand you object.

3 MR. BELFER: We do, Your Honor.

4 Plaintiffs filing last night was wholly improper
5 because those declarations could have been filed when
6 Plaintiffs filed their original PI motion.

7 With regard to the Zuckerman declaration, Plaintiffs
8 claim that that responds to our arguments that Plaintiffs have
9 not shown evidence of improper influence.

10 But it was no surprise that in our PI opposition, we
11 would contest whether they had evidence of inappropriate
12 influence. That was wholly predictable.

13 And if Plaintiffs had evidence supporting their
14 inappropriate influence claim, they should have presented that
15 evidence in their PI motion.

16 In particular, the Zuckerman declaration is about
17 events that occurred on June 12th, 2025. That's eight months
18 ago. There is no excuse whatsoever for filing a declaration on
19 the eve of a PI hearing about evidence that occurred eight
20 months ago. If Plaintiffs had evidence, it should have been in
21 their PI motion, not filed last night.

22 With regard to the Kressly and Berman declarations,
23 those simply provide more evidence about what Plaintiffs allege
24 is additional harm, but, again, those declarations could have
25 been filed when Plaintiffs filed their PI motion.

1 They're based on a post from Robert Malone on
2 December 18th, 2025. That is well before Plaintiffs filed
3 their PI motion. There is, again, no excuse whatsoever for
4 filing declarations on the eve of the PI hearing in February
5 when those declarations are based on a post from December 18th,
6 2025, and could have been submitted with Plaintiffs' PI motion.

7 The only new information that postdates Plaintiffs' PI
8 motion is the Kearney article regarding the KFF tracking poll
9 which is from February 6th, 2026. That is the only information
10 that is new.

11 Even there, that's from February 6th, that could have
12 been filed before last night giving us at least an opportunity
13 to respond, so we don't think there's any excuse for filing it
14 last night, but even with regard to that, I think if -- you
15 know, we think all of this is improper. If the Court were to
16 consider any of this, we would request at least several
17 business days to respond.

18 But, again, we think that all of these declarations,
19 you know, should have been filed, you know, when Plaintiffs
20 filed their original PI motion. There's no excuse for filing
21 them last night.

22 THE COURT: Thank you, Mr. Belfer.

23 I am sympathetic to -- you know, I only read this at
24 6:30 this morning, that would have -- I would have preferred to
25 read it earlier, not this morning but earlier in time on a

1 previous day, so I'm sympathetic to your argument.

2 What I was wrestling with this morning is I had told
3 you all I was open to taking evidence today and putting on
4 witnesses, and given that that is what I had told you I was
5 open to doing, I am inclined to accept these declarations.

6 I think your request that you have several days is
7 more than reasonable, so recognizing that I have to make -- I
8 have to make a decision on this case on an uncomfortably tight
9 time frame, if I gave you until next Tuesday or Wednesday,
10 would that be enough time for you to respond?

11 MR. BELFER: Next Wednesday, yes. Thank you.

12 THE COURT: Let's say next Wednesday by 5 o'clock, and
13 I think, you know, what's good for the goose is good for the
14 gander, I think you can respond -- I'm not limiting you on what
15 you can respond with, so if you want to add additional
16 declarations that are directly opposed to this, I can tell you
17 of the -- I will say this only to set the table a little bit, I
18 don't find the tracking poll information to be terribly
19 compelling.

20 I will have some questions as we get into the hearing
21 today about the VFC implications. I did find that to be an
22 interesting point and one worth considering, so, again, submit
23 whatever you want. I will read and consider whatever you want
24 to submit, but just by way of what my initial inclinations are,
25 that tracking poll is not -- I am not finding it particularly

1 | persuasive.

2 So the motion for leave to file is allowed. I'll deem
3 these -- well, you'll file it later -- you know, we file it
4 today as the motion for leave to file allowed.

5 MR. OH: So that motion has been granted.

6 THE COURT: Yes.

7 MR. OH: So then it would be appropriate for me to
8 refer to those declarations later -- during the course of this
9 hearing.

10 THE COURT: Yes.

11 MR. OH: Thank you, Your Honor.

12 THE COURT: So we have two remaining items. The first
13 one is the motion to amend, and the second one is the motion
14 for the PI. I want to do the motion to amend first because I
15 think it -- in terms of what we're considering, that just makes
16 sense.

17 So, Mr. Oh, I'll give you the floor on your motion to
18 amend.

19 MR. OH: Thank you, Your Honor.

20 Anticipating that you were going to be taking this up
21 first, so I think it's important to go through the case
22 chronology to put into perspective how we got here with the
23 fourth amended complaint.

24 So when we first filed this action on July 7th, it
25 challenged the May 19 secretarial directive, and then within 21

1 days, we amended as a matter of course, a matter of right under
2 the federal rules, so it was -- that was not a substantive
3 change to the complaint other than adding the Massachusetts
4 Chapter of the American Academy of Pediatrics and a Jane Doe.

5 So the first amended complaint really is the one that,
6 kind of, kicked off this case. Then on August 20th, we were
7 able to find another Jane Doe 3; she resides on Bainbridge
8 Island off the coast of Seattle, and we added a modest number
9 of factual allegations, so that also wasn't a substantive
10 amendment.

11 And then that is the complaint on which we set a
12 briefing schedule on Defendants' motion to dismiss, and
13 Judge Young ordered a briefing schedule that would have taken
14 us into the beginning of October, and we know what happened at
15 the beginning of October.

16 Once the judge set that schedule, Mr. Belfer reached
17 out to me to ask to move the hearing date because of Yom
18 Kippur. The hearing was going to fall on October 1st, and so
19 we filed a joint motion to modify the schedule, and the hearing
20 was moved to October 8th. Okay.

21 And then when we got to the hearing, by the time the
22 hearing was supposed to happen in the interim, the ACIP met on
23 September 19th, and that was the date on which they voted to
24 downgrade the recommendation of the COVID vaccine for everyone
25 under 65, and it may have been an effort to legitimize the

1 secretary's directive that came out on May 19th to downgrade or
2 to remove, actually, the recommendation that children and
3 pregnant women receive the COVID vaccine.

4 And then if you'll recall -- I know we're taking this
5 up at the next hearing -- but if we will recall, inexplicably
6 the schedule was changed from -- on the childhood schedule
7 part, from routine to shared clinical decision-making when the
8 secretary announced in his video on X that it was -- he
9 instructed the CDC to remove it.

10 So -- but regardless, the government shut down
11 October 1st. We filed a motion to lift the stay. That is when
12 the case got transferred to you, and then we had a hearing in
13 this courtroom on October 30th.

14 And at that time, the government argued, and Isaac had
15 told me, that the government believed that the September 19th
16 ACIP action mooted our second amended complaint, so, of course,
17 to head that off, we said we'd file an amended complaint that
18 would incorporate also a challenge to the September 19th, 2025,
19 downgrade vote.

20 And we filed our third amended complaint on
21 November 15th -- I'm sorry -- November 5th. And in that, that
22 is what -- really what was a first real substantive amendment
23 to the complaint where we challenged the May 19th secretarial
24 directive, the September 19th downgrade to shared clinical
25 decision-making.

1 And then by that time, we had had two meetings of this
2 ACIP, and we felt that the record had developed enough to be
3 able to state a plausible claim under FACA with regard to the
4 ACIP, so the motion to dismiss the third amended complaint was
5 filed on November 19th, and then shortly thereafter the ACIP
6 met on December 4 and 5.

7 And that was when they voted to remove the birth dose
8 of the hepatitis B vaccine, and, as we stated in our PI motion
9 brief, there were a host of false and misleading statements
10 made at that meeting.

11 And so at the hearing on the motion to dismiss on
12 December 17th, we -- I think I might have indicated to Isaac
13 that we would likely be filing a fourth amended complaint.

14 So the Court took our -- the motion to dismiss under
15 advisement. We made you and your staff work through the
16 Christmas holiday, and you came out with your decision denying
17 the motion to dismiss on January 6th.

18 Now, the day before was when the big announcement came
19 of the change to the childhood schedule and that the
20 January 12th status hearing is when this fourth amended
21 complaint was filed.

22 THE COURT: Right.

23 MR. OH: So it's a little bit of a miscount, I think,
24 to say that there were three amendments to the complaint in
25 that the first one was amendment as a right; the second one was

1 just adding two other parties; and then -- so the third amended
2 complaint was one that really joined together in this court
3 the -- most of the issues that are now before the Court.

4 So given that timeline, I think it was reasonable for
5 us to file this fourth amended complaint and put these issues
6 before Your Honor, because, I think contrary to what the
7 government says in their opposition, all these actions are
8 related. That has been our theory, quite frankly, throughout,
9 that the secretary is trying to undertake fundamental changes
10 to United States vaccine policy, and he's doing it in a variety
11 of different ways.

12 And we talked at the January 12th status about, well,
13 if we amend the complaint, we could -- we had the option of
14 filing another case; we likely would have filed it here. It
15 clearly is a related case. It would have ended up in your
16 courtroom, and then --

17 THE COURT: Well, let me ask you, I get all those
18 points. I think you could have filed another case. There's no
19 question. It would have been deemed related, that's true.

20 What's the -- spin out the next six months. I mean, I
21 think Mr. Belfer's going to say you can't amend the complaint
22 every three weeks to add additional actions that were
23 undertaken by the various parties.

24 And I find that -- I don't know where to draw that
25 line, so help me figure that out. Like, where it --

1 MR. OH: Where to draw the line?

2 THE COURT: Yeah. At what point do we say we have to
3 move forward with the allegations as they are? So you don't
4 anticipate amending it again.

5 MR. OH: Well, I do not want to make a commitment not
6 to amend a complaint or filing another action.

7 THE COURT: And I'm not asking you to. I'm not asking
8 you to make that commitment, but if there's another six months
9 that -- you know, we -- we will eventually set a schedule for,
10 you know, substantive discovery and resolving the case on the
11 merits, and that's going to be certainly several months at a
12 minimum.

13 Other things could happen, and every time something
14 else happens, it seems like we could get back to this point,
15 and so I understand that you have a right to amend the
16 complaint, and different things happen and that's why -- things
17 happened and that's why you amended. I'm not saying that's
18 unreasonable, but I wonder where -- I wonder how I'm supposed
19 to cabin it.

20 MR. OH: Well, I think this might be an exercise in
21 drawing a couple of lines, and on this particular last action
22 that was taken, we would truly like to get to a decision on the
23 merits as soon as possible, and so that would --

24 THE COURT: The January action?

25 MR. OH: The January action.

1 THE COURT: Okay.

2 MR. OH: We know that filing another amended complaint
3 would restart the clock in a way. They'd file another motion
4 to dismiss. They'd use that as an excuse not to produce an
5 administrative record again, and we do not want that -- either
6 of those to happen.

7 THE COURT: Okay.

8 MR. OH: So at this particular point in time, we would
9 like to stand firm and draw the line here on the actions
10 challenged in the fourth amended complaint and get to a
11 decision on the merits.

12 I hear what you're saying with regard to are we going
13 to amend again, and it's duly noted what impact that would have
14 on you and on the case and on my clients, so at this particular
15 point, there is a line drawn; let's get to a decision on the
16 merits on what allegations are -- claims are in the fourth
17 amended complaint.

18 THE COURT: Thank you, Mr. Oh.

19 Mr. Belfer.

20 MR. BELFER: In their proposed fourth amended
21 complaint, Plaintiffs add three new and unrelated actions.
22 They challenge ACIP's June 2025 vote regarding the use of
23 thimerosal as a preservative in influenza vaccines, ACIP's
24 December 2025 vote regarding the hepatitis B vaccine, and then
25 the January 2026 changes to certain childhood and adolescent

1 immunization recommendations which did not change the
2 recommendation for COVID-19 vaccines.

3 So at a high level, before the fourth amended
4 complaint, this case focused on the COVID-19 vaccine. Now they
5 want to add new actions, unrelated actions regarding views of
6 thimerosal in the influenza vaccine and the hepatitis B vaccine
7 and then the other vaccines that were affected in January.

8 And so this amendment is improper for several reasons.
9 First, it would unduly prejudice Defendants and delay the
10 resolution of this case.

11 Second, it's futile.

12 And third, specifically with regard to the June 2025
13 ACIP recommendations, those were unduly delayed.

14 So to start with prejudice to Defendants, as
15 discussed, the new complaint adds novel claims against three
16 separate actions which regard the influenza vaccines, the
17 hepatitis B vaccine, and other vaccines that were affected by
18 the January action, specifically vaccine recommendations for
19 rotavirus, influenza, meningococcal disease, hepatitis A, and
20 hepatitis B. The hepatitis B vaccine actually was revised in
21 December, but still there were changes regarding rotavirus,
22 influenza, meningococcal disease, and hepatitis A.

23 The COVID-19 vaccine recommendations were not changed
24 in January, and so the action in June was about influenza. The
25 action in December was about hepatitis B, and the action in

1 January was about rotavirus, influenza, meningococcal disease,
2 and hepatitis A, again, not about COVID-19.

3 And so these new claims do not arise out of the same
4 factual allegations pleaded in the third amended complaint.
5 They're different actions with different administrative records
6 related to different vaccines and, in some cases, involving
7 wholly different actors. Adding these unrelated claims is
8 inefficient and would delay the date of a final appealable
9 order in this case.

10 Now, Plaintiffs have admitted -- they admitted at the
11 last status conference and they again admitted today that
12 they're not going to stop at a fourth amended complaint.

13 What they said at the last status conference is from
14 the beginning the facts are going to develop every day and
15 there might be new actions that need to be challenged, so this
16 case will continue to metastasize.

17 Plaintiffs are going to try to thwart any change in
18 federal vaccine policy, but that's simply improper. Plaintiffs
19 cannot keep -- they cannot subject Defendants to a moving
20 target of litigation and bombard the Court with amendment after
21 amendment, and that's from the *Thomas* case in this court. Both
22 Defendants and this Court must have certainty about the scope
23 of this case and the end point for resolution.

24 And, again, as Your Honor discussed with Plaintiffs,
25 they could simply file a new case. That would be wholly

1 proper, and the benefit there is that that would allow this
2 case to reach a final appealable judgment sooner rather than
3 later, which I think is in everyone's interests.

4 We also would not concede that any new case would be
5 related, you know. Under this Court's local rules, a case is
6 related if they involve the same or substantially similar
7 issues of fact, and, as discussed, we don't think that's true
8 here.

9 Under local Rule 40.1(g)(3) civil cases, even though
10 they involve some of the same parties, shall not be deemed
11 related to each other solely on the ground they involve the
12 same or substantially similar challenges to a law, regulation,
13 or government policy or practice or otherwise involve a common
14 question of law.

15 So we certainly would not concede that any new case
16 would be related, but even if it were related, the benefit of
17 filing a new action challenging these new claims related to new
18 vaccines is that it would allow this Court to reach a final
19 appealable judgment as soon as possible on the existing claims,
20 which I think is in everyone's interest.

21 Turning to futility, you know, first, we maintain that
22 Plaintiffs lack standing to assert their new claims. In their
23 motion for leave to amend, they do not even attempt to allege
24 that the June 2025 ACIP recommendation about thimerosal injured
25 them. There's no allegation of injury from the June vote, so

1 right off the bat, there's no basis to challenge the June ACIP
2 vote.

3 There's this, kind of, general allegation that the
4 final agency actions challenged herein injured them, but
5 Plaintiffs then go on to focus on the December ACIP vote about
6 hepatitis B and the January 5th actions.

7 But you can't have that, kind of, general allegation
8 that the actions challenged herein harm you. Under binding
9 precedent, under the Supreme Court's decision in *Lujan* and the
10 First Circuit's decision in *Hochendoner*, you have to show
11 injury traceable to each challenged action and the Court has to
12 assess standing claim by claim, and so because Plaintiffs have
13 not even alleged any injury from the June action, there's no
14 basis to challenge that claim.

15 And then regarding the December ACIP vote and the
16 January action, Plaintiffs basically reprise their standing
17 theory from the third amended complaint, and, you know, in our
18 PI motion, we talked about those standing issues, and so we
19 think they don't have standing for any of their claims but
20 certainly not for the June ACIP vote.

21 We also believe that the new actions aren't reviewable
22 because they are committed to agency discretion and not final
23 agency action, which we can talk about when we get to the PI.

24 And then the final reason why this amended complaint
25 is improper is that Plaintiffs unduly delayed challenging the

June 2025 ACIP recommendation.

In *National Federation of the Blind*, this district held that undue delay on its own may be enough to justify denying a motion for leave to amend.

And in *Steyr*, the First Circuit held "The longer a plaintiff delays, the more likely the motion to amend will be denied, a protracted delay, with its intended burden on the opponent and the Court, is itself a sufficient reason for the Court to withhold permission to amend."

So the substantial delay in challenging the June action is itself reason to prevent Plaintiffs from challenging that action now.

So under relevant case law, you have to consider what Plaintiffs knew or should have known and what they did or should have done that's based on this Court's decision in *Ryan*.

And so here, considering what Plaintiffs knew or should have known last year, they unduly delayed challenging the June action. They did not challenge this at the earliest opportunity as they claim.

And, you know, we can contrast this to cases where amendment is proper, so, you know, this is not a case where there's newly discovered evidence which was not previously available that suddenly came to light.

Here, Plaintiffs knew about the factual predicate for the challenge of the June action back in June. There's no

1 excuse for waiting eight months or at least seven months to
2 challenge it now.

3 They could have challenged the June action in their
4 original complaint or certainly by the time they filed their
5 first or second amended complaint. By the time they filed
6 their second amended complaint, CDC had adopted the June
7 recommendation, so the June recommendation certainly could have
8 been challenged in the second or third amended complaint.
9 There's no excuse for waiting until now.

10 So, essentially, the plaintiffs would need to show due
11 diligence and a reason for the substantial delay, and they have
12 not shown that. There's no explanation for why they waited
13 until now to challenge the June 2025 vote.

14 And so -- and comparing the timelines here to other
15 cases, Plaintiffs waited until January 19th, 2026, which is
16 over six months after filing the original complaint and over
17 four months after filing their seconded amended complaint.
18 That exceeds the delays of four months and even less than three
19 months that the First Circuit has found to be undue delay
20 warranting denial of a motion for leave to amend, and you can
21 see that's the *Ryan* case citing the First Circuit's decisions
22 in *Villanueva* and *Kay*.

23 So, again, the First Circuit has held that delays of
24 three or four months are sufficient delay to deny leave to
25 amend. And here, Plaintiffs waited over six months and

1 certainly over four months after filing their second amended
2 complaint.

3 And so what the First Circuit held in *Nikitine* --
4 sorry -- yes, in *Nikitine*, is that when there's been -- a
5 considerable period of time has passed between the filing of a
6 complaint and the motion to amend, Courts have placed the
7 burden on the movant to show some valid reason for his neglect
8 and delay.

9 Here, Plaintiffs don't even attempt to meet that
10 burden to show why they delayed so long to challenge the June
11 action.

12 And then, you know, a final point is that this delay
13 would be prejudicial because, again, adding a new action,
14 challenging a new vaccine with a new administrative record
15 would delay this case. It would require the production of a
16 new administrative record likely delaying final resolution of
17 this case, and so it would prejudice Defendants to add that
18 claim now.

19 And so I think for all those reasons, because it would
20 prejudice Defendants, because the new claims are futile, and
21 because especially the challenge to the June action was
22 substantially and unreasonably delayed, we believe the Court
23 should deny leave to amend.

24 THE COURT: Thank you, Mr. Belfer.

25 Mr. Oh, any --

1 MR. OH: May I --

2 THE COURT: -- response?

3 MR. OH: -- respond?

4 THE COURT: Sure.

5 MR. OH: Would you mind putting the PowerPoint back
6 up?

7 THE COURT: Would I mind what?

8 MR. OH: Thank you.

9 So in terms of delay, we filed our fourth amended
10 complaint two weeks after the decision memo came out, so we did
11 that as quickly as possible. There was already a pending
12 motion to dismiss when the ACIP met -- I believe the motion to
13 dismiss was pending by then -- yes, by the time the ACIP met on
14 December 4th, and so in terms of certainly those two actions,
15 there was no delay.

16 We had already covered the September action in our
17 third amended complaint, and with regard to the June vote,
18 again, as this case has developed and you see, kind of, the
19 drip, drip, drip of what they're doing, the June ACIP meeting
20 was the first meeting of this ACIP.

21 And at that meeting, a woman by the name of Lyn
22 Redwood was invited to speak. She is the former president of
23 Children's Health Defense, the anti-vaccine organization
24 founded by Robert F. Kennedy, and she was there to speak on
25 thimerosal, an issue that has been thought -- people thought

1 had been pretty well settled for 20 years that thimerosal does
2 not cause autism.

3 And what thimerosal is important for is as a
4 preservative in multidose vials of, like, flu vaccine, so when
5 there are -- let's say, in this country rural community health
6 centers or rural pediatric offices or federally qualified
7 health centers where they need to stock up on flu vaccine and
8 sometimes they need to have these multidose vials for storage
9 reasons, for cost reasons, and when you keep sticking a needle
10 into that same vial, you do want to have a preservative in
11 there.

12 And the amounts of thimerosal in this multidose vials
13 are so miniscule, but it does have an impact on, yes, a pretty
14 small percentage of the providers and the folks who give
15 vaccines in this country. It actually has a much bigger impact
16 overseas.

17 Regardless, when we had the opportunity to amend, we
18 thought we should also include that because this was, again,
19 another example of a continuing pattern of trying to change
20 fundamental vaccine policy for really unexplained, in our view,
21 not reasonable and not rational reasons.

22 And so I do, kind of, think that the defendants'
23 argument that we're creating a moving target and that
24 Plaintiffs' metastasizing complaint is more delay in the entry
25 of final judgment, I find that -- those arguments to be a

1 little bit rich in that they're the ones creating the moving
2 target.

3 They're the ones who have -- are trying to implement
4 policy that is fundamentally different from what the U.S. has
5 done up until last year.

6 And what they are doing is metas -- I need to be able
7 to pronounce that correctly -- metastasizing harm throughout
8 the United States by their, I think, ill-conceived changes in
9 policy.

10 So we have people in this courtroom who have had the
11 courage to stand up and take on the federal government in a
12 pretty hostile environment these days, and they've had the
13 courage because they care about what is happening, and so we
14 should be given in the interest of justice -- and you have
15 discretion -- great discretion in allowing amendments to
16 complaints -- we have been diligent. We have been working
17 around the clock. And I've got to thank my team for that
18 because there's been so much material to handle, and we have
19 been moving with dispatch.

20 And so, as I said, right now with this fourth amended
21 complaint we need to address that childhood schedule. It was
22 timely. And the whole issue about us delaying when --
23 Defendants when they came before Your Honor and filed their
24 joint status report on when they would produce the
25 administrative record, if you'll recall, they said, give us 135

1 days to produce administrative record on the January 5 action,
2 until June 5th. I mean, talk about delay.

3 So we are moving with dispatch to try to at least
4 deter, if not stop, what we think is policy that is harming the
5 public. So I -- I implore Your Honor to grant leave to amend.

6 THE COURT: Thank you, Mr. Oh.

7 So my thinking on this is as follows: I am sensitive,
8 Mr. Belfer, quite sensitive, to the fact that the complaint has
9 grown to encompass a much broader set of administrative actions
10 then was initially present.

11 I do see that the ACIP composition runs throughout
12 them, and so they are -- I don't know if they would be -- if
13 all of the possible complaints they could file would be deemed
14 related under the local rules but certainly a lot of them would
15 be, and I do see the ACIP composition being a theme that is
16 common throughout all of them.

17 This case has had some unfortunate delays as a result
18 of the government shutdown, as a result of it being transferred
19 between sessions in this building, but at this point, we
20 haven't started to collect the administrative record.

21 And so your very reasonable point that collecting the
22 administrative record and then being asked to collect a
23 different administrative record is a huge burden, but we
24 haven't gotten there yet, and so I'm not going to find that
25 the undue prejudice from the delayed amendment is sufficient to

1 deny the motion to amend.

2 As to the June 2025, the undue delay in adding that, I
3 think that that -- that is a close call for me. It's a very
4 close call, but since it falls within the general umbrella of
5 the composition of the ACIP to begin with, I don't think that
6 there is much of an additional burden in adding that to the
7 complaint.

8 As to whether -- you know, as to whether or not
9 they've alleged standing on all of those issues and whether or
10 not some of those decisions are committed to agency discretion,
11 that is very well briefed in the PI. I'm going to essentially
12 table those because I think that that's a decision I have to
13 make on the PI action.

14 So in terms of the argument that the amendment is
15 futile, I'm going to deny that argument at this stage because
16 I'm going to take it up much more substantively at the
17 preliminary injunction, which is what we're going to get to
18 shortly, so at this time, I'm going to allow the amendment.

19 I will just caution that if the administrative record
20 had been produced, I might feel very differently because I
21 do -- Mr. Belfer, you have said, and, Mr. Oh, you have said,
22 you are all anxious to get this case resolved; I agree. I
23 think my inclination to get the case resolved is evident in the
24 rulings that I've made about the timing in this case thus far
25 and setting myself up to have to render a decision on this

1 motion with -- in what I would normally like to be several
2 weeks and instead several days. I can tell you that I will do
3 everything I can to accelerate resolution of this case to every
4 possible degree.

5 And further amendments, Mr. Oh, I hear your argument
6 that, how can I -- how could the Court fault me for wanting to
7 amend, because actions you believe are illegal continue to
8 occur, right. That's a compelling argument.

9 But there is -- Mr. Belfer's response of, if the
10 administrative record changes every day, how is the case ever
11 going to go anywhere? It is going to go places, so I am going
12 to allow the motion to amend.

13 I'm not precluding you from arguing the futility
14 arguments in the PI. I think I have to deal with them much
15 more substantively there. I've wrestled specifically with
16 committed to agency discretion. That's an argument you briefed
17 very well, and I have spent a lot of time thinking about it.

18 But since I'm going to be resolving that in the PI
19 context and since I think, for the sake of completeness, moving
20 this case forward with everything that is in front of it,
21 including all the ACIP actions, makes sense, I'm going to allow
22 the motion to amend.

23 But thank you both for your arguments on it. I
24 appreciated them.

25 That turns us to what I thought and I suspect is the

1 most substantive part of today's hearing which is the
2 preliminary injunction hearing.

3 Mr. Oh, I will leave it to you to take that up in the
4 manner in which I suspect you've already planned, but the floor
5 is yours.

6 MR. OH: Thank you, Your Honor.

7 So just in terms of logistics here, I take it that the
8 last 45 minutes doesn't cut into my two hours that you were
9 going to allow for --

10 THE COURT: This is a matter of significant
11 importance. This is a matter that I have spent several hours
12 on just this morning as a result of your filings last night, so
13 I am not -- I am not going to impose a hard -- I am not going
14 to set a timer to say that you have to be done, but I will say
15 that brevity is the soul of wit.

16 MR. OH: Is that --

17 THE COURT: And, Mr. Oh, could I ask you to speak into
18 a microphone?

19 MR. OH: I'm sorry.

20 So, also, just should we -- would you like to take a
21 break at some point this morning?

22 THE COURT: We will take a break at 10:30, from 10:30
23 to 10:45.

24 MR. OH: Got it.

25 THE COURT: But you have the floor. I will ask you

1 questions as we go along.

2 MR. OH: Right.

3 THE COURT: But plan on taking a break at 10:45.

4 Mr. Belfer, the same goes to you. I'm not going to
5 limit your response in a substantive way. You'll have all the
6 time that you need.

7 MR. BELFER: Okay.

8 MR. OH: Thank you, Your Honor.

9 So this hearing is to address two actions or two
10 issues. So before we get there, I thought I'd set some
11 context, and I know I've introduced the party plaintiffs, but
12 for a little more context, we've got American Academy of
13 Pediatrics with 67,000 members; the American College of
14 physicians with 162,000; American Public Health Association
15 with 23,000 individual and 425 organizations, 524; the
16 Infectious Diseases Society of America has 13,000 members;
17 we've got the Massachusetts Public Health Association, also
18 known as the Massachusetts Public Health Alliance with 400
19 individual and organizational members; the Society for
20 Maternal-Fetal Medicine, 6500 members; the Massachusetts
21 Chapter of the American Academy of Pediatrics, 1600. So we've
22 got 275,000 members being represented in this courtroom of
23 people who are standing up because they care about America's
24 public health.

25 And they are working on behalf of these Jane Does and

1 others who have been affected and impacted by the changes
2 coming out of Washington from HHS; two of whom -- Jane Doe's a
3 physician, lives in New England; the other Jane Doe is also --
4 is a Massachusetts resident, and then I've already told you
5 about Jane Doe 3 over in Seattle.

6 And then we had amici come out of the woodwork here.
7 We had seven amicus briefs, and I do commend you and your
8 clerks to reading them. They are extraordinarily well written
9 and --

10 THE COURT: I assure you, Mr. Oh, we've read them.

11 MR. OH: And the amici, I'm sure, thank you. And
12 there are 25 medical and public health organizations
13 representing over 600,000 members who all wanted to do
14 something and volunteer to do something because they care, and
15 that's close to a million members who are permeating this
16 courtroom with the message that we believed and trusted in a
17 process for the last six decades. We believed and trusted in a
18 process that, since 1993, has been incorporated into federal
19 statute.

20 And they are standing up for what they believe is
21 right, and they're standing up for what they believe is
22 fundamentally incorrect, and they would like to see reasonable
23 explanations and not pretextual ones for what is happening now
24 to vaccine policy.

25 And so I'm going to jump into the January 5, 2026,

1 action to change the childhood schedule. So you indicated that
2 you had some questions about the argument about agency
3 discretion and committed to agency discretion.

4 So I will point out for -- in terms of the legal
5 framework, there is a strong presumption of judicial review
6 under the APA of agency action.

7 The committed to agency discretion language in the
8 statute has been interpreted by the Supreme Court to be a very
9 narrow exception and federal action is nearly always reviewable
10 for conformity with statutory obligations.

11 And the Supreme Court said in *Weyerhaeuser* -- the
12 *Weyerhaeuser* case, 586 U.S. 9, that even if a statute confers a
13 great deal of discretion on an agency, that does not make an
14 action unreviewable. Otherwise, a Court could never determine
15 that an agency abused its discretion if all matters committed
16 to agency discretion were unreviewable, so that's the legal
17 framework I think under which --

18 THE COURT: Let me ask you a hypothetical because this
19 is one of the things I've struggled with a little bit. So
20 assume that you think ACIP is correctly constituted; they go
21 through the correct process; they use the evidence-based -- is
22 it EtR?

23 MR. OH: EtR.

24 THE COURT: They go -- they use that correctly. They
25 come up with some recommendations. They give a recommendation

1 on January 2nd that says, we keep the childhood vaccine
2 schedule the same way.

3 And then the agency says, we listened to it; we
4 reviewed that recommendation; we're going to rely on this
5 other -- the other study that they reference, and we're going
6 to not follow the ACIP.

7 Is it possible that that decision by the agency to not
8 follow the ACIP is committed to agency discretion if they had
9 done those initial steps correctly?

10 MR. OH: So the way the process works is that the ACIP
11 makes recommendations and then the CDC adopts.

12 THE COURT: Right.

13 MR. OH: There is really a -- one regulation in the
14 charter that actually spell that out. And so there have been a
15 few instances in history where the CDC director has not adopted
16 a recommendation of the ACIP, but that has been after the ACIP
17 has gone through the rigorous process.

18 THE COURT: Right. So let me rephrase. Let me
19 clarify my question.

20 If that had happened -- when this had previously
21 happened, I don't -- if that was in the briefing, I don't
22 recall it, but if it --

23 MR. OH: I'll be walking you through some.

24 THE COURT: Assume that it happened, that the ACIP had
25 gone through -- it was properly constituted in your mind; it

1 had gone through the evidence-based process, had made its
2 recommendation, had done everything correctly up to the point
3 where it went to the CDC, and the CDC just said, we disagree,
4 and even cited -- maybe cited a similar study. My question is:
5 Is the decision by the CDC committed to agency discretion?

6 MR. OH: I believe it is, Your Honor, but it is not
7 unfettered discretion.

8 THE COURT: Right.

9 MR. OH: There are still guardrails around the CDC
10 director, and those guardrails include the APA's arbitrary and
11 capricious, not in accordance with law, you didn't consider
12 factors, you need to give a reasoned explanation, but, yes, the
13 CDC director does have the authority and the discretion to say,
14 I'm not going to -- I'm not going to adopt the ACIP's
15 recommendation.

16 THE COURT: Okay. Thank you.

17 MR. OH: Okay. So on this issue of being committed to
18 agency discretion, the government cites one statute,
19 Section 243(a). I'm sure you've read it. I've put it here in
20 the PowerPoint just to refresh our recollections as to what it
21 actually says.

22 And I'll first note that I think that this argument is
23 based on a factual fallacy.

24 THE COURT: Okay.

25 MR. OH: The factual fallacy is CDC's issuance of

1 immunization recommendations. Now, issuance is a slightly --
2 it's got different meanings. Okay. And I'm not sure if the
3 government means that the CDC is the one who makes those
4 recommendations, and if that is the meaning that they intended,
5 that is incorrect, because it is the ACIP that makes
6 recommendations and the CDC adopts.

7 So there's a little ambiguity in how they phrased it.
8 I -- we may have parsed that out in a reply brief, but here we
9 are, and if what they meant was the CDC makes recommendations,
10 that is a -- that's incorrect.

11 Now, they say that there's no meaningful standard for
12 the Court to apply in Section 243(a), but I beg to differ,
13 because that statute says that -- and let's also step back and
14 take a look at, kind of, what the purpose of this statute is.
15 It's federal-state cooperation. That's what really the thrust
16 of this statutory section is.

17 And it's the secretary shall also assist states and
18 their political subdivisions in the prevention and suppression
19 of communicable disease, and it also says "shall advise the
20 several states on matters relating to the preservation and
21 improvement of the public health."

22 I don't think it's too difficult to see that this
23 statutory provision provides the Court with the means to decide
24 whether or not downgrading recommendations, reducing access to
25 proven vaccines is consistent with this statutory provision.

1 That's number one.

2 But I think even more egregious, Your Honor, is that
3 the government's brief ignores 13 statutes that have been
4 enacted since 1993 that provide meaningful standards for this
5 Court to review the agency actions challenged here.

6 And I intend to go through all 13, not all 13 in great
7 detail, but I think it's important to run through these 13
8 statutes to see how Congress has relied on the ACIP process
9 to -- and incorporated them into statutes and have relied on
10 the ACIP being an independent expert advisory committee that
11 applies science, is objective, and is insulated as much as
12 possible from considerations like budget and other political
13 potential issues. Budgets -- budgets are a political issue.

14 THE COURT: Sure.

15 MR. OH: So it starts with -- let's see if this will
16 advance. Thank you.

17 Before we get into those 13 statutes, the secretary --
18 I think the analysis starts with 42 U.S.C., Section 217(a)
19 where it gives the authority to the secretary to appoint such
20 advisory councils or committees as he deems desirable for such
21 period commencing on a date specified by the secretary to
22 advise him in connection with his functions. Okay. This is a
23 discretionary advisory committee.

24 Now, you mentioned that you had some questions
25 potentially about the Vaccines for Children Program, and that,

1 quite frankly, is where we're going to start.

2 THE COURT: Great.

3 MR. OH: And there is some very interesting history
4 behind this program. There is a professor of law at George --
5 emeritus professor of law at George Washington University by
6 the name of Sara Rosenbaum, who was a mentor to Richard Hughes
7 here, also to Will Walters somewhere here in the gallery, and
8 she was instrumental in shepherding this program through to it
9 becoming law, and this is the first statute chronologically
10 that incorporated specifically reference to the ACIP, and so
11 the provision --

12 THE COURT: Can you walk -- this is probably something
13 that is included in your briefing and I just didn't understand
14 it, but the Vaccine for Children program, as I understand it,
15 covers 50 percent of children in the United States; right?

16 MR. OH: Yes.

17 THE COURT: But is distinct from the Medicare program;
18 right?

19 MR. OH: It is.

20 THE COURT: These are not --

21 MR. OH: Medicaid program.

22 THE COURT: These are not 100 percent overlapping.
23 Yeah. I'm sorry. Yes. There's no 65-year-olds at least as
24 we're talking about here.

25 So tell me how do you -- who qualifies for it?

1 Because there's a lot of talk about when we're on this program
2 and when we're not, but I don't totally understand.

3 MR. OH: Essentially, it's all children covered by
4 Medicaid.

5 THE COURT: But it's more than that; right?

6 MR. HUGHES: Your Honor, in addition to Medicaid
7 beneficiaries, it also covers underinsured, uninsured, Alaska,
8 Native, and American Indian children.

9 THE COURT: That's how you get to 50 percent.

10 MR. HUGHES: Yes.

11 THE COURT: You add to Medicaid, which is something
12 like 30 percent, and then --

13 MR. HUGHES: Yes.

14 THE COURT: -- you get to --

15 MR. HUGHES: Yes. Correct.

16 THE COURT: Great. I didn't totally understand it,
17 but that clears it up. Thank you.

18 MR. OH: Now, we pulled the legislative history, and I
19 think that this passage is pretty telling as to why Congress
20 decided to vest responsibility in the ACIP and not the CDC
21 director or not the HHS secretary to make recommendations on
22 immunizations, and so this is a house report, Number 103-111,
23 dated May 25 of 1993.

24 Quote, the committee intends that the ACIP be allowed
25 to conduct its work in an objective manner concerned only with

1 issues of public health and medicine. While decisions
2 regarding the listing of recommended vaccines will undoubtedly
3 have some budget implication for the UAIP, Universal Access to
4 Immunizations Program, and the secretary, it is the committee's
5 intention that the ACIP's work be rigorously separated from
6 such concerns.

7 So another way to read that is that Congress wanted to
8 insulate the ACIP from political pressure. Congress wanted to
9 take the decision on what the immunization recommendation
10 should be away from those who had -- who are political
11 appointees, those who have to be nominated and confirmed by the
12 Senate or -- and so the HHS secretary is not named here, the
13 CDC director is not named here. It is the ACIP.

14 And this is a first example of Congress recognizing in
15 statute that science is going to develop; new vaccines are
16 going to be developed. We do not want to have to relegislate
17 every time there's a new vaccine developed. We are going to
18 vest that responsibility in an independent, objective advisory
19 committee whom we, at this point, know is filled with people
20 who have the scientific expertise in all facets of vaccinology,
21 which is, as you are probably beginning to understand, has many
22 different domains.

23 And so with VFC, Congress thought, well, we've got an
24 advisory committee that we believe the secretary has appointed
25 in good faith and we trust this ACIP to be and we want them to

1 be screened from political budgetary concerns, and so that's
2 the start of incorporation of the ACIP into congressional
3 statute.

4 THE COURT: You're showing me legislative history
5 that's not about the creation of ACIP. It's about the VFC.
6 It's just referencing ACIP.

7 MR. OH: It is. The ACIP had been around since 1964.

8 THE COURT: Right.

9 MR. OH: So then I think this is a good time to talk
10 about the HepB road. I'm going to jump ahead in time here to
11 the January 5 action to try to put it into context with what we
12 just saw about the VFC.

13 So it was only two years before the VFC program became
14 law that the ACIP recommended a universal birth dose of the
15 HepB vaccine, and it was in 1991. And the ACIP struggled with
16 HepB for a decade in the 1980s, and they adopted this
17 risk-based approach.

18 THE COURT: Right.

19 MR. OH: But it was not catching nearly enough people,
20 and if -- if someone doesn't get vaccinated early, it often
21 happens that they don't come back or they fall through the
22 cracks and then they are vulnerable to HepB, which is a
23 devastating disease, and that targeted strategy, that
24 risk-based approach, didn't work, but that is exactly what the
25 January 5 action is doing. It's reverting back to the 1980s.

1 THE COURT: Right.

2 MR. OH: And as we say in our brief at page 20, a
3 targeted strategy that focused on vaccinating only infants with
4 HepB positive mothers was implemented throughout the '80s and
5 it was unsuccessful at decreasing rates of disease, and we cite
6 to the 1991 CDC MMWR.

7 And once there was a switch to the universal
8 vaccination, it reduced pediatric hepatitis B cases by 99
9 percent, from 16,000 annually to fewer than 20 annually. Talk
10 about a success. That was a successful recommendation that has
11 saved lives. It has prevented hospitalizations, prevented
12 serious illness.

13 And one of the just very obvious omissions from the
14 Hoeg/Kulldorff assessment that is the main justification for
15 the January 5 action doesn't mention this at all, so it seems
16 like an irrational explanation and an irrational decision for
17 the secretary and the CDC director to remove the birth dose of
18 hepatitis B.

19 And, Your Honor, so we threw a lot of paper at you,
20 and attached to our preliminary injunction motion at ECF 185-23
21 is a federal rule of evidence 1006 summary exhibit that walks
22 through every single time the ACIP took up the HepB vaccine and
23 what to do and how much rigor and analysis and study that they
24 did. Now, there was no GRADE, no EtR back then.

25 THE COURT: Yeah.

1 MR. OH: But it started October 14th, 1981, and it
2 goes all the way through to, of course, 1991 where they arrived
3 at a universal birth dose.

4 And there's no explanation for why they ignored the
5 mountain of evidence that had been developed in the 1980s about
6 the HepB vaccine, and there is no rational explanation given
7 for why they ignored all the times that the ACIP studied this
8 vaccine and debated it and then ultimately ended up with the
9 universal birth dose recommendation.

10 I think that the practitioners in the gallery here
11 or who are potentially going to -- I don't know -- read this
12 transcript or read your decision are going to be -- they're all
13 wondering, we went through this in the 1980s and we know that
14 the ACIP made this recommendation in 1991 that has reduced the
15 rate of HepB by 99 percent with this universal birth dose, so
16 explain to us, give us a rational explanation for why you're
17 doing this.

18 And nothing that they have provided so far -- we don't
19 have an administrative record -- but nothing that they have
20 provided us has shown that.

21 So, you know, this was a slide I showed you at the
22 motion to dismiss hearing. I do think it's -- it shows just --
23 it's one degree of separation from an ACIP recommendation that
24 ends up on the CDC immunization schedule to all the medical
25 organizations, to public health organizations, to physicians in

1 private practice, the patients, the pharmacists, insurers, et
2 cetera.

3 And when you change the recommendation on a very,
4 very, very successful immunization, these people deserve a
5 better explanation than what they've gotten.

6 So after VFC, Congress amended the Immigration and
7 Nationality Act and the veterans' benefit statute to, again,
8 incorporate recommendations by the Advisory Committee on
9 Immunization Practices, so the amendment to the Immigration and
10 Nationality Act was 8 U.S.C., Section 1182(a)(1)(A)(2),
11 effective September 30, 1996; veterans' benefits 38 U.S.C.,
12 Section 1701(9)G and 10, effective October 9th of 1996.

13 Then there were a variety of preventive measures that
14 were incorporated into the ACA, passed in 2010, if you recall,
15 so there's a statute or provision within the ACA on education
16 and outreach campaign regarding preventive benefits
17 incorporating the Advisory Committee on Immunization Practices,
18 coverage of preventive health services.

19 There's no cost sharing for immunizations that have,
20 in effect, a recommendation from the Advisory Committee on
21 Immunization Practices or the Centers for Disease Control and
22 Prevention.

23 Medicare Part B, another preventive measure, so for
24 seniors at a wellness visit.

25 THE COURT: What happens -- you said on at least a

couple of occasions the director of the CDC has not adopted the recommendation, so if the recommendation is not adopted, how does that interact with these statutes?

MR. OH: Well, it hasn't happened, number one.

THE COURT: I thought you said it had happened.

MR. OH: Pardon me?

THE COURT: I thought you said it had happened.

MR. OH: There have been -- you can fill me in here, Richard. What were the two to three times?

MR. HUGHES: Your Honor, there have been three instances in history in which the CDC director has modified an ACIP recommendation following their recommendation. It happened -- Dr. David Satcher in 1999 rescinded the rotavirus vaccine recommendation. There was a recognition that there were a large number of safety events that were concerning enough that he rescinded the recommendation. He then --

THE COURT: He rescinded it after it had been adopted.

MR. HUGHES: Yes.

THE COURT: Okay.

MR. HUGHES: He then later reconsulted the committee, and they reinstated the recommendation once there was a safer vaccine on the market.

And then there were two other instances where CDC directors actually expanded the recommendation, so Dr. Julie Gerberding with the anthrax recommendation -- anthrax

1 vaccination recommendation as well as Dr. Rochelle Walensky
2 expanded the COVID vaccine recommendation. In both of those
3 instances, they wanted to assure that there was broader access
4 than what the ACIP recommended.

5 THE COURT: So both of those recommended -- I assume
6 anthrax wasn't recommended for everyone. They broadened the
7 constellation of people that it was recommended that would
8 receive it.

9 MR. HUGHES: Yes, additional personnel who were at
10 increased risk, yes.

11 THE COURT: Was that done -- I understand that the CDC
12 has some emergency ability to change these recommendations, but
13 was COVID and the anthrax one done under that emergency
14 authorization?

15 MR. HUGHES: There was no citation to emergency
16 authority. They just did this because they have the authority
17 to make these changes.

18 THE COURT: Okay. And so on those occasions -- well,
19 both of those are -- the two that are expanding -- the two that
20 are expanding the recommendation, I suppose, don't change this
21 that much, but the one that was narrowing the recommendation,
22 would that mean that, for example, under Medicare Part B, that
23 it would stop covering the rotavirus vaccination, or would this
24 statute still look to the ACIP recommendation even though it
25 conflicted with the CDC recommendation?

1 MR. HUGHES: This -- in my view, Your Honor, the
2 statute does point directly to the recommendations. The --

3 MR. OH: And I would say that, yes, the CDC director
4 does have the authority not to adopt an ACIP recommendation,
5 and that --

6 THE COURT: That recommendation still carries today in
7 these statutes that you're walking me through.

8 MR. OH: Well, it is Congress's intent to have the
9 ACIP make the recommendation. None of these statutes say that
10 the CDC director has to adopt them, but Congress wants to vest
11 responsibility in the initial instance in the ACIP to make the
12 recommendation.

13 And they recognize that there's authority -- they
14 recognize that, basically, under, I think, the nondelegation
15 doctrine that the CDC director needs to have the authority to
16 either adopt or not adopt the recommendation of the ACIP, so as
17 long as the recommendation came out of the ACIP, then you're
18 consistent with the statute. Does that make sense?

19 THE COURT: Yes. That does make sense.

20 MR. OH: Okay.

21 THE COURT: Yeah. No. That make sense. Thank you.

22 MR. OH: The Medicaid definition of medical
23 assistance, also part of the ACA, again, no cost sharing with
24 respect to an adult or individual, approved vaccines
25 recommended by the Advisory Committee on Immunization

1 Practices.

2 CHIP, the Children's Health Insurance Program, that's
3 a program that tries to fill the gap between Medicaid and
4 private insurance where there are some people who fall in the
5 middle who don't qualify for Medicaid but can't afford private
6 insurance.

7 This was a little bit mind-numbing trying to work my
8 way through the different statutory provisions to get to the
9 ACIP but the list that the CHIP program uses is the list
10 established and periodically reviewed and, as appropriate,
11 revised by the Advisory Committee on Immunization Practices.

12 And if you look at that parenthetical, an advisory
13 committee established by the secretary acting through the
14 director of the Centers for Disease Control and Prevention, I
15 think -- and there are a number of these different statutes
16 that specifically reference that they are operating through the
17 director of the Centers for Disease Control and Prevention,
18 that is Congress recognizing that the CDC has the authority
19 ultimately to adopt or not adopt immunization recommendations.
20 I think that also --

21 THE COURT: I'm a little -- I'm not sure I'm following
22 you, because these statutes seem to say that it is the ACIP
23 recommendation that matters and not the secretary's adoption of
24 it such that in the rotavirus example that was just given up,
25 it would seem like the vaccine list in 1999 when he just -- I

1 think he said in 1999, rotavirus was taken off the list by the
2 secretary of the CDC, it would seem like, under this statute,
3 it would remain; is that correct?

4 MR. OH: I don't believe that is correct, Your Honor.

5 I think that what -- what the -- the way that Congress
6 drafted these statutes is to recognize that the ACIP is an
7 advisory committee. It can make recommendations.

8 And that, quite frankly, is another reason why -- and
9 this is a little bit of a tangent -- why the secretary and
10 current members of the ACIP who keep talking about mandates,
11 that's just off base. It doesn't -- it's not really relevant
12 because what the ACIP does is make recommendations that than
13 are adopted by the CDC director, but --

14 THE COURT: When they say "the list established by
15 ACIP" in this statute, you're saying what that really means is
16 as adopted by the CDC director.

17 MR. OH: Yes.

18 THE COURT: Okay.

19 MR. OH: Yes. In order --

20 THE COURT: And that's why the Supreme Court in
21 *Kennedy v.* --

22 MR. OH: Yes.

23 THE COURT: -- Bradshaw or whatever that --

24 MR. OH: *Braidwood*.

25 THE COURT: -- is saying, it's because the CDC

1 director is the one that says this is the list and the ACIP
2 recommendation thereto. If it is in conflict in all of these
3 statutes, your understanding is that it is the CDC's director
4 adoption or nonadoption of that recommendation that carries the
5 day.

6 MR. OH: And that is what makes it a final agency
7 action, quite frankly, is what that really means for purposes
8 of an APA case.

9 THE COURT: Okay.

10 MR. OH: We wouldn't -- we wouldn't be challenging an
11 action taken by the ACIP if it hadn't been adopted by the CDC
12 director because it doesn't become a final agency action. Once
13 the CDC director adopts it, technically if it gets published in
14 the MMWR, that's really final final.

15 THE COURT: Right.

16 MR. OH: But then if the ACIP makes a recommendation
17 and then the CDC posts on their website a new immunization
18 schedule before the government can get around to publishing it
19 in MMWR, that is still final agency action because legal
20 consequences and other consequences follow through.

21 THE COURT: I understand. Thank you.

22 MR. OH: So the 21st Century Cures Act passed
23 effective December 13, 2016, 21 U.S.C., Section 360(b)(b)(b),
24 small Bs, dash, 4, Public Law 114-255. Now, this is an
25 interesting statute for purposes of this case because it

1 actually speaks to the ACIP process, and in a sense, this
2 particular part of this pretty lengthy statute was an effort by
3 Congress to kind of nudge the ACIP along to working a little
4 bit more expeditiously.

5 And so that is why they included this provision,
6 consideration of new vaccines, you need to take it up at the
7 next regularly scheduled ACIP meeting. It doesn't say you have
8 to vote on it.

9 THE COURT: Right.

10 MR. OH: But you do have to take it up and consider
11 it, and then if you're not going to vote on it, explain why.

12 Again, the 21st Century Cures Act, the subtitle of
13 this particular section is "Vaccine Access, Certainty, and
14 Innovation." The 21st Century Cures Act was also -- some
15 people look at it as encouraging the health care industry,
16 medical industry to embrace technology and advance medical
17 science.

18 So the director of the Centers for Disease Control and
19 Prevention shall conduct a review of the processes used by the
20 Advisory Committee on Immunization Practices in formulating and
21 issuing recommendations pertaining to vaccines.

22 And then if you look at -- this is Section 3092 of
23 Public Law 114-255, this is 2016, and by that time, the ACIP
24 had adopted the grave -- I'm sorry -- the GRADE, all caps,
25 approach to the review and analysis of scientific and economic

1 data.

2 So this is -- ACIP had adopted GRADE. EtR hadn't been
3 adopted yet, but this is Congress's recognition that the ACIP
4 had a process, a process that should be followed that they are
5 implicitly endorsing here, and they're not saying change the
6 process or jettison the process or we don't want a process. We
7 understand that the ACIP has had a process in place for years.
8 We have trusted the secretary to appoint members to the ACIP
9 who are going to act in good faith, who are going to follow the
10 science, who are going to rely on objective evidence, do a
11 rigorous study and analysis of the data, and then come up with
12 a recommendation, and they're just -- they wanted some
13 assurance that the processes that the ACIP were following were
14 in tune with the times.

15 So -- and here's some legislative history on the Cures
16 Act specifically mentioning the Advisory Committee on
17 Immunization Practices, the specific mention and knowledge of
18 the working groups of the ACIP.

19 And as we say in our preliminary injunction motion,
20 Your Honor, the work groups are really the engine that drives
21 the ACIP. They are the ones who do -- get their hands dirty,
22 who are pouring through all the data and all the evidence, and
23 they're applying now the EtR approach and looking at all the
24 different domains within the EtR approach, and then they are
25 coming up with language to vote -- for the ACIP to vote on

1 ultimately when they're ready.

2 Statute Number 11 in this series of laws that Congress
3 has incorporated reference to the ACIP bond, the Coronavirus
4 Aid Relief and Economic Security Act or the CARES Act, 42
5 U.S.C., Section 300gg-13, and if you look at the date there,
6 March 27th of 2020, that was right at the beginning of the
7 pandemic.

8 And there were no immunizations yet. They didn't come
9 until the end of the year, and, actually, Operation Warp Speed
10 had yet to be announced. I think it was in the works, but
11 it -- it hadn't been announced yet.

12 And I think, as we may have said in a previous
13 complaint, and I'm not sure why I didn't include it in this
14 one, the -- that's probably the singular crowning achievement
15 of the first Trump administration, to gather all -- from around
16 the globe the most credentialed, experienced, qualified, smart
17 experts from all walks of the vaccine ecosystem to, in record
18 time, be able to produce immunizations that saved countless
19 number of lives. Were mistakes made during the pandemic
20 response upon which the secretary has latched about various
21 things? Yes.

22 But ultimately, was Operation Warp Speed a great
23 success that saved millions of lives? Absolutely yes. And
24 even before they came up with immunizations, they knew it was
25 in the works, they said, a qualifying Coronavirus preventive

1 service means an immunization that has in effect a
2 recommendation from the ACIP, not the secretary, not the CDC
3 director.

4 The Inflation Reduction Act included -- and this is
5 where Medicare Part D came in. Medicare Part D provides for
6 private insurers to offer health insurance coverage to seniors,
7 and, again, no cost sharing for adult vaccines recommended by
8 the Advisory Committee on Immunization Practices.

9 And then Statute Number 13 of the 13 statutes that the
10 government ignored in their brief, a public awareness campaign
11 on the importance of vaccinations, December 27th, 2020.

12 So if you go back to the Coronavirus or the CARES Act
13 on March 27th of 2020, nine months later -- nine months later,
14 were the immunizations out by then, Richard?

15 MR. HUGHES: Yes.

16 MR. OH: Yes.

17 And the phrasing of this particular statutory
18 provision in 42 U.S.C., Section 245(d), I'll get to in a
19 moment, but 245(a) I think is one of the clearest statements of
20 what the United States policy is on vaccines and on
21 immunizations.

22 Now, yes, it talks about a public awareness campaign,
23 but what is this public awareness campaign supposed to do?
24 It's to carry out a national evidence-based campaign to
25 increase awareness and knowledge of the safety and

1 effectiveness of vaccines for the prevention and control of
2 diseases, combat misinformation about vaccines, and disseminate
3 scientific and evidence-based vaccine related information with
4 the goal of increasing rates of vaccination across all ages,
5 and that was a law signed by President Trump.

6 And then in Subsection D of 42 U.S.C.,
7 Section 245(4)(b), it provides that this public awareness
8 campaign -- now this is where it gets kind of funky in its
9 wording -- may also include information on vaccines for
10 individuals with impunities, including individuals for whom
11 vaccines are not recommended by the Advisory Committee for
12 Immunization Practices, and the effects of low vaccination
13 rates within a community.

14 Now, I think in context at the time, if you recall,
15 when the vaccines first came out, there was a triaging of who
16 could get them first, immunocompromised, seniors, and so this
17 statutory provision was intended to help people understand why
18 they were or not -- were not included in, let's say, the first
19 tranche of people who were going to be able to get the vaccine.

20 And so this kind of goes to one of the questions
21 you've had throughout, the CDC director's role is adoption, not
22 recommendation, and here are two examples of where it
23 specifically states that the role of the CDC director is to
24 adopt and not recommend. It's coverage of preventive health
25 insurance services, this is part of the ACA.

1 MR. HUGHES: Yes.

2 MR. OH: And so, again, this shows that a final agency
3 action occurs when a recommendation from the ACIP has been
4 adopted.

5 And then the ACIP charter provides for recommendations
6 made by the ACIP are reviewed by the CDC director and if
7 adopted, then published in the MMWR.

8 So bringing this back to their argument about
9 committed to agency discretion, there are meaningful standards
10 for this Court to apply and there's statutes explicitly
11 incorporating reliance on ACIP recommendations. You've got the
12 First Circuit opining as such in *Union of Concerned Scientists*
13 *versus Wheeler*, 954 F.3rd 11, and these statutes demonstrate
14 congressional understanding, expectation, and reliance on the
15 ACIP process to make recommendations on the use of vaccines in
16 U.S. population groups.

17 So the exception should not swallow the rule. The
18 presumption is that this is justiciable and reviewable, and
19 Congress, interestingly, in the last 60 years has not seen the
20 need to specifically legislate the ACIP into existence in a way
21 because it has -- the whole health care system in many respects
22 operates on trust. It operates on people acting in good faith
23 and acting consistent with the policy of increasing rates of
24 vaccination across all ages.

25 So I think that the government's argument about this

1 is committed to agency discretion just has no merit, and so I
2 would ask the Court to reject that argument.

3 If you have any other questions about this particular
4 subject, I'm happy to entertain them. I'm wondering if this
5 would be a good time --

6 THE COURT: I think this is a good time for a break.
7 Thank you for that portion of your presentation. We will pick
8 up again at 10 of, so 15 minutes.

9 THE CLERK: All rise.

10 (The Honorable Court exited.)

11 (Brief break from 10:35 a.m. to 10:58 a.m.)

12 THE CLERK: All rise.

13 (The Honorable Court entered.)

14 THE CLERK: Please be seated.

15 THE COURT: Welcome back.

16 Mr. Oh, you're welcome to continue.

17 MR. OH: Thank you.

18 I think I wanted to do just a little bit of cleanup
19 and just make sure that I stated clearly with regard to the CDC
20 director's role, the CDC director certainly has discretion not
21 to adopt an ACIP recommendation. Traditionally the CDC
22 director has, so I just wanted to make sure it was clear for
23 the record.

24 And then also, I wanted to just point you to a couple
25 of cases regarding the exception -- the exception involving

1 committed to agency discretion, and the first is *Department of*
2 *Homeland Security versus Regents of the University* -- I believe
3 it was California, 591 U.S. 1, and this is at page 17, the APA
4 establishes a basic presumption of judicial review for one
5 suffering legal wrong because of agency action. That
6 presumption can be rebutted by a showing that the relevant
7 statute precludes review -- Section 701(a)(1) -- or that the
8 agency action is committed to agency discretion by law.

9 And in *Department of Homeland Security*, the Supreme
10 Court said, "To honor the presumption of review, we have read
11 the exception in Section 701(a)(2) quite narrowly" -- citing
12 *Weyerhaeuser* -- "confining it to those rare administrative
13 decisions traditionally left to agency discretion, this limited
14 category of unreviewable actions includes an agency's decision
15 not to institute enforcement proceedings," which is obviously
16 not the situation here.

17 THE COURT: Right.

18 MR. OH: And then in *Union of Concerned Scientists*
19 *versus Wheeler*, 954 F.3d 11, at page 18, and that decision
20 cites also to *Weyerhaeuser* and quotes from *Weyerhaeuser* in a
21 parenthetical that says "The few cases in which we have applied
22 the 701(a)(2) exception involved agency decisions that Courts
23 have traditionally regarded as unreviewable, such as the
24 allocation of funds from a lump-sum allocation or a decision
25 not to reconsider a final action," so -- all right.

1 So let's turn to once we get past that the narrow
2 exception here doesn't apply on the merits or the likelihood of
3 success on the merits, the January 5 childhood schedule change
4 was arbitrary and capricious.

5 And there are four reasons I'm going to walk through.
6 There was unexplained departure from process and practice; no
7 reasoned or rational explanation is number two; failed to
8 consider important aspects of the problem; and failed to
9 consider reliance interests.

10 So it is quite obvious that the January 5 action
11 departed from the ACIP process that Congress and the HHS
12 secretary has repeatedly relied upon and reenforced.

13 And there are essentially two documents that were
14 published and publicized on January 5 to explain the decision.
15 It was the decision memo sent to acting CDC director Jim
16 O'Neill by CMS administrator Dr. Oz, NIH director Dr. Jay
17 Bhattacharya, and FDA commissioner Marty Makary.

18 Would you like the spellings of Bhattacharya and
19 Makary? Okay. Let me see if I get Bhattacharya correct.
20 B-H-A-T-T-A-C-H-A-R-Y-A, that's Bhattacharya. Makary is
21 M-A-K-A-R-Y.

22 So there was no explanation as to why they didn't
23 follow this -- the GRADE or the EtR process and to put -- or
24 why they disregarded, quite frankly, the GRADE and EtR process
25 that had been utilized for all of the immunizations on the CDC

1 schedule currently.

2 And we put in three examples in our -- in our PI
3 motion, and I direct the Court's attention to ECF 185-23; it is
4 the summary exhibit on hepatitis B; ECF 185-24, the summary
5 exhibit on RSV; and then this one, ECF 185-22, is a summary
6 exhibit regarding the vaccine for pneumococcal pneumonia that
7 went under the name of Prevnar, and I think the significance of
8 that example, Your Honor, is that this is the one time the ACIP
9 downgraded a recommendation from routine to shared clinical
10 decision-making before this past year.

11 THE COURT: I thought there were four examples of
12 shared clinical decision-making prior to the last year.

13 MR. OH: There were, but those were ones that --

14 THE COURT: They began. They weren't downgraded.
15 They began.

16 MR. OH: They were not, exactly.

17 THE COURT: Thank you.

18 MR. OH: And one good way to summarize the rigor at
19 which -- that the ACIP applied before downgrading Prevnar to
20 shared clinical decision-making is that there were 34
21 presentations at ACIP meetings before they did that.

22 I think it was driving the industry a little bit crazy
23 that it took them that long, but -- and so if we -- I don't
24 know if it's worthwhile walking through the Summary
25 Exhibit 185-22, but -- so Prevnar was authorized by the FDA on

1 December 30th of 2011.

2 THE COURT: If you're asking me to follow along on the
3 exhibit, give me just --

4 MR. OH: Yes, could you --

5 THE COURT: Give me just one minute.

6 MR. OH: Yeah. Okay. If you find it helpful to walk
7 through this.

8 THE COURT: Yeah, just give me 30 seconds.

9 MR. OH: Sure.

10 THE COURT: Okay. I have it.

11 MR. OH: So on February 24th of 2011, Prevnar was
12 introduced, discussion of the safety and immunogenicity of
13 PCV13 in adults, and they took a vote on June 20th for
14 recommending routine use for adults aged 19 or older with
15 immunocompromising conditions, and then adopted, published in
16 the MMWR October 12th of 2012.

17 Then you go to June 23rd of 2011, and there were --
18 there was a vote on recommendations for a pneumococcal vaccine
19 among immunocompromised adults and adopted in MMWR to
20 recommended PCV13 use amount adults aged 65 and older, brought
21 up again at an ACIP meeting October 26 of 2011. There was no
22 vote; February 22 of 2012 it was also brought up, no vote; then
23 June 20th of 2012, again, brought up, presented on, no vote;
24 February 26 of 2014, it was brought up and then voted on on
25 August 13th of 2014, and they voted to recommend routine use of

1 PCV13 among adults aged 65 and older and then with specific
2 directions on administering in a series with the 23-valent
3 pneumococcal, P-N-E-U -- P-N-E-U-M-O-C-O-C-C-A-L,
4 polysaccharide vaccine, published in the MMWR about a month
5 later; again, discussed, brought up at an ACIP meeting in
6 August of -- 13th of 2014, and multiple other times brought
7 up -- I mean, we can go through this ad nauseam, and you
8 finally get to June 26 of 2019 and February -- I'm sorry --
9 February 12th of 2018, this is on page 11 of 15.

10 THE COURT: Yeah.

11 MR. OH: Of 185-22.

12 THE COURT: I've got it.

13 MR. OH: Vote number three, recommend shared clinical
14 decision-making for PCV13 for adults 65 years of age not
15 previously vaccinated, vote 13 to 1.

16 And so that is the one time before this past year that
17 the ACIP had decided to -- and voted on downgrading a vaccine
18 from shared clinical decision-making -- from routine to shared
19 clinical decision-making.

20 And it took them from February 24th, 2011, through
21 numerous, numerous ACIP meetings, 34 presentations at ACIP
22 meetings, until they reached a decision seven years later to
23 downgrade.

24 And why is there no explanation as to, well, we
25 considered this and we decided to go the other way because?

1 There's nothing.

2 So bypassing the ACIP process and bypassing entirely
3 the ACIP for the January 5, 2026, schedule challenge is, quite
4 frankly, one of those is -- is the most, in our view, egregious
5 decisions coming out of this -- out of the secretary and the
6 CDC director that really set off alarm bells and, quite
7 frankly, just poured fuel on the fire that the secretary
8 started certainly with the June 9th termination of all the ACIP
9 members.

10 And so then the APA requires an agency to give a
11 reasoned or rational explanation for the decision, and there is
12 no indication that they considered the mountain of high-quality
13 evidence that supported prior recommendations.

14 And so, again, I commend you to look at the summary
15 exhibits that we have at 185-22 through 24 of the three
16 examples that show just how transparent, how rigorous, and how
17 objective and how independently the ACIP worked in trying to
18 evaluate and do the best job they could to make a
19 recommendation that would fit this country's population.

20 And so, as you know, there's a lot of evidence in the
21 record about how there's -- I don't know when this really
22 started, but certainly at the December ACIP meeting when there
23 were presentations by Aaron Siri on the childhood schedule, by
24 Dr. Tracy Beth Hoeg on a comparison of the U.S. schedule to
25 Denmark's, there was this then move and movement to say that

1 Denmark is a peer nation of the United States as supposedly
2 Japan and Germany are and align the U.S. schedule with that of
3 peer nations.

4 When I first saw that, I, kind of, thought to myself,
5 well, the U.S. has no peer, but Denmark certainly isn't a peer
6 nation, and if you -- I think the amicus brief of the
7 Administrative Law Scholars at ECF 217 at page 17, the amicus
8 brief of Defend Public Health ECF 238 at pages 15 to 16 provide
9 a very succinct explanation as to how Denmark, Japan, and
10 Germany are not comparable in the vaccine space, in the
11 immunization space.

12 And one major reason is that they have universal
13 health care there, and if you do a dive into some of the
14 characteristics of Denmark, yeah, HepB isn't a routinely
15 recommended vaccine.

16 However, they have an incredible surveillance and
17 monitoring system. They have centralized medical records.
18 They know when a pregnant woman hasn't been tested for HepB
19 before birth, and they'll go call them up, knock on the door,
20 send them an e-mail saying, you need to be tested for HepB. We
21 don't have that here.

22 So -- and then I know that they tried to take cover
23 under the presidential memo that was just coincidentally issued
24 on the night of December 5th, which is right after the last
25 ACIP meeting, and they didn't follow what the presidential memo

1 said they should do in that they were supposed to examine the
2 best practices of these peer countries, and based on their
3 scientific review of the evidence, if they think that the best
4 practices of those peer countries are superior to the United
5 States, then align the U.S. schedule with those peer countries.

6 The only best practice, if you could even call it a
7 practice, it's really more of a result. The only thing that
8 the assessment and the decision memo really focus on as a best
9 practice is the number of immunizations on their schedule.

10 And if they were to have done their job as the
11 president said they should do and examine the best practices,
12 then why is there no discussion of NITAGs which are -- so the
13 ACIP is a NITAG -- and, Richard, help me out here, what does
14 NITAG stand for again?

15 MR. HUGHES: It's National Immunization Technical
16 Advisory Group.

17 MR. OH: Thank you.

18 And they would have discovered that the NITAGs in
19 these countries, they call it EtD, it's evidence to decision.
20 There's no discussion of that.

21 There's no discussion and no citation to new data,
22 evidence, or studies that would indicate and warrant change of
23 the recommendation for any of those downgraded immunizations on
24 the schedule. And I would direct the Court's attention to
25 Dr. Racine's declaration at ECF 185-34.

1 THE COURT: 185 dash what?

2 MR. OH: 185-34.

3 THE COURT: Okay.

4 MR. OH: And then also the Defend Public Health amicus
5 brief, and there are just -- there's just no explanation and
6 just ipse dixit. It's just a dogmatic conclusory statement
7 that we need to align with these peer nations, and if we do so,
8 that would restore trust, but how that is going to restore
9 trust is not really -- it is not explained in the decision
10 memo. It is not explained in the assessment. It is just a
11 conclusory statement that is unsupported by evidence.

12 And sorry I didn't put in specific citations to the
13 declarations of Dr. Benjamin, Kressly, K-R-E-S-S-L-Y, Nahass,
14 N-A-H-A-S-S, Chen, Bornstein, and Jaeger, but this is kind of
15 an example of, I think, them saying that this is what they
16 intended to do, but that is, I think, an example of a
17 pretextual explanation. It's unsupported by evidence, and it,
18 quite frankly, has had the opposite effect.

19 And I think the *State Farm* and *NIH* cases, *NIH 1*, are
20 really on point, and one of the things about the *State Farm*
21 case, which is an oft-cited case in the APA arena, is that that
22 is a case that involved the withdrawal, the removal, the
23 recision of a safety measure which is very similar to here, and
24 it was clear to the Court that the agency had not considered
25 very relevant factors that should have been considered and,

1 therefore, didn't provide a reasoned or rational explanation.
2 So there are -- Exhibit 185-22 referenced that.

3 And if you look at the number of times that the ACIP
4 took up PCV13 vaccines in adults and the amount of time that it
5 took them to get to that decision and if this were a reasoned
6 and rational decision, think about the timeline here.

7 From what we know, the presidential memo comes out on
8 December 5. Somewhere around December 17th, there was an
9 announcement by HHS that they were going to have an
10 announcement about children's health the next day, a Friday.

11 And then that evening on the day of the announcement,
12 they canceled that meeting, but it was pretty clear, and it was
13 pretty clear from reporting, that the intention was to,
14 somewhere around December 18th, to make the announcement that
15 they made on January 5th, and so it took them potentially two
16 weeks, and maybe they had another couple weeks to get to
17 January 5 to make that announcement, to do a thorough,
18 exhaustive, and Secretary Kennedy on the press release issued
19 on January 5 said an, quote, exhaustive review, end of quote,
20 had been done.

21 But how do you do an exhaustive review of 20 peer
22 nations' best practices in two weeks or in four weeks? That
23 timeline in and of itself speaks to a predetermined result that
24 is later justified by a decision memo and assessment. That's
25 pretext.

1 And with regard to HepB, again, this is 185-23, the
2 amount of effort, rigor, study, analysis done of the HepB
3 vaccine in children that resulted in a -- a universal
4 recommendation that reduced the rate of HepB by 99, and it took
5 them two weeks or a month to make this decision; it's just --
6 it's just not credible.

7 Failed to consider important aspects of the problem,
8 we laid out these 12 factors that should have been considered
9 in our brief. I don't need to read through every single one of
10 them right now, but these are 12 factors that a fairly balanced
11 ACIP would have considered or that if the CDC director and the
12 secretary had the authority to make immunization
13 recommendations for the schedule, they should have considered
14 these factors and they were not.

15 And then you have 33 years at least -- and I'm
16 counting the 33 from 1993 to today, the VFC statute to today, a
17 reliance on an open, transparent, objective, nonpolitical
18 scientific process that Congress has relied on and has
19 repeatedly relied on since 1993.

20 And then from the visual I have of the centrality of
21 the ACIP recommendations that end up on the CDC immunization
22 schedule and the one degree of separation to school systems, to
23 state governments, to state public health officials, to
24 insurers, to hospital systems, to a pediatrician in Crossville,
25 Tennessee, who has the one pediatric practice in three or four

1 counties in rural Tennessee, they rely on the trustworthiness
2 and the credibility of the ACIP process. And when you abandon
3 that process, give us a reasonable explanation as to why.

4 That -- we're not saying and we're not contesting that
5 the secretary and any new administration that comes in has the
6 discretion and the ability to change policy, but there are
7 constraints, and the APA provides that constraint.

8 And it's -- a little bit of history on the APA --
9 passed in 1946, and think about the year 1946. It's one year
10 after the conclusion of World War 2 when the allied forces had
11 defeated authoritarian dictators; that was somewhat of a
12 political atmosphere there. You had had a president who had
13 been in term for -- been elected four times. You had a
14 Congress that was changing at the midterms potentially.

15 And so both parties at that time saw that there needs
16 to be some guardrails put on executive agencies to when they're
17 going to change policy, at least give reasoned explanations, do
18 so in accordance with law and follow and then explain if you're
19 not going to be -- if you're changing a policy that has created
20 significant reliance interest around the country, just give us
21 a good explanation, and that has absolutely not been done here.

22 So, you know, what is the problem that the secretary
23 and the CDC director allegedly are trying to solve? Restore
24 trust. Granted I think this country is still suffering a
25 little bit from PTSD from the pandemic. Some of the potential

1 errors in judgment that came out of the pandemic response are
2 something that people have latched on to fairly perhaps.

3 But it is being used as a diversion and a distraction
4 to somehow change vaccine policy in a way that is inconsistent
5 with the way the process that has been followed for 60 years.

6 And so the doctors here in this room are experiencing
7 this every day, that, well, I heard Secretary Kennedy say this
8 on TV; I've heard, you know, the HHS has changed -- the CDC has
9 changed its guidance.

10 And so rather than restore trust, it has actually
11 enhanced and increased the level of skepticism and question --
12 it's enhanced the level of questioning that people have about
13 vaccines.

14 And so you want to change vaccine policy, we're
15 saying, okay, but do so in a way that is consistent with the
16 law, in accordance with the law, in accordance with the APA,
17 these guardrails that have existed since 1946, and paragraphs 9
18 to 11 in Dr. Jason Goldman's declaration at 185-35 -- I
19 misspelled Kressly on that slide -- ECF 185-27; paragraph 46 of
20 Dr. Susan Kressly, K-R-E-S-S-L-Y, I think; and then Dr. Brenda
21 Pring, paragraph 46, ECF 185-42, so, yes, everyone makes
22 mistakes, and -- but when it is on a matter so consequential
23 and so universal, I think that this country deserves more than
24 what they got by way of explanation on January 5.

25 So I think the argument that the government made about

1 final agency action can be quickly dispatched in that the
2 decision memo was signed by the person with the authority to
3 adopt immunization recommendations. That was final agency
4 action when he put his signature to that decision memo.

5 Now, there's a little bit of a disconnect on HHS's own
6 websites because, as of yesterday, the new childhood schedule
7 is on the HHS website, but when you go to the CDC's website,
8 the old schedule is up.

9 So there are legal and real-life consequences that
10 flow from this action. That's just, like, indisputable. This
11 is final agency action that's justiciable.

12 So the arbitrary and capricious -- I've been making a
13 little joke to my team here, remember back in law school the
14 concept of res ipsa loquitur? The translation is it speaks for
15 itself. It's kind of obvious when a piano falls out of a third
16 floor window and lands on someone, there's -- obviously,
17 something was wrong.

18 This -- I don't mean to be glib about this, but
19 it's -- it seems so patently obvious that the explanations that
20 they have given are just unreasonable and irrational and
21 pretextual and intended -- which we don't know yet until we get
22 the administrative record, what potentially is the real
23 motivation here, don't know -- but the -- this is a clear,
24 blatant, arbitrary, and capricious decision.

25 So if you have any questions about that, other than

1 that, I will move on, then, to the next topic or subject of
2 this hearing, and that is the next ACIP meeting that is now
3 scheduled for February 25 and 27.

4 So I would call this a concession, that they concede
5 that the FACA plan is justiciable, because at page 13 of their
6 brief, ECF 232, they try to say that the January 5 action isn't
7 justiciable because of the absence of meaningful standards, but
8 it's highlighted by a contrast with FACA's fair balance and
9 inappropriate influence provisions which the First Circuit held
10 provides sufficient standards for meaningful review, *Union of*
11 *Concerned Scientists*, 954 F.3rd at 20.

12 So FACA, as you know, has no private right of action,
13 you can pursue a claim for violation of FACA under the APA, and
14 FACA also provides some guardrails on the exercise of agency
15 discretion.

16 And there are two provisions within FACA that are
17 relevant here; one is the fair balance and one is inappropriate
18 influence.

19 And on the fair balance question, I just want to make
20 clear that my clients and I think everyone would agree that
21 people are entitled to their own views on vaccines. Okay.

22 However, you need to look at the objective, the
23 nature, and function of this particular federal advisory
24 committee to see if there is fair balance and if there is
25 inappropriate influence.

1 And the regulation of 41 CFR, Section 102-3.60 speaks
2 to fairly balanced membership, and it states that a description
3 of the agency's plan to attain fairly balanced membership as
4 appropriate based on the nature and functions, the nature and
5 functions, of the advisory committee as documented through the
6 agency's membership balance plan.

7 And it also has a provision about where advisory
8 committees require technical expertise, you should include
9 persons with demonstrated professional or personal
10 qualifications and experience relevant to the functions and
11 tasks to be performed by the committee, experience relevant to
12 the functions and tasks to be performed by the committee.

13 So look at this committee in the context of, why does
14 it exist? It's -- the name speaks for itself. The Advisory
15 Committee on Immunization Practices.

16 The charter, the ACIP charter, says the ACIP shall
17 provide advice and guidance to the director of the CDC
18 regarding the use of vaccines and related agents for effective
19 control of vaccine-preventable diseases in the civilian
20 population of the United States.

21 And I will say that they're -- at this particular
22 moment in time, on this secretary's watch, there has not been
23 effective control of vaccine-preventable diseases, namely
24 measles.

25 Now, one thing that the government doesn't address in

1 their brief except for one little throwaway line at the end is
2 the membership balance plan.

3 The ACIP charter requires a membership balance plan.
4 The regulation says you -- the fairly balanced membership
5 should be documented through the agency's membership balance
6 plan.

7 And when you get into the membership balance plan, it
8 states, "ACIP members are selected based on their expertise and
9 experience and qualifications necessary to contribute to the
10 accomplishments of the committee's objectives," the committee's
11 objectives, "therefore, members are elected based upon the
12 following criteria: Expertise in the field of immunization
13 practices; multidisciplinary expertise in public health;
14 expertise in the use of vaccines and immunologic agents;
15 knowledge of vaccine development, evaluation, safety, and
16 delivery."

17 And in the case of a consumer representative,
18 knowledge about consumer perspectives and/or social and
19 community aspects of immunization programs.

20 So the membership balance plan, as required by binding
21 regulation, defines the standard to be applied with regard to
22 membership on this committee.

23 And I submit, Your Honor, that to not follow this
24 membership balance plan is to not have a fairly balanced
25 committee, and there is no evidence in the record at all -- and

1 I kind of doubt that when they produce the administrative
2 record, there will be any evidence -- that consideration was
3 given to the requirements of the membership balance plan.

4 And that, kind of, points to the real relevance of
5 Dr. Diana Zuckerman's declaration. I had it out somewhere.

6 THE COURT: Which declaration are you talking about?

7 MR. OH: The one that you just granted leave for us to
8 file.

9 THE COURT: Sure.

10 MR. OH: ECF 240-1, and this, I think, goes to both
11 fair balance and inappropriate influence.

12 THE COURT: Let me just make sure, the membership
13 balance plan, are you drawing from the ACIP charter?

14 MR. OH: No. I will show it to you, Your Honor. If I
15 may approach.

16 THE COURT: Sure.

17 MR. BELFER: We'd like to see a copy of it. I don't
18 think this was submitted with your PI motion.

19 MR. OH: Oh, it's in there.

20 MR. BELFER: Is it cited?

21 THE COURT: Give Mr. Belfer a copy anyway.

22 MR. BELFER: It's certainly not attached.

23 MR. OH: It's not attached. It's in a footnote.

24 THE COURT: Mr. Oh, give Mr. Belfer a copy.

25 MR. OH: I'm sorry?

1 THE COURT: Give Mr. Belfer a copy.

2 MR. OH: This is one thing I came unprepared for.

3 Sorry, Your Honor.

4 Well, it's a nice color document.

5 THE COURT: Let him take a look at it. Let him look
6 at it before you talk to me about it.

7 MR. OH: Sure.

8 THE COURT: And if need be -- you know what, we're
9 going to take a five-minute recess. We're going to make you a
10 couple copies of that. We're going to make sure Mr. Belfer has
11 one and I have one.

12 MR. BELFER: Thank you.

13 THE COURT: To make sure we're looking at the same
14 document.

15 MR. OH: I apologize.

16 THE COURT: We'll talk a five-minute recess. We'll go
17 make some copies.

18 THE CLERK: All rise.

19 (The Honorable Court exited.)

20 (Brief break from 11:41 a.m. to 11:52 a.m.)

21 THE CLERK: All rise.

22 (The Honorable Court entered.)

23 THE CLERK: Please be seated.

24 THE COURT: Just for everyone's planning, it is five
25 of 12. We will take a break from 1 to 2. Mr. Oh, how --

1 MR. OH: I should be done by then.

2 THE COURT: You think you'll finish by 1.

3 MR. OH: Yes.

4 THE COURT: Okay. Then, Mr. Belfer, I think you
5 should assume you'll probably pick up at 2 o'clock if that's
6 okay with you.

7 MR. BELFER: Yes. Thanks.

8 THE COURT: In terms of the membership balance plan,
9 so this is -- where is this? Where does it come from?

10 MR. OH: It is --

11 THE COURT: I understand what it is.

12 MR. OH: It is in a government database. The
13 regulations require when you submit your charter to --

14 THE COURT: The FACA regulations.

15 MR. OH: I'm sorry?

16 THE COURT: The FACA regulations require this.

17 MR. OH: Yes.

18 THE COURT: Okay.

19 MR. OH: That when you submit your charter, you also
20 are supposed to submit a membership balance plan.

21 And I was just informed that when we were filing our
22 PI motion and we do have a citation in a footnote to the
23 membership balance plan and when we went to the government
24 website to pull the most recent or, you know, pull one right
25 for when we filed, the website was down.

1 THE COURT: Okay. I know you referenced it in your
2 briefing.

3 MR. OH: Yes.

4 THE COURT: I think you have fairly raised it.

5 The -- which is written -- the charter is written
6 first, and the membership balance plan is written second. Is
7 that the correct sequencing of events?

8 MR. OH: Yes. And the charter is supposed to be
9 renewed every two years, and the secretary actually just signed
10 an amended charter in December of last year which changed a
11 couple words that actually had a reference to a vice chair, but
12 that was it.

13 THE COURT: This is the 12/3/25 version.

14 MR. OH: Yes.

15 THE COURT: Okay.

16 MR. OH: Which is basically the same as the one that
17 had been in existence for the two years before that.

18 THE COURT: Okay.

19 MR. OH: And if you don't mind, I actually powered up
20 the Elmo here.

21 THE COURT: Sure. Fire away.

22 MR. OH: It's been a long time since I've used an
23 Elmo.

24 THE COURT: It's like riding a bike.

25 MR. OH: So it's potentially a good learning

1 experience for some folks in the room. This is an Elmo that
2 before there were all -- you know, laptops and the like, if we
3 were presenting exhibits on a screen, we'd use this fancy
4 device which for some reason is called an Elmo.

5 And so I have the membership balance plan for the ACIP
6 up on the Elmo. Let me see if I can -- so federal advisory
7 committee name, it's Advisory Committee on Immunization
8 Practices. It gives the authority section. Mission, and
9 function, provide advice and guidance to the director of the
10 CDC regarding the use of vaccines, related agents for effective
11 control of vaccine-preventable diseases in the civilian
12 population.

13 And it goes through the procedure, upon licensure,
14 what the ACIP is supposed to do. And if you notice down at the
15 bottom, there is a reference to the VFC program. It's right
16 here at the bottom.

17 So then -- okay. So from a slide I previously showed
18 you, this is where I pulled in what the selection criteria are
19 for membership on the ACIP, those five bullet points which I've
20 already been through.

21 It speaks to liaison organizations. Liaison
22 representatives must represent organizations that have broad
23 immunization interests that present large constituencies.

24 And if you notice, there is also reference to --
25 there's an ACIP steering committee. It comprises at least 14

1 senior representatives from CDC's national centers and the
2 current ACIP chair.

3 Steering committee members -- I'm sorry if I'm not
4 centering this well -- are aware of the need for balanced
5 membership on the ACIP. And there's no evidence in the record
6 that the ACIP steering committee was consulted at all with
7 regard to the secretary's appointments of current members to
8 the ACIP.

9 THE COURT: Is the ACIP steering committee, was it
10 disbanded at the same time that the 17 people were removed from
11 the prior ACIP?

12 MR. OH: I do not know that, Your Honor.

13 THE COURT: So you don't know if the ACIP steering
14 committee currently exists.

15 MR. OH: Quite frankly, I'd be a little bit surprised
16 if it has been convened under this secretary, but if you
17 notice, it's senior representatives from these particular --

18 THE COURT: Right.

19 MR. OH: -- centers, and a steering committee meeting
20 needs to be called, and we have certainly not heard of any
21 steering committee meeting where membership applicants were
22 considered.

23 THE COURT: Mr. Belfer, I know we're in the weeds here
24 a little bit, so I don't blame you if you don't know the
25 answer, but do you know if the ACIP steering committee exists,

1 if it was convened, if it was consulted?

2 MR. BELFER: I'm not sure of the details right now.

3 THE COURT: Okay. Thank you.

4 MR. OH: So then page 3 of that membership balance
5 plan speaks to other balance factors, departmental policy
6 provides that committee membership be fairly balanced in terms
7 of views, representative, and the committee's function, look at
8 diverse geographic areas, geographical balance, and balance of
9 specialty areas, pediatrics, internal medicine, family
10 medicine, nursing, consumer issues, state and local health
11 department perspective, economic perspective, public health
12 perspective.

13 And then here is the candidate identification process,
14 and solicit candidates' names through the following channels;
15 application for ACIP membership are detailed on the ACIP
16 website; the secretary accepts applications in a continuous
17 process throughout the year; and the ACIP steering committee
18 finalizes a proposed nomination package annually during
19 November and December; solicitation of potential candidates is
20 conducted via e-mail request that is distributed widely on an
21 annual basis sent to all 30 ACIP liaison organizations.

22 I do not believe that happened this year, Your Honor.

23 THE COURT: You don't believe or you don't know.

24 MR. OH: I -- well, I would give it a clear and
25 convincing standard as opposed to beyond a reasonable doubt

1 that it didn't happen.

2 THE COURT: Your confidence level?

3 MR. OH: Confidence level, yes.

4 THE COURT: We know --

5 MR. OH: I do know that there were no solicitation of
6 posted candidates -- of potential candidates posted annually in
7 the federal register because we checked.

8 THE COURT: Okay. Don't we also -- never mind. I'm
9 sorry.

10 MR. OH: So our --

11 THE COURT: We know that the -- well, I don't know.
12 Was there an ACIP steering committee that finalized a proposed
13 nomination package during the November or December time period
14 as delineated at point 1 under part 6?

15 MR. OH: We don't have the administrative record yet,
16 but the -- this selection process and the candidate
17 identification process that is set forth in this plan was not
18 followed. There is no evidence. There was no public record
19 evidence of --

20 THE COURT: Remind me what month the new ACIP members
21 were appointed.

22 MR. OH: I'm sorry?

23 THE COURT: What month were the new ACIP members
24 appointed?

25 MR. OH: There were eight members appointed on

1 June 11th, four new members in September, and then two new
2 members in January of this year.

3 THE COURT: But I could certainly conclude, without
4 any more information, that the June and September appointments
5 were not a result of the ACIP steering committee considering
6 something in November and December.

7 MR. OH: You -- I think you very well could conclude
8 that, and I know that we're at the preliminary injunction stage
9 where they haven't produced the administrative record, but had
10 the government wanted to come forward with any evidence in
11 opposition to our motion for preliminary injunction on this,
12 they could have done some selection of the record, attached it
13 to their opposition to show, that, hey, we followed the
14 process, but they didn't do that.

15 THE COURT: Is your position that it is violative of
16 the APA -- well, violative of FACA and ergo the APA if they
17 don't follow what is delineated in the membership balance plan?

18 MR. OH: Absolutely.

19 THE COURT: And do you think I need to go any farther
20 than that?

21 MR. OH: No.

22 But there's --

23 THE COURT: I know you have more.

24 MR. OH: There is more. There is more.

25 And, again, people have been coming out of the

1 woodwork because they want to help. In today's day and age, I
2 know people feel a little bit helpless about trying to do
3 something, and so you get an outreach from Diana Zuckerman,
4 Ph.D., who has a doctorate in psychology from the Ohio State
5 University.

6 THE COURT: Is that the one from last night?

7 MR. OH: Yes, it was. It was Exhibit A to our motion.

8 THE COURT: Okay. Now I remember this.

9 MR. OH: Yeah.

10 And June 9th, ACIP members all terminated in Wall
11 Street op-ed. June 11th, eight new members appointed,
12 announcement of the appointments.

13 And there was an immediate carfuffle in the atmosphere
14 about these appointments because they seemed to be consistent
15 with the secretary's disclaimed but previously well-stated
16 views on vaccines, statements that he -- testimony he gave to
17 Congress that said he wouldn't mess with the ACIP, testimony
18 given at Congress that he wasn't anti-vaccine, that he wouldn't
19 take vaccines away from people, but then the alarm bells went
20 off even more when these eight new appointments were announced.

21 Then interestingly, after there had been widespread,
22 quite frankly, condemnation of the appointments, the next day a
23 partner at the law firm of Siri & Glimstad reached out to
24 Dr. Zuckerman to see if she was interested in talking about
25 membership on the ACIP.

1 And we put the e-mail into paragraph 6 of her
2 declaration which she signed yesterday. "Pleasure to meet
3 you." And this is from June 12th, 2025, 5:44 p.m. from
4 Elizabeth Brehm, B-R-E-H-M, and her signature line says,
5 Elizabeth A. Brehm, Esquire, Siri Glimstad in New York, New
6 York.

7 "Hi, Diane. Pleasure to meet you. I received your
8 e-mail address from" -- "I wanted to see if you had a few
9 minutes to chat about ACIP today this evening. If so, can you
10 please share" --

11 THE COURT: Mr. Belfer, I just read this this morning,
12 but I'm going to interrupt you for just one second -- not
13 Mr. Belfer -- Mr. Oh. I'm sorry. I want to give Mr. Belfer a
14 chance to respond while this is in front of us to this, if you
15 feel like you're in a position to do so, Mr. Oh just argued
16 that the membership balance plan as required by FACA is this --
17 is this document -- I don't know that anyone's contesting
18 that -- and if the appointments violate the selection criteria
19 and process that is delineated in the membership balance plan,
20 then that's an -- that's a FACA violation which is an APA
21 violation; is that true?

22 MR. BELFER: No, Your Honor.

23 FACA does not require exact compliance with the
24 membership balance plan. And, you know, I think on that point,
25 I would say two things. With regard to the procedural

1 requirements, whether the candidate selection procedure was
2 consistent with the membership balance plan, we just don't know
3 that yet because we don't have the record, so, you know, once
4 we have the record, we'll know, kind of, how the appointments
5 went --

6 THE COURT: Well, sure, I do. I mean, I know -- I
7 know because it said that the selection happens during November
8 and December, and the appointments were made in June. I know
9 that it wasn't followed. Now, you could tell me that doesn't
10 matter and that might be -- like, whether they meet in November
11 or whether they meet in May, maybe doesn't make a difference.

12 But assume for the sake of argument this wasn't
13 followed, so if this document on how you select members wasn't
14 followed, is that a violation of FACA? And if it's a violation
15 of FACA, is that a violation of the APA?

16 MR. BELFER: We do not concede that even if this
17 membership balance plan were not followed that that would be
18 per se a violation of FACA, no.

19 THE COURT: Okay.

20 MR. BELFER: I think FACA requires what the statute
21 says, fairly balanced and not inappropriately influenced, and,
22 you know, we can make arguments about that.

23 But, you know, even if Plaintiff's right that the
24 precise terms of the membership balance plan were not followed,
25 that does not automatically mean a violation of FACA.

1 THE COURT: Okay. Fair. Thank you, Mr. Belfer.

2 I'm sorry. Mr. Oh, you were talking about the
3 affidavit. It is especially fresh in my mind having read it
4 shortly after I woke up this morning, so you don't have to walk
5 me through that one again.

6 MR. OH: I would note that the regulation at 41 CFR,
7 Section 102-3.603(b) (I) or 1 has a statement in it that says
8 that the MBP shall describe the agency's conclusions regarding
9 the points of view that would promote fairly balanced committee
10 membership.

11 Now, I will also note that this regulation was
12 modified on December 16th of 2025, but that particular
13 provision was in effect during the time that the secretary made
14 his appointments except for the last two.

15 THE COURT: So I guess one of the things that I'm -- I
16 had not looked at this document before right now, the
17 membership balance plan --

18 MR. OH: That's our fault. We didn't give it to you.

19 THE COURT: It's fine.

20 What I'm a little curious about is so Mr. -- I think
21 what Mr. Belfer -- the point he was making was a failure to
22 adhere to every particular detail of the membership balance
23 plan may not in and of itself be sufficient to trigger an APA
24 violation.

25 And the makeup, the diversity of membership on the

1 board is much more difficult for me to assess, and it's
2 especially difficult for me to assess on a preliminary basis.

3 But I think your argument is that I don't even have
4 to -- that -- well, maybe I don't -- am I understanding your
5 argument to be that it -- I don't have to get to comparing the
6 qualifications of the newly comprised ACIP --

7 MR. OH: Correct.

8 THE COURT: -- if I conclude that they did not follow
9 the candidate identification process delineated in the
10 membership balance plan, meaning maybe they lucked into it and
11 the new ACIP people do happen to make all -- meet all of the
12 qualifications, but if they didn't follow the candidate
13 identification process, is it your argument that that alone
14 constitutes a FACA violation ergo an APA violation?

15 MR. OH: Yes.

16 And when you look at the way the statute and then the
17 regulation, it's a continuum of regulation says charter and MBP
18 must be filed with the secretary, and that means, therefore,
19 that the secretary needs to not only submit the charter but
20 submit and follow a membership balance plan.

21 And I, quite frankly, would be surprised if the
22 secretary or Aaron Siri looked at this document when they were
23 searching around for members of the ACIP, and so --

24 THE COURT: Okay.

25 MR. OH: -- it is kind of similar to they bypass the

1 entire ACIP process with regard to the January 5 schedule.
2 They bypass the entire accepted process for finding,
3 identifying, vetting, and appointing candidates to the ACIP.

4 And, I mean, timing is incredibly suspicious. He
5 fires them on June 9th, and then on June 11th, he identifies
6 eight new members to the ACIP, so he had to have been working
7 behind the scenes somehow to find some ACIP members contrary to
8 what they're supposed to do in the membership balance plan.

9 And back to this declaration, one of his -- Aaron
10 Siri's partners calls and speaks to Dr. Zuckerman on the
11 evening of June 12th. She identified herself as an attorney at
12 Siri & Glimstad and stated that she was assisting Mr. Siri in
13 identifying potential candidates for the ACIP.

14 I think that in and of itself establishes a violation
15 of FACA, the regulations, and the membership balance plan. Why
16 is one of the most prominent anti-vaccine lawyers vetting
17 candidates for the ACIP, a lawyer who had teamed up with RFK
18 before, had represented RFK before, who spoke at the
19 December 5 meeting, and if you recall at the motion to dismiss
20 hearing, I played a little clip of his two minutes of
21 disclosures he had to give as to all the conflicts he has
22 against HHS because of all the lawsuits he's filed taking a
23 position against vaccines or the vaccine injury compensation
24 program and the like.

25 So the fact that -- and I commend Dr. Zuckerman for

1 her courage in coming forward to reach out to us and to say --
2 and to tell us under oath that she was assisting Aaron Siri in
3 identifying potential candidates for the ACIP.

4 And if a fulsome administrative record is produced on
5 the selection process that the secretary followed, we would
6 expect to see communications from Siri & Glimstad to any
7 candidate -- other candidate that they tried -- that they
8 reached out to and vetted on behalf of Aaron Siri both before
9 and after June 12th.

10 Now, the declaration goes on to describe their
11 conversation, and it was clear to Dr. Zuckerman that she did
12 not give answers that were satisfactory to Ms. Brehm, and,
13 therefore, the interview was over.

14 And another very interesting nugget that is in this
15 declaration is that Ms. Brehm volunteered and brought up the
16 vaccine schedule for children in June of last year, the vaccine
17 schedule for children that was just changed on January 5th to
18 the benefit of Mr. Siri and his law firm.

19 It's a little bit on the befuddling side why the
20 secretary would go outside of the ACIP steering committee,
21 would go outside of the secretary -- the ACIP secretary, would
22 use an outside consultant who aligns with his views to find and
23 vet candidates for a federal advisory committee whose charge is
24 to control vaccine-preventable diseases in this country.

25 That demonstrates a pattern and practice of this

1 secretary trying to fundamentally change vaccine policy in this
2 country without good explanation and through, dare I say it,
3 underhanded means.

4 It is, quite frankly, a little bit on the disturbing
5 side that this is happening. It's a little bit on the
6 disturbing side that you have Aaron Siri given an hour and a
7 half to talk about the childhood schedule on December 5, and,
8 lo and behold, one month later that childhood schedule is
9 changed to the benefit of his law firm because, quite frankly,
10 if the childhood schedule changes, then the vaccine injury
11 compensation program is next, which is the -- basically
12 workers' comp for vaccines established in the 1980s because
13 vaccine manufacturers had left the U.S. market because of us
14 lawyers suing them in class action lawsuits that just created
15 too much liability for them to continue manufacturing in the
16 United States, and by the end of the '80s, the -- with the
17 vaccine injury compensation program coming into effect,
18 manufacturers returned.

19 And so I don't know if this is what they're really up
20 to, but circumstantial evidence indicates that the reasons they
21 are giving for making these changes are pretextual. The
22 reasons they are giving to change policy and the reasons that
23 they are employing Aaron Siri's law firm to vet candidates for
24 the ACIP that they know is embedded into these 13 statutes to
25 make recommendations for the immunization schedule is for some

1 other purpose than what with they're saying, to restore trust,
2 so now --

3 THE COURT: I'm going to interrupt you for one second,
4 because I know there are a lot of lawyers sitting here, and so
5 I have a question that if someone has an answer for after
6 lunch, I would -- it would be welcome, which is: If there is
7 any case that is interpreting FACA to say failure to follow a
8 membership plan as published in the -- wherever it's published,
9 the FACA database or what have you, if there is a case that
10 says failure to follow the membership balance plan equals a
11 FACA violation and that FACA violation equals an APA violation,
12 I would welcome being directed to that case.

13 Mr. Oh, I'm not asking you to come up with it off the
14 top of my head, but I say that only because this is not a point
15 that I -- this is not a point that I clearly understood from
16 the briefing, and if this is a point that is clearly
17 established in either direction, either that it is an APA
18 violation or that it's not an APA violation, there's a lot of
19 lawyers sitting out there, if someone comes up with a case on
20 point, I would welcome that direction. I didn't mean to throw
21 you off.

22 MR. OH: *Union of Concerned Scientists* did concern
23 membership on the federal advisory committee, and in that case,
24 both the District Court and the First Circuit were able to just
25 rely on the statute and regulation to find that there was

1 improper balance.

2 Now, in a way, I think that this case is easier
3 because there are -- there is this actual specific document,
4 the membership balance plan, that is required by regulation and
5 there is zero evidence, and, quite frankly, there's evidence to
6 the contrary that it was not adhered to let alone even
7 considered.

8 And so that's another explanation that is lacking in
9 the government's briefing. Well, the regulations say here are
10 the qualifications and expertise. The ACIP charter says here
11 are the qualifications and expertise. The membership balance
12 plan says here are the qualifications and expertise that should
13 be considered when considering membership to the ACIP, and
14 there's nothing in the government briefing that indicates that
15 they considered any of that.

16 And, again, this is similar, then, okay, you're
17 going -- you're going to abandon what regulations say you're
18 supposed to follow, then tell us why, and they haven't done
19 that.

20 So, by the way, I have to apologize to Ms. Beatty for
21 making some requests about positioning of the podium during
22 this proceeding. I know I was driving her a little bit crazy
23 this week, so I apologize for that.

24 THE COURT: Thank you for that.

25 MR. OH: So if you wouldn't mind, Ms. Beatty, if we

1 could switch back, I'm going to plug back in my HDMI here.

2 Just a couple other points on inappropriate influence,
3 and then I think I'll go into harm, Your Honor. Failure to
4 follow the selection process, now, this case does present novel
5 issues for Your Honor. Yes, you're going to find that there
6 isn't too much case law that directly discusses the ACIP and
7 its role, and so analogy to other precedent is going to be
8 necessary. There isn't much case law on what inappropriate
9 influence means, but that's why they put you in that chair to
10 make that decision.

11 And, you know, just the facts here indicate, okay,
12 what does influence mean? Well, I'm trying to influence Your
13 Honor here to find in our favor by speaking at a meeting.

14 And at the meetings -- this ACIP in June, September,
15 and December, you have invited speakers coming in to state
16 their points of view that clearly are intended to influence how
17 the ACIP members vote.

18 And you have Lyn Redwood, again, the former president
19 of Children's Health Defense; you have Mark Blaxill and Cynthia
20 Nevison who coauthored an article on vaccines that did get
21 published but then had to be retracted by the journal because
22 of misstatement of evidence, poor methodology, et cetera; Mark
23 Blaxill has written a book about how he believes vaccines
24 caused his child's autism; and then there is Aaron Siri, and
25 they were there to speak and influence the members of the ACIP

1 on how to vote.

2 And then when you have the misinformation and
3 disinformation spoken by -- including people like Vicky
4 Pebsworth, who sits on the ACIP who has prior connections 20
5 years ago to Children's Health Defense and Lyn Redwood, you've
6 got -- you've got the conditions for the ACIP members being
7 inappropriately influenced, and that, I believe, would -- is a
8 sufficient factual basis or another factual basis upon which
9 the Court would find inappropriate influence.

10 So I don't think we need to address harm too much
11 here, Your Honor, in that Your Honor has already denied the
12 motion to dismiss on standing grounds, and the harms that are
13 coming out of the January 5 childhood schedule change are
14 amplifying the harms that Your Honor already found sufficient
15 to establish standing.

16 THE COURT: So I am interested in hearing you talk
17 about irreparable harm because the briefing does a thorough job
18 of talking about the irreparable harm that might flow to -- to
19 unvaccinated children, to the -- the larger health effects that
20 might happen.

21 I don't think I can consider that in terms of the
22 irreparable harm analysis on the issuance of a preliminary
23 injunction here, because those people are not plaintiffs.

24 So, A, I'd like to know if you agree that that is --
25 that I cannot consider that harm when deciding whether or not

1 irreparable harm is shown here, and then, secondly, when
2 looking at the irreparable harm that will be borne by the
3 plaintiffs, I understand there's some economic harm that you've
4 laid that out quite successfully in your various briefings;
5 economic harm is typically not enough to find irreparable harm
6 in the sake of a -- for the sake of a preliminary injunction.
7 The impossibility of compensating irreparable harm is another
8 point, and so I am -- while I'm not -- there is a difference
9 between harm for standing and harm for -- irreparable harm for
10 the issuance of a preliminary injunction.

11 MR. OH: Agreed. Agreed.

12 And that's one of the reasons why we felt it would be
13 helpful to Your Honor to file the supplemental declarations.

14 THE COURT: That was. That is -- I paid a lot of
15 attention to that this morning.

16 MR. OH: Yeah, of Dr. Kressly and Dr. Berman, and they
17 immediately -- the American Academy of Pediatrics, for example,
18 had to immediately, again, jump into diverting resources to
19 combat the, in our view, unlawful action.

20 And so this declaration of Dr. Kressly and then, I
21 think, previous -- the declaration submitted in support of our
22 preliminary injunction motion show that immediately the AAP
23 has -- you know, it went from a five-alarm fire to a six-alarm
24 fire in terms of what they had to do to combat and then also
25 provide advice and counsel to their members with respect to how

1 to handle the change to the schedule.

2 And so the case law is pretty clear that when you are
3 diverting resources immediately in response to an action that
4 really is contrary to the mission of your organization, that is
5 sufficient to establish standing.

6 And then you have Dr. Suzanne Berman who herself is a
7 little mini-organization called Plateau Pediatrics in
8 Crossville, Tennessee, and she herself has had to change the
9 way her practice operates as a result of the changes to the
10 vaccine schedule, so that -- the diversion of resources, the
11 application of resources to reconfigure how you operate a
12 pediatric practice and how you operate an organization with
13 67,000 members is sufficient to establish the irreparable harm
14 to support our preliminary injunction motion.

15 So, yeah, I -- we aren't here directly representing
16 the children who are going to be affected by that, but in a
17 way, I know that these folks would feel responsible for them.

18 THE COURT: And I'm not saying that that's not
19 something that can be considered at all, but I think I have to
20 put that --

21 MR. OH: It's public interest.

22 THE COURT: Exactly, yes, I think I have to put it in
23 the public interest bucket. I can't put it in the irreparable
24 harm bucket.

25 MR. OH: And in full disclosure, I'll be honest with

1 you, I've been given a little note from my cocounsel here --

2 THE COURT: Sure.

3 MR. OH: -- on some other harms, and I do think it's
4 appropriate to point out that this -- the childhood schedule
5 change is totally frustrating the mission of the American
6 Academy of Pediatrics.

7 And this is not evidence you should consider for
8 purposes of this preliminary injunction motion, but I will just
9 point out that, wow, they are getting targeted. I mean, the
10 day before our motion to dismiss hearing -- you might not have
11 heard this --

12 THE COURT: I did.

13 MR. OH: -- but they had 18 million dollars in grants
14 pulled which they had to file a lawsuit on to recoup. They
15 have been sued in a RICO case for some odd reason by clearly
16 someone who -- well, who is a pretty well-known anti-vaccine
17 lawyer out on the West Coast.

18 And so they're in the crosshairs. They're in the
19 thick of it, and they are standing up for their -- their
20 pediatric schedule that has consistently aligned with the CDC
21 schedule up until this past year.

22 And now they are having to do more, expend more
23 resources to try to convince the public that we are and should
24 be the trusted organization for when you make the decision to
25 vaccinate your child, and so that is a harm directly flowing

1 from January 5.

2 And it also is compromising -- it is compromising the
3 standard of care that doctors have been employing for the last
4 few decades or decades and placing them in an uncomfortable
5 position of follow the CDC schedule, follow public health
6 authorities, or follow what I believe is the proper standard of
7 care and then potentially face a lawsuit or liability from
8 people who are saying, well, you're not following federal
9 health regulations and guidelines.

10 And it's kind of in both buckets here, the public
11 interest and the irreparable harm, but this is a clear and
12 present danger to public health.

13 And when there is that clear and present danger to
14 public health, that is going to harm the practices of doctors
15 and the function and mission of these organizations who are
16 just trying to care for the American public.

17 And I will also note that in their 10 pages of
18 briefing on irreparable harm, I don't think there was one
19 mention of *Diamond Alternative Energy* in their brief.

20 And I understand it's a pet peeve of yours when
21 counsel knows that there is a case out there that is contrary
22 to the position that they'd like to take but then they don't
23 mention it and don't address it.

24 THE COURT: I'm quite familiar with that case.

25 MR. OH: One final note on the injunctive relief, the

1 argument that they make at the end of their brief, they're
2 saying and you already said that it's tough for you to parse
3 the credentials of 14 different members who are currently on
4 the ACIP versus, let's say, prior membership.

5 They're asking you to tailor appointments to the ACIP.
6 I don't think that is your job. So in terms of the injunctive
7 relief, I don't think what we're asking for is overbroad.

8 So I won't run through all seven amicus briefs. I
9 know you've read them. And if you would give me one moment,
10 I'd like to ask my team if they think I have forgotten anything
11 or said something that I need to correct.

12 THE COURT: Sure. I'm going to take a moment myself.

13 MR. OH: I'd like to conclude with directing Your
14 Honor's attention to page 47 of our preliminary injunction
15 brief. It's ECF 184, and the heading is "The Challenge Actions
16 Are Causing and Will Continue to Cause Imminent Public Health
17 Harms." And we lead that section with this quote, "Threats to
18 public health and safety constitute irreparable harm that will
19 support an injunction."

20 And to get a little bit into epidemiology here, when
21 you have policies that are going to have an impact on and
22 reduce what they call herd immunity, that is going to lead to
23 increased illness, hospitalization, and death, and that is
24 irreparable harm to the public health and safety that would
25 support an injunction.

1 So in conclusion, Your Honor, I'd like to thank you
2 for indulging me and the plaintiffs and giving us the time we
3 feel was necessary to try to explain this, hopefully, in an
4 understandable fashion.

5 And we do appreciate the expedition that you have put
6 on this case. I know it puts a lot of pressure on you and your
7 clerks to get out a decision, but, as you recognize, this is a
8 case of great importance to the public health, to everyone in
9 this room, and I would ask that you grant our motion for
10 preliminary injunction.

11 THE COURT: Thank you, Mr. Oh.

12 We're going to take a break until -- until 2 o'clock.
13 Then, at that point, it will be --

14 MR. BELFER: Just one question, Your Honor, as we
15 prepare our presentation, are there issues you'd like us to
16 focus on in our presentation?

17 THE COURT: So I'm -- I am curious what your
18 consideration -- what you think I should do with *Kennedy v.*
19 *Braidwood* and what that implies to how I should treat the ACIP.

20 I am curious about the idea of what's committed to
21 agency discretion. I think that that's a difficult question
22 for me; this issue that we talked about that I hadn't really
23 given much consideration to that I already mentioned about
24 whether or not following the plan I think is quite important,
25 and a discussion of irreparable harm and whether or not the

1 last thing that Mr. Oh said, that I can consider the broader
2 health impacts when deciding whether or not the issuance of a
3 preliminary injunction is correct, I'm not sure that I can, and
4 given that I just said that, I suspect you're going to tell me
5 I can't, but what do I look at in terms of irreparable harm?
6 Am I confined to looking at just the irreparable harm to the
7 parties? If the parties are as they are a bunch of doctors,
8 does that mean I can look at larger health effects or not?
9 That question is a close one for me.

10 I did look at the newly filed affidavit this morning
11 that was about the childhood vaccine -- the childhood vaccine
12 program -- now I've forgotten it -- the childhood vaccine
13 program -- I just said the wrong thing -- but you know what I'm
14 talking about, so should I be looking at that? So all of those
15 issues stand out for me. And I'd be -- I'd welcome anything
16 else you would have to tell me.

17 MR. BELFER: Thank you.

18 THE COURT: Thank you, Mr. Belfer. Thank you, Mr. Oh.
19 Thank you, all. I'll see you at 2:00.

20 THE CLERK: All rise.

21 (The Honorable Court exited.)

22 (Lunch break from 12:44 p.m. to 2:09 p.m.)

23 THE CLERK: All rise.

24 (The Honorable Court entered.)

25 THE CLERK: Please be seated.

1 THE COURT: Good afternoon.

2 Mr. Belfer, we're all fed and rested and ready to get
3 going again. The floor is yours.

4 MR. OH: I'm sorry to interrupt for one second. I
5 forget to ask to reserve just a little bit of rebuttal.

6 THE COURT: I'll give you a little bit, yes.

7 MR. BELFER: So to start, thank you for letting us
8 know the issues that concern the Court. We will address those
9 as we go through the issues.

10 THE COURT: Great. Thank you.

11 MR. BELFER: I'd like to start by taking a step back
12 and thinking about what this case is about. Plaintiffs and
13 amici try to frame this case as pro-vaccine versus
14 anti-vaccine. That framing is false.

15 Defendants' goal, which was expressly stated in the
16 scientific assessment and in the January 2026 decision
17 memorandum, is to restore public trust in public health
18 institutions, including the vaccine schedule which had taken a
19 hit during the pandemic. And in doing so, the government's
20 goal is to increase vaccine uptake of consensus vaccines such
21 as the measles vaccine. So, again, this is not pro- versus
22 anti-vaccine. Both sides here believe in vaccines.

23 Indeed, the January decision memo affirmed that
24 vaccines provide a critical public health tool. What we have
25 instead are different approaches to vaccine policy, different

1 ways to promote the public health.

2 Plaintiffs believe the best way to promote public
3 health is to have a schedule that recommends a large number of
4 vaccines for all children.

5 The government's approach is to focus the recommended
6 for all children category on a more tailored set of vaccines
7 with the idea that that will promote public trust and vaccine
8 uptake, so just different approaches to vaccine policy.

9 There is room for reasonable disagreement here. We
10 certainly don't claim to have the only approach. And indeed,
11 in the scientific assessment, the authors noted that
12 different -- in light of the imperfect information out there
13 about vaccines, different countries have taken different
14 approaches, and that's fine. There is room for disagreement
15 here.

16 However, under our constitution, the democratically
17 accountable executive branch including the presidentially
18 appointed and Senate-confirmed officials who took the actions
19 in January have the authority to make policy decisions.

20 They have discretion to choose from among an array of
21 reasonable policy options and choose the option that best
22 promotes their priorities.

23 And I think instructive is the Supreme Court's case in
24 *Department of Commerce versus New York* from 2019. There the
25 Court said that a Court may not set aside an agency's

1 policymaking decision solely because it might have been
2 influenced by political considerations or prompted by an
3 administration's priorities. Agency policymaking is not a
4 verified technocratic process unaffected by political
5 considerations or the presence of presidential power.

6 So as the Supreme Court has recognized, it is
7 completely legitimate and normal for the executive branch, the
8 democratically accountable executive branch, to pursue its
9 priorities in exercising its authority to choose from among
10 reasonable policy options.

11 Now, Plaintiffs may disagree with the policy that we
12 have chosen, and indeed, what the record shows is they do
13 disagree and they have published their own immunization
14 schedules that many states have taken a different approach and
15 that many doctors are choosing to follow the schedules
16 recommended by AAP, for example, and not follow the
17 government's schedule. That's fine.

18 We welcome spirited debate about vaccine policy. It
19 is completely fine and consistent with our system of government
20 for the government to express its view on vaccine policy and
21 for, you know, states and private organizations and just
22 Plaintiffs, if they think it's wrong, they can disagree, and
23 that's fine.

24 What Plaintiffs cannot do, however, is enjoin the
25 January 2026 action under the APA. Under the APA, the question

1 is whether the agency acted reasonably. The Court cannot
2 substitute its judgment for that of the agency, and it cannot
3 reconsider the evidence anew. It must defer to the agency as
4 long as the agency acted reasonably.

5 And here, what you have is politically accountable
6 decision-makers making a reasonable decision about vaccine
7 policy.

8 Similarly, Plaintiffs cannot seek to silence the
9 government from --

10 THE COURT: Can I get you to slow down just a little?
11 We've asked a lot of our transcription today.

12 MR. BELFER: Yes.

13 So, you know, just as Plaintiffs cannot ask this Court
14 to substitute its judgment for that of the agency under the
15 APA, Plaintiffs, under First Amendment values, cannot ask this
16 Court to silence opinions with which they disagree.

17 Plaintiffs label what ACIP has been saying is
18 misinformation, but that's just another way of saying they
19 disagree with what ACIP is saying, with what the government is
20 saying.

21 And under First Amendment values, you cannot just use
22 this Court to shut down debate. Our country benefits when
23 there is a spirited debate about important matters of public
24 policy, and the government, just like private citizens, is
25 entitled to express its view of the best vaccine policy, to

1 express its view of the best vaccine schedule, and Plaintiffs
2 should not be allowed to silence the government from expressing
3 that.

4 And similarly, with regard to the ACIP meeting,
5 Plaintiffs have been very clear that what they object to is
6 what they call misinformation. They're not trying to stop the
7 ACIP meeting because of any particular decision that we know is
8 going to happen. In fact, there isn't even an agenda yet.

9 What they're focused on is they don't want ACIP
10 members to express beliefs that Plaintiffs disagree with, and
11 using the Court to silence ACIP members from expressing beliefs
12 about vaccine policy that Plaintiffs disagree with, that is
13 fundamentally inconsistent with our constitution and our system
14 of government.

15 So I think -- something else that I think would help
16 to frame this motion is the administration's priorities that
17 have been running through the challenged actions. So the
18 January 2026 actions talk a lot about public trust, restoring
19 public trust and confidence in the vaccine policy, and I think
20 it's important to note that that priority of this
21 administration has been consistent at least since last May.

22 So, for example, on May 23rd, 2025, the president
23 issued the Restoring Gold Standard Science executive order.
24 That executive order stated, "Over the last five years,
25 confidence that scientists act in the best interests of the

1 public has fallen significantly. Scientific integrity in the
2 production and use of science by the federal government is
3 critical to maintaining the trust of the American people and
4 ensuring confidence in government decisions informed by
5 science."

6 And the executive order concluded, "We must restore
7 the American people's faith in the scientific enterprise and
8 institutions that create and apply scientific knowledge and
9 service of the public good." That is not hostile to science.
10 That is saying we need to restore trust in science.

11 Similarly, when Secretary Kennedy published the
12 editorial in the Wall Street Journal when he reconstituted
13 ACIP, and this is in June 2025, the secretary said, "The U.S.
14 faces a crisis of public trust. Whether towards health
15 agencies, pharmaceutical companies, or vaccines themselves,
16 public confidence is waning."

17 The secretary noted that ACIP has an history of
18 conflicts of interest and had been too pro-industry and had
19 failed to scrutinize vaccine products given to babies and
20 pregnant women.

21 Thus, the secretary decided that a clean sweep was
22 necessary to reestablish public confidence in vaccine science,
23 and he appointed members that would exercise independent
24 judgment and foster a culture of critical inquiry.

25 And what the secretary said is he was putting the

1 restoration of public trust above any pro- or anti-vaccine
2 agenda. "The public must know that unbiased science guides the
3 recommendations from our health agencies. This will ensure the
4 American people receive the safest vaccines possible."

5 So, again, we're not seeking to discourage vaccines or
6 undermine science. We're trying to restore public trust in
7 public health institutions, including vaccines.

8 And then this continued in January 2026, so in the
9 scientific assessment, the agency cited substantial evidence of
10 a loss of trust in public -- the loss of the public trust in
11 vaccines.

12 So to give a few examples, the scientific assessment
13 noted that between 2020 and 2024 trust in health care declined
14 steeply from 71 and a half percent to 40.1 percent coinciding
15 with school closures and other government responses to the
16 pandemic.

17 Over the same period, there was a decline in childhood
18 vaccination rates across the country, for example, a reduction
19 in measles, mumps, and rubella, or MMR, vaccination from 95.2
20 to 92.7 percent.

21 And the assessment noted that in the 2024-2025 school
22 year, 16 states had MMR vaccination rates below 90 percent.
23 Whereas, rubella has a community immunity threshold of 83 to 85
24 percent, and, thus, people in those communities were at risk of
25 getting those diseases.

1 It also noted there were 49 measles outbreaks reported
2 in the U.S. in 2025. And with regard to the COVID-19 vaccine,
3 even though CDC had recommended that vaccine for all children
4 in 2023, the uptake was less than 10 percent.

5 So that is all evidence of the loss of public trust
6 and confidence in the vaccine schedule and the need to take
7 steps to restore public trust.

8 And so the question is, how do we do that? And to
9 answer that question consistent with the December 2025
10 presidential memorandum, the assessment looked to peer
11 countries.

12 And what it found is that peer countries have shown
13 that transparent and trustworthy public health authorities can
14 achieve very high voluntary vaccination rates while preserving
15 informed consent.

16 For example, it noted that Denmark has achieved
17 consistently high rates of uptake for the consensus-recommended
18 vaccines and has had a lack of serious disease outbreaks. And
19 it quoted something from a Danish public health authority. It
20 said, "If one includes a vaccine which some consider less
21 important, it could negatively affect the view of vaccines in
22 general. The result of this could be the current vaccination
23 program would have lower uptake."

24 And so, again, the problem we're trying to address is
25 a serious reduction in public trust and confidence in vaccines.

1 We're looking to peer countries to see how have they addressed
2 this problem, because they have, you know, high rates of trust,
3 high rates of vaccine uptake, so what are they doing? And
4 we're seeing, well, these peer countries are having a more
5 focused vaccine schedule on consensus vaccines. So what are
6 the lessons for the United States?

7 The assessment noted that in 2024 the U.S. recommended
8 more childhood vaccines than any peer nation and more than
9 twice as many doses as some European nations.

10 And it found, in light of its analysis and its
11 consideration to peer countries, that a new U.S. childhood
12 schedule that removes the routine recommendation for
13 non-consensus vaccines could increase public trust, and
14 focusing on the consensus vaccines is more likely to reverse
15 the declining uptake of these vaccines.

16 And so what we're seeing is, again, far from any
17 anti-vaccine agenda, this is just a different approach to
18 vaccine policy. This is saying, let's focus on a more narrow
19 set of vaccines in order to increase public trust and increase
20 uptake of those critical consensus vaccines such as for
21 measles.

22 And then, finally, looking to the decision memo that
23 was based on the scientific assessment, what the decision memo
24 said was the loss of trust in the COVID vaccines coincided with
25 less adherence to the full CDC childhood vaccine schedule which

1 has resulted in lower immunization rates of well-established
2 vaccines such as those for measles, rubella, pertussis, and
3 polio.

4 And it affirmed that robust immunization programs are
5 an essential public health tool, but those tools are only
6 effective when there is public trust, and the memo concluded
7 that focusing on consensus vaccines is more likely to reverse
8 the declining uptake of those vaccines.

9 So what all of this shows is that the administration
10 has had a consistent priority to increase public trust in
11 public health institutions, including the vaccine schedule, and
12 essentially the government is taking a different approach to
13 vaccine policy than what Plaintiffs would prefer.

14 There is a reasonable disagreement about the best
15 vaccine policy in order to promote public health. That
16 disagreement is fine. But under the APA, having a policy
17 disagreement is not enough, and certainly under the First
18 Amendment values, Plaintiffs cannot use this Court to silence
19 the government from expressing its view of the best vaccine
20 policy for promoting public health.

21 And so with that framing, I'd like to move into the PI
22 factors, and so maybe we can start with the public interest and
23 irreparable harm, and then we can turn to the merits.

24 THE COURT: Sure.

25 MR. BELFER: The public interest disfavors Plaintiffs'

1 extraordinary proposal to enjoin HHS from giving nonbinding
2 recommendations to states and localities and from holding
3 advisory meetings.

4 The Supreme Court has been clear, and this is the
5 *Citizens United* decision from 2010, the Supreme Court held the
6 right of citizens to inquire, to hear, to speak, and to use
7 information is a precondition to enlightened self-government
8 and a necessary means to protect it.

9 Similarly, the First Circuit in the *Rosaura Building*
10 *Corporation* decision held that there is an important -- a
11 significant public interest having free and unhindered debate
12 of matters of public importance.

13 As we just discussed, the government supports having a
14 vigorous debate about vaccine policy, but what Plaintiffs are
15 trying to do is to stifle debate about vaccine policy.

16 They want -- and if you look at the proposed order
17 that they submitted, they want the Court to prohibit the
18 government from convening, holding, or conducting the ACIP
19 meetings currently scheduled for February and any subsequent
20 meetings.

21 They also are asking the Court to prohibit the
22 government from publishing or disseminating the immunization
23 schedule adopted in January 2026 as well as any guidance
24 documents, decision memoranda, work product, or public-facing
25 materials that reflect this action. That is far overbroad,

1 and, frankly, it is offensive to First Amendment values.

2 Plaintiffs may disagree with the statements and with
3 the health-related information that ACIP speakers have said,
4 and they may disagree with the vaccine recommendations that the
5 CDC acting director implemented in January 2026.

6 But just because you disagree with vaccine policy, you
7 think it's wrong, you disagree with how the agency evaluated
8 the evidence, that is not sufficient reason to silence the
9 government from expressing its views and to silence ACIP from
10 having a full discussion of vaccine policy.

11 THE COURT: What -- so I am very much undecided on
12 this, but assume for a minute that I concluded that the
13 composition of the ACIP was violative of the APA, maybe because
14 of the issue we talked about earlier that involved some
15 significant investigation on my point, but just assume for the
16 sake of argument that the composition of the ACIP violates the
17 APA, what's next?

18 What is -- so I'm responding to their requested
19 injunction is overbroad. I get that. And, again, I don't know
20 what I'm going to do, but the idea that I would say there can
21 be no ACIP meetings in the future is unlikely, right, but
22 assume I find that the ACIP composition is violative of the
23 APA, what would a more narrow, you know, temporary remedy be?

24 MR. BELFER: Sure.

25 So if the -- for example, if the Court were to find

1 that ACIP is not fairly balanced --

2 THE COURT: Sure.

3 MR. BELFER: -- an appropriate remedy could be to
4 remand to the agency to constitute ACIP in a fairly balanced
5 way, that way the Court is enforcing FACA while still giving
6 the agency an opportunity to exercise its statutory prerogative
7 to select ACIP members.

8 THE COURT: Well, let me just throw it out there, that
9 I'm not selecting the ACIP members, so that's -- that is --
10 certainly, that is not on the table as an option.

11 So assume that that's -- I appreciate that answer,
12 that the -- that if I find that it's not fairly balanced, that
13 the answer should be to kick it back to the agency to say
14 follow -- you know, follow FACA and reconstitute it.

15 What does that do with -- if that happens, what about
16 all of the votes that ACIP has made while, in this scenario,
17 unlawfully constituted?

18 MR. BELFER: So that's a subject for the next stage of
19 the PI proceedings because in part 2 of the proceedings --

20 THE COURT: Okay. Fair enough.

21 MR. BELFER: -- we're going to address the May --

22 THE COURT: Fair enough.

23 MR. BELFER: -- September, and December, so we can
24 address that question when we're back here in a month.

25 THE COURT: Okay. That's a perfectly fair answer.

1 MR. BELFER: Right.

2 So maybe just to close the loop on the scope of the
3 injunction, I think, as Your Honor recognized just wholly
4 enjoining ACIP from meeting in order to prevent them from
5 expressing beliefs that Plaintiffs disagree with that is
6 unacceptable and overbroad.

7 With regard to the January 2026 action, again,
8 preventing -- an order that prevents the agency from not only
9 enforcing but also discussing or publicizing anything about the
10 vaccine schedule is, again, far overbroad and is not tailored
11 to the alleged harm.

12 So in terms of what might be an appropriate remedy if
13 the Court were to find, for example, that the January 2026
14 action was inadequately explained, the remedy could be to
15 remand to the agency to provide an adequate explanation that
16 complies with the APA, and so there are possible remedies --

17 THE COURT: If that were to happen, does the temporary
18 order involve temporary vacatur?

19 MR. BELFER: I mean, it could. I mean, that would be
20 up to the Court.

21 THE COURT: Okay.

22 MR. BELFER: But, yeah, I mean, I think if the Court
23 were to find that the January 2026 action was unlawful and the
24 question is what's, then, the remedy; I think the most
25 appropriate, narrow-tailored remedy would be to remand and

1 possibly in conjunction with vacatur and say, you know, I find
2 the action inadequately explained, I remand to the agency to
3 provide a full explanation consistent with the APA.

4 THE COURT: Okay.

5 MR. BELFER: Period. So, you know, if the Court were
6 to grant relief, that would be the appropriate scope.

7 But, of course, we don't think that any relief is
8 appropriate, and so let's go back to the PI factors, and we can
9 turn to irreparable harm, so --

10 THE COURT: I assume -- well, assume for a moment that
11 what the plaintiffs argued, that this could have deleterious
12 public health effects, am I able to consider that in the
13 irreparable harm analysis?

14 MR. BELFER: No. In the *CMM Cable* case by the First
15 Circuit from 1995, the First Circuit expressly held that you
16 only consider irreparable harm to the movant rather than third
17 parties, so the answer is very clearly no. You only consider
18 harm to the movant in assessing irreparable harm.

19 You also do not consider harm that's suffered in the
20 past. You're just focused on prospective harms, and you also
21 are not looking long term. You're only looking at the narrow
22 window between the issuance of the PI and final judgment.

23 THE COURT: Right.

24 MR. BELFER: And in this case, as Your Honor knows, we
25 are on a pretty expedited schedule. The government's going to

1 be producing the administrative record pretty soon, and so we
2 are on a path to final judgment before too long.

3 And so really the question for the Court is quite
4 narrow. It is: Have Plaintiffs shown that Plaintiffs
5 themselves will suffer irreparable harm in the short period of
6 time between now and final judgment? And the answer is no.

7 And so let's look at the different categories of
8 plaintiffs. With regard to the individual plaintiffs, they
9 allege, kind of, generalized anxiety about the risk of illness
10 and the prospect of future vaccinations for their children, but
11 there's no evidence to substantiate those fears. All we have
12 is, kind of, unsubstantiated conjecture, unsubstantiated fears
13 which are not enough for irreparable harm.

14 For the organizational plaintiffs, their theory is
15 that they are diverting resources to address the confusion from
16 the January 2026 action and potentially from this upcoming
17 meeting, and we'll talk about standing later.

18 But I think the important point here is that what
19 Plaintiffs are doing actually is fully consistent with their
20 missions.

21 So just to give two examples, the American Public
22 Health Association, their mission, according to the Benjamin
23 declaration at ECF 185-25, the APHA's mission includes
24 professional and public education on how to improve community
25 health and promoting effective policy and practice.

1 To take the other example, the AAP -- and this is from
2 the Kressly declaration at ECF Number 185-27, AAP's mission
3 includes the publication of policies on a broad range of topics
4 including publication of AAP's immunization recommendations and
5 preparing guidance documents, answering questions from members.
6 That sort of providing guidance, education, providing AAP's
7 recommendation to its members, that is all part of its normal
8 mission.

9 And so here, to the extent that Plaintiffs are
10 answering questions from members, they are providing guidance
11 about, you know, the best vaccine policy, that is all part of
12 their normal practice. It's part of their missions.

13 So if they are spending time and resources on
14 education and guidance to members and making recommendations
15 and updating recommendations, that is just part of their --
16 them pursuing their mission.

17 It is not irreparable harm. It is not diverting them
18 from their mission. It is their mission.

19 And I think one helpful fact is AAP talks about how
20 they pushed the Red Book. They published their immunization
21 recommendations, but it's not just that they publish it one
22 time. They actually update it regularly.

23 And we cited the AAP Red Book Online which says that
24 because, you know, science develops, the facts develop,
25 immunization recommendations develop, AAP updates the Red Book

1 Online regularly. And so part of their normal operations,
2 their normal mission is to provide and regularly update
3 immunization recommendations.

4 So to the extent that they're doing that here, they're
5 saying, here's our recommendations for vaccines, here's our
6 guidance on how to best promote public health, best protect
7 your patients, that is them doing their normal mission. It is
8 no diversion of resources. It's just them doing what they
9 normally do.

10 THE COURT: On the irreparable harm front, can you
11 talk to me a little bit about -- so I did find that the
12 declaration of Dr. Kressly concerning the Vaccines for Children
13 Program and what -- now, there are two things, so the first is
14 maybe you don't agree that the potential implication of the
15 hearing in February in two weeks would have the effect that
16 they're saying it would, so -- and if you don't know the answer
17 to that, that's forgivable. You just got it this morning.

18 But if it's true, right, if their apprehension about
19 what's going to happen at the meeting in February is true,
20 which would mean much more quantifiable harm for the plaintiffs
21 here -- and, by the way, I agree with you, that I don't think
22 that in an irreparable harm analysis, I'm allowed to consider
23 public health effects; your point is well made both in writing
24 and here -- but this is a direct effect on the plaintiffs
25 themselves, so on the moving party, so tell me what I should do

1 with that.

2 MR. BELFER: VFC coverage would not be affected, so
3 the change that was made in January was to change several
4 vaccines from recommended for all children to recommended under
5 shared clinical decision-making. All the vaccines stated in
6 the schedule, they just move from one box to another box.

7 THE COURT: Right. So you think what this --
8 Dr. Kressly says, you don't think is true.

9 MR. BELFER: So the change from recommended for all
10 children to recommended under a shared clinical decision-making
11 does not change VFC coverage because under the VFC, something
12 is covered if it is anywhere on the schedule. Whether it's
13 recommended for all children or risk-based or shared clinical
14 decision-making, those are all covered under VFC.

15 So the change that was made in January to shared
16 clinical decision-making does not affect VFC coverage because
17 those vaccines will still be covered under the VFC program.

18 THE COURT: Okay.

19 MR. BELFER: And so continuing with irreparable harm,
20 Plaintiffs also have alleged that they basically have a
21 difference of opinion with CDC's current immunization
22 recommendations.

23 But, of course, the mere fact that the government is
24 publishing immunization recommendations that Plaintiffs
25 disagree with, that is not irreparable harm, and, in fact,

1 organizations such as AAP have long published their own vaccine
2 recommendations, that this isn't new; they've been doing this
3 for a long time.

4 And, in fact, in the past, there has been
5 disagreements between AAP and the government, you know. There
6 have been years where they agree, but there have been years
7 where they don't agree.

8 And so the mere fact that the government is
9 publicizing -- the government is issuing an immunization
10 schedule that Plaintiffs disagree with and that might differ
11 from AAP's recommendations that does not --

12 THE COURT: How often did that happen in the past?

13 How often was that a problem, was it a conflict?

14 MR. BELFER: I don't know, kind of, exactly, like, how
15 many times, but I know that -- and I think we discussed in our
16 brief I think in more detail --

17 THE COURT: I just can't remember.

18 MR. BELFER: -- but I know that there are -- there
19 have been examples in the past where they have deviated,
20 there's been disagreements.

21 THE COURT: Okay.

22 MR. BELFER: And so, again, the mere fact that there's
23 a disagreement between Plaintiffs and the government's schedule
24 does not show irreparable harm.

25 Let's turn to the doctor members of the organizational

1 plaintiffs. I think an important fact to keep in mind is that
2 the recommendations that were made in January are nonbinding.
3 They are not commands. They are not orders. They do not order
4 doctors to do anything, and they do not override doctors'
5 independent medical judgment.

6 Now, doctors may be regulated under state, you know,
7 regulation of medical practice, but ACIP's recommendations are
8 that; they are recommendations, and they are not requiring
9 doctors to do anything.

10 You know, in fact, as we discussed, other entities
11 such as states and professional organizations like AAP have
12 made their own recommendations.

13 And, you know, these are all nonbinding
14 recommendations that health care providers have discretion to
15 consider in issuing -- in exercising their independent,
16 professional judgment.

17 And, in fact, what we see from Plaintiffs'
18 declarations is that many providers are choosing to follow the
19 vaccine recommendations from states or from AAP, from other
20 organizations.

21 Doctors have a choice which nonbinding recommendations
22 to follow. Many are saying, I'm going to follow AAP's
23 recommendation or I'm going to follow my state's
24 recommendation, and that's fine. Doctors have a discretion
25 about which recommendations to follow, and they're doing that.

1 And so there's certainly no irreparable harm to
2 doctors because they have a choice. They still have the
3 ability to exercise their own independent judgment to act
4 consistent with the standard of care and they can choose which
5 guidelines to follow.

6 And even for doctors who are engaging in shared
7 clinical decision-making with patients, there's still no
8 irreparable harm because shared clinical decision-making is
9 minimal at best of a --

10 THE COURT: Assume that shared clinical
11 decision-making reduces the number of patients a doctor can see
12 from 12 to eight, and even if -- even if at the end of the day,
13 if I don't issue a preliminary injunction, but I did disagree
14 with you at the end of the day six months from now, that doctor
15 will have served eight patients a day instead of 12 patients a
16 day for six months, is that irreparable harm?

17 It's not -- because it is financial harm, but it's not
18 compensable, right. There's no way to recover that money in
19 the way -- and I'm just speaking out loud so you understand
20 where I'm coming from.

21 I understand and I believe that economic damages are
22 generally not the basis for preliminary injunctions, and there
23 has been no allegation raised by the plaintiffs that the
24 economic damages would be -- I forget the exact word in the
25 case law -- but, sort of, existential, that it would result in

1 the end of the entity.

2 So is that -- the fact that the -- that there are a
3 reduction in the number of patients they could serve would
4 exist for the pendency of this case and that reduction would be
5 uncompensable down the road, is that irreparable harm?

6 MR. BELFER: No. So one of the critical concessions
7 made in Plaintiffs' declarations was that there is now a
8 billing code for shared clinical decision-making.

9 Even if a patient chooses not to get vaccinated, the
10 doctor can still bill for the time spent in shared clinical
11 decision-making.

12 And Plaintiffs' declarations also concede that some
13 insurers are, in fact, compensating doctors for that time.
14 Some may -- some insurers may compensate. Some may not, but,
15 ultimately, that is not anything the defendants are causing.
16 That is the independent decision of the insurance company.

17 And so because we know from those declarations that it
18 is possible for doctors to get compensated for the time spent
19 on shared clinical decision-making, that's no injury because
20 spending time counseling a patient and getting compensated for
21 that is no injury.

22 Right. And so, you know, another reason why there's
23 no injury is that -- well, I guess two more points. One is
24 that the declarations concede that, you know, not every patient
25 chooses to have conversations about vaccines. Some say I don't

1 want to talk about it. Maybe some are satisfied with, you
2 know, 30 seconds of discussion, so how much time a doctor
3 spends with any patient on shared clinical decision-making will
4 vary, and that will largely depend on the independent decision
5 of each patient.

6 And I think it's also undisputed that there is no
7 defined structure to shared clinical decision-making. All it
8 really says is patients should consult with a health care
9 provider. It could be a doctor or a nurse or even a
10 pharmacist, just talk to some provider and then they will, you
11 know, counsel you about the vaccine.

12 And so that's all that defendants are doing. They're
13 advising patients to talk to some provider about the vaccine,
14 and whether any particular patient chooses to engage in that
15 conversation and how long they choose to talk, that is the
16 independent decision of patients.

17 And then another reason why this is not irreparable
18 harm is that if doctors choose to see fewer patients, that's
19 their own choice. That's a self-inflicted harm. No one is
20 saying, you know, you can only spend, you know, five hours a
21 day seeing patients.

22 It's up to doctors how many patients they see, how
23 long they spend with patients, what they talk about with
24 patients. That's all within their discretion, and so if a
25 doctor chooses to see fewer patients, that is a self-inflicted

1 injury, and it's not irreparable harm.

2 Okay. Right. And so I think the -- I think for all
3 of those reasons Plaintiffs simply have not shown any
4 irreparable harm from any of the actions challenged here.

5 I think at the very end of their presentation --
6 actually, no. We'll talk about that later. So I think that
7 covers it for the equitable factors, so I think we can move on
8 to the merits.

9 And so let's start with committed to agency discretion
10 by law because that was something that we talked about a lot in
11 the first part of this hearing.

12 So under the APA -- 5 U.S.C., Section 701(a)(2), the
13 APA does not apply where agency action is committed to agency
14 discretion by law. And under the First Circuit's decision in
15 *Union of Concerned Scientists*, that exception applies when the
16 relevant statute is drawn so that a Court would have no
17 meaningful standard against which to judge the agency's
18 exercise of discretion.

19 Now, something the plaintiffs, raise which is a bit
20 misleading, is that there are actually two different categories
21 here under which something can be committed to agency
22 discretion by law, and this is set out in *Union of Concerned*
23 *Scientists*.

24 The first category is actions that are traditionally
25 committed to agency discretion, so that would be, for example,

1 a decision not to prosecute or certain things in foreign
2 affairs, that's within the kind of traditional agency
3 discretion category.

4 There's also a second category which is independent,
5 and the second category is when there is no meaningful standard
6 against which to judge the agency's exercise of discretion.

7 And, you know, there's no doubt it is a narrow
8 exception to the APA, but it is a meaningful exception. The
9 Court does have to look to the particular statutory language at
10 issue and ask whether that statutory language provides a
11 meaningful standard against which to judge the agency's
12 exercise of discretion.

13 Now, in applying that standard here, there were
14 several important points made at the first part of this hearing
15 that I think really narrow this inquiry.

16 Well, I guess the first thing is that, you know,
17 Plaintiffs talked this morning about -- they talked about FACA
18 considerations and fair balance. We're just talking about the
19 January 2026 action here, so we're not -- we're not talking
20 about FACA.

21 We don't dispute that FACA is justiciable under First
22 Circuit precedent, so we're just talking about the January 2026
23 action. We're not talking about FACA considerations, and we're
24 also not -- Plaintiffs talked a lot about hepatitis B. That's
25 not relevant to this question, you know, Plaintiffs'

1 disagreement about the evidence in vaccine policy or hepatitis
2 B is not relevant here.

3 We're really just focused on the statute, and we're
4 focused on the legal question about whether the statute
5 provides meaningful standards.

6 And I think the critical concession that Plaintiffs
7 made at the very beginning in response to Your Honor's
8 question, Your Honor asked Plaintiffs' counsel let's suppose
9 hypothetically that ACIP made a decision and CDC then rejected
10 it, would that be within the agency's discretion? And
11 Plaintiffs said yes.

12 They don't dispute that CDC has discretion, indeed
13 unreviewable discretion under the statute, in setting vaccine
14 recommendations.

15 All that they're challenging is the fact that CDC did
16 not first rely on an ACIP recommendation, so it's really just
17 that very narrow procedural question. It's was -- was the CDC
18 required to base its vaccine recommendations on ACIP
19 recommendations, or does CDC have discretion whether or not to
20 base its recommendations on ACIP recommendations? That is the
21 only question that's now before the Court.

22 So let's look into that. The relevant statute here is
23 42 U.S.C., Section 243(a). That statute says that HHS has
24 authority to assist states in their political subdivisions in
25 the prevention and suppression of communicable diseases and has

1 authority to advise the several states on matters relating to
2 the preservation and improvement of the public health. So
3 there's this very broad grant of authority to assist states and
4 localities in preventing communicable diseases and improving
5 public health. That's it.

6 The statute does not say anything about how CDC should
7 go about fulfilling that authority. They don't say that you
8 have -- they don't say anything about vaccine recommendations.
9 It doesn't say anything about ACIP. There is no meaningful
10 standard with which to guide how CDC exercises that very broad
11 statutory authority.

12 And I think it's important to read this statute in
13 light of FACA. And this is 5 U.S.C., Section 1008,
14 Subsection B, also 42 U.S.C., Section 217(a), and FACA confirms
15 that ACIP simply provides advisory functions and really only to
16 the extent that the secretary or the CDC director require
17 advice to make their own determinations about policy.

18 So what we see from FACA is that ACIP is purely
19 advisory. It solely exists to help the secretary and HHS
20 officials exercise their duties.

21 And then when you look to the actual statute that
22 gives CDC authority here, 42 U.S.C., 243(a), all we have is
23 this very broad grant of authority that gives no guidance about
24 how HHS should exercise that authority.

25 THE COURT: It gives some guidance, right. I mean,

1 will you agree with me that assuming that there is a large
2 quantum of things that are committed to agency discretion, but
3 let's say that instead of revising the vaccine schedule, the
4 CDC said, actually, we think measles is good for you; you
5 should go have lunch with someone with measles, and we are
6 sponsoring measles lunches in every city, come have some
7 measles lunch, that would seem to -- that would seem to go
8 right up against the goal of preventing communicable diseases.
9 Would such a policy by the CDC be judicially reviewable?

10 MR. BELFER: I think that would still be committed to
11 agency discretion by law.

12 THE COURT: So even if what the agency was saying is
13 we like communicable diseases and we think you should get more
14 of them, that's not judicially reviewable.

15 MR. BELFER: No. And I think if you look to the case
16 law, that gives more guidance on what this requirement means.

17 And so, for example, in the First Circuit's decision
18 in *Union of Concerned Scientists*, the Court asked about whether
19 the statute tells Courts what Congress intended the agency to
20 consider about how to exercise the statutory authority.

21 So -- and, you know, they contrasted this with FACA,
22 you know, FACA says, you know, in exercising your authority to
23 appoint committee members, you should consider promoting fair
24 balance and avoiding inappropriate influence. Those are the
25 factors to guide your decision-making in exercising your

1 authority.

2 Here, we don't have that. All we have are broad
3 authority to help states promote public health, but there's no
4 guidance about what you should consider. There's no statutory
5 guidance. There's no statutory constraint about what you
6 should consider, what you can or cannot consider, what factors
7 matter.

8 You know, it would be -- this would be a different
9 statute if, for example, the statute said, you know, in
10 exercising this authority, you should consider, kind of, these
11 particular factors, you know, to guide your decision.

12 THE COURT: But they pointed out some factors; right?
13 They said the factors are to prevent communicable diseases and
14 improving public health.

15 MR. BELFER: Those are the goals to pursue, yes, but
16 what we don't have is guidance about how the agency should go
17 about exercising its discretion. There's nothing to guide the
18 agency of, like, what you should consider in promoting public
19 health. There's just this broad grant of authority to promote
20 public health but no guidance as to how the agency should go
21 about doing that, what factors it should consider, nothing to
22 guide that decision process.

23 And I think if we turn back to the particular question
24 before us now -- because, again, Plaintiffs have conceded that
25 the agency has authority -- has really unreviewable authority

1 in issuing that vaccine recommendations. The only thing that's
2 before us now -- the only thing Plaintiffs are still contesting
3 is whether ACIP is required -- sorry -- whether CDC is required
4 to, kind of, go through ACIP.

5 THE COURT: Right.

6 MR. BELFER: So that's the question before us.

7 And so Plaintiffs, in their presentation, they cited,
8 I think, 13 statutes, and they said, well, these statutes show
9 that Congress is requiring CDC to go through ACIP, but that's
10 not what any of those statutes say.

11 What those statutes do is Congress is recognizing that
12 ACIP exists. They're recognizing that one pathway to issuing
13 vaccine recommendations is for ACIP to make recommendations and
14 for CDC to adopt them, so, you know, Congress is recognizing
15 that is a pathway.

16 And, you know, I think we'd agree, you know, this
17 might be a different case if the challenged action was to,
18 like, dissolve ACIP. Like, if the agency just totally
19 dissolved ACIP, then you could say, well, maybe that's in
20 conflict with the statute that's saying -- that's recognizing
21 that ACIP exists, but that's not at issue here. ACIP still
22 exists.

23 And, in fact, the January action actually referenced
24 several ACIP decisions. In the January scientific assessment,
25 it noted ACIP's September vote on COVID-19, and it noted the

1 December vote on hepatitis B, and so it recognized that ACIP
2 did these votes, and so that's what we have before us.

3 And so, I guess, turning again to those 13 statutes,
4 all that they do is they recognize that ACIP exists, but they
5 do not constrain CDC's authority to issue vaccine
6 recommendations because CDC's authority is from 42 U.S.C.,
7 243(a), and that, again, gives a very broad discretion to
8 assist states in promoting public health.

9 The various statutes that recognize that ACIP exists
10 and its one method for making vaccine recommendations, those
11 are not a constraint on the secretary's authority.

12 Now, if Congress wanted to constrain the secretary's
13 authority, it knows how to do that. For example, Congress
14 could have passed a statute that says, in issuing vaccine
15 recommendations, CDC must first go through ACIP. Congress
16 could have said, the only -- you know, we are requiring the CDC
17 director to base any vaccine recommendations on ACIP
18 recommendations.

19 But Congress never did that. There is no statute
20 requiring CDC to go through ACIP. And the Supreme Court has
21 been clear, you know, this Court should not rewrite the
22 statutes. This Court should not invent a statute that requires
23 CDC to first go through ACIP where no such statute exists.

24 And, you know, something else that Plaintiffs said is
25 they said, well, you know, Congress is -- is recognizing that

1 we're taking vaccine recommendations away from political
2 appointees. Not at all.

3 We're recognizing that, again, one method of vaccine
4 recommendations is through ACIP, but there is nothing
5 whatsoever in any of the statutes Plaintiffs cited that
6 constrains CDC's authority, the authority of the democratically
7 accountable executive branch, to issue vaccine recommendations.

8 I think another issue that was discussed was, you
9 know, Plaintiffs have conceded there are actually three
10 examples in the past of CDC issuing vaccine recommendations
11 that deviate from ACIP recommendations, so there's a history of
12 this.

13 Plaintiffs would argue that there's a distinction
14 between ACIP making a recommendation and CDC deviating from
15 that, and what we have here is CDC just making a recommendation
16 that wasn't based on ACIP.

17 But there is no distinction there. The commonality in
18 both of those cases is that CDC is making a vaccine
19 recommendation that is not based on ACIP's recommendation but
20 instead is based on CDC's own independent judgment.

21 Whether or not historically -- or whether or not in
22 any given case a CDC decision is preceded by an ACIP decision,
23 the important fact is there is -- there are multiple historical
24 examples, including recently during the COVID-19 pandemic,
25 where CDC has said, we are not following ACIP's recommendation;

1 we are going to make our own recommendation apart from ACIP
2 based on our own independent judgment.

3 And so what that confirms is that not only does the
4 statute provide why -- an indeed unreviewable discretion to CDC
5 in issuing vaccine recommendations, but, in fact, CDC has used
6 that authority to issue its own recommendations not based on
7 ACIP, you know.

8 Plaintiffs also argued that the agency, you know,
9 didn't follow the GRADE framework or the EtR framework which
10 also, kind of, gets more to irreparable -- sorry -- it gets
11 more to arbitrary and capricious.

12 But I think the important point here is that there is
13 no requirement under the statute for CDC to follow any
14 particular procedure in issuing vaccine recommendations.
15 Indeed, the Statute 243(a) doesn't even mention vaccine
16 schedules let alone constrain how CDC should go about making
17 vaccine recommendations.

18 There simply is nothing in the relevant statute,
19 243(a), to constrain the agency's discretion in deciding what
20 to consider and ultimately, you know, how to issue vaccine
21 recommendations.

22 Okay. So I think that probably covers it. Oh, yeah.
23 I think that covers it for committed to agency discretion. And
24 so I think we can -- we can move on to the next -- the next
25 issue which I think is final agency action.

1 And here, you know, as the Court knows, under
2 5 U.S.C., Section 704, the APA provides review only of final
3 agency action, and final agency action must be one by which
4 rights or obligations have been determined or from which legal
5 consequences will flow, and that's the Supreme Court's decision
6 in *Bennett*.

7 Here, for the January action in particular, that does
8 not meet those requirements, because it does not have any legal
9 consequences. It did not change state's authority to regulate
10 the prescription and administration of vaccines or to make
11 policy decisions about which vaccines to require. It is not
12 binding. It is a nonbinding recommendation for, kind of,
13 states and localities and doctors to consider.

14 And so, you know, I think Plaintiffs say, well, it's
15 indisputable that the January action was final agency action
16 but not at all. We definitely dispute that, because the
17 January recommendation was nonbinding; it was a nonbinding
18 recommendation. It did not have any legal consequences and,
19 thus, was not final agency action.

20 Now, you know, Plaintiffs in their PI motion, they
21 say, well, we've been forced to grapple with, you know, the
22 long-term public health and economic effects of CDC's
23 recommendation, you know. They say various, kind of,
24 collateral consequences.

25 But, you know, even if that's true, a collateral

1 consequence felt by a plaintiff does not show final agency
2 action because it's not a legal consequence of the action. You
3 need legal consequences. And here, the January 2026 action
4 does not have the legal consequences required for final agency
5 action.

6 So I think we can turn to the arbitrary and capricious
7 argument. And so to set the stage here, under 5 -- so
8 5 U.S.C., Section 706(2) (A) provides the arbitrary and
9 capricious standard.

10 And the First Circuit in the *District 4 Lodge* case
11 clarified that Courts have only a narrow role to play in
12 reviewing agency action under 5 U.S.C., Section 706(2) (A).

13 In the *Prometheus Radio Project* case, the U.S. Supreme
14 Court held that the arbitrary and capricious standard simply
15 ensures that the agency has acted within a zone of
16 reasonableness, in particular has reasonably considered the
17 relevant issues and reasonably explained the decision.

18 In *State Farm*, the Supreme Court held that the Court
19 cannot substitute its judgment for that of the agency, and,
20 again, in *District 4 Lodge*, the First Circuit clarified that a
21 mere difference in opinion on how to evaluate evidence has no
22 place in arbitrary and capricious review.

23 In other words, the question is not whether the Court
24 agrees with how the agency evaluated the evidence and the Court
25 cannot substitute its judgment for the best vaccine policy for

1 that of the agency. Instead, the Court must defer to the
2 agency's judgment as long as the agency's decision is
3 reasonable -- you know, reasonably consider the relevant issues
4 and reasonably explain its decision. And here, that standard
5 was amply met.

6 And so let's first address the reasonably explained
7 factor, and then we can turn to the, kind of, consideration of
8 the relevant factors.

9 THE COURT: Okay.

10 MR. BELFER: And I think one thing that's also
11 important to set the stage is that in *Department of Commerce*
12 *versus New York*, the Supreme Court made clear that, you know,
13 it's fine for agency actions to be influenced by agency
14 priorities, by political considerations, and, you know, the
15 Court's role is not to examine all the motivations of a
16 government decision-maker and see, well, I don't like this
17 motivation.

18 What -- the Court's role is to look at the reasons the
19 agency gave for its decision, ask whether those reasons were
20 reasonable and reasonably considered the relevant issues, and
21 here, that was satisfied in spades.

22 And so, you know, the January decision memo was based
23 on a scientific assessment by two high-ranking HHS officials
24 who both had extensive experience in areas relevant to vaccine
25 policy.

1 In addition to the scientific assessment, the acting
2 CDC director relied on discussions with CDC, FDA, and
3 peer-developed nation health officials. And then ultimately
4 when the CDC director made the decision, he relied on the
5 unanimous recommendation of the authors of the memo which were
6 the NIH director, the CMS administrator, and the commissioner
7 of Food and Drugs, so this decision was based on the highly
8 qualified authors of the scientific assessment as well as the
9 heads of CDC -- of NIH, CMS, and FDA.

10 And the Supreme Court has been clear, and this is in
11 the *Marsh* case, that an agency must have discretion to rely on
12 the reasonable opinions of its own qualified experts.

13 And it also held in *Baltimore Gas and Electric* that
14 when an agency makes a scientific determination that is within
15 its area of special expertise, a reviewing Court must generally
16 be at its most deferential.

17 Similarly, in the *Rempfer* case, the D.C. Circuit held
18 that Courts must afford a high level of deference to agency's
19 scientific judgment within their area of expertise. And so
20 that's the framework for the Court to arbitrary and capricious
21 analysis.

22 So let's look at what the agency actually said in the
23 scientific assessment. Plaintiffs have argued that, well, the
24 agency did not explain its change; it didn't explain why it was
25 deviating from past agency recommendations.

1 But, in fact, the scientific assessment recognized
2 what the existing recommendations were, and it said we need to
3 change for these reasons, so it definitely -- it acknowledged
4 the past recommendations, and then it explained why it was
5 making a change.

6 And so, you know, let's look at what the scientific
7 assessment actually said. So the assessment described the
8 impairment in vaccine uptake and trust since the COVID-19
9 pandemic and it found that trust could be rebuilt by focusing
10 the recommended for all children category on vaccines for which
11 there is international consensus such as the measles vaccine.

12 Now, in Plaintiffs' argument, they disagreed with how
13 the agency evaluated public trust. They said, well, in fact,
14 the agency is not promoting public trust.

15 However, the government gets discretion in, you know,
16 making these judgments within its area of expertise, and the
17 question about how best to promote public health and which
18 vaccine schedules will promote public health and promote
19 vaccine uptake, that is well within FDA's area of expertise,
20 and so the Court should defer to that, and Plaintiffs cannot
21 simply disagree with how the agency has evaluated the evidence
22 regarding public trust and vaccine uptake.

23 And also, you know, Plaintiffs have submitted
24 declarations saying that, well, if you look at the last month,
25 in fact, the January action has not increased public health,

1 but that is not acceptable in arbitrary and capricious review.

2 As the Supreme Court held in the *Vermont Yankee* case,
3 this sort of Monday morning quarterbacking has no place in APA
4 review. The Court has to focus on the information available to
5 the agency when it made the challenged decision.

6 And similarly, in the *Berkey International* case from
7 the District of Puerto Rico, which we cite, in a PI, when the
8 Court is evaluating likelihood of success on the merits, you
9 also should focus on, you know, at least what you have of the
10 administrative record. The focus is on what was before the
11 agency at the time it made its decision, and so these
12 after-the-fact declarations from after the January action are
13 simply irrelevant for arbitrary and capricious review.

14 So the assessment focused on how best to uphold and to
15 restore public trust in vaccines and vaccine uptake. To
16 identify, you know, how to do that, the government -- the
17 assessment looked to peer countries, again, as directed by the
18 presidential memorandum from December 2025. It looked at 20
19 peer countries.

20 Now, Plaintiffs have argued that, well, Denmark and
21 Japan and Germany, those are different. Those are not
22 analogous. They kind of -- they focus just on those countries,
23 but the assessment did not just focus on those countries. The
24 assessment looked at 20 peer-developed countries, so it was
25 actually quite a broad sample.

1 And it said looking at all those 20 peer countries
2 comparing that to the United States, the assessment found the
3 United States actually recommends significantly more vaccines
4 than peer countries.

5 In addition to comparing the United States to peer
6 countries, the assessment also looked at vaccine risks and
7 benefits. It actually did consider evidence of vaccine safety
8 and vaccine efficacy and on public trust, and it looked at
9 where there was evidence missing or maybe, you know, we do not
10 have adequate scientific studies about safety or efficacy. It
11 considered all of that. It considered the state of the
12 evidence.

13 And so based on its consideration of other countries'
14 practices and on the high levels of trust and uptake in other
15 countries compared to the United States and also considering
16 vaccine safety and efficacy, the assessment reached the
17 reasonable conclusion that the best way to restore public trust
18 and thereby restore vaccine uptake, kind of, encourage people
19 to get these important consensus vaccines, such as the measles
20 vaccine, is to focus the vaccine schedule, in particular focus
21 on the recommended for all children category, on those vaccines
22 where there is an international consensus while maintaining
23 access and insurance coverage for other vaccines.

24 And so I think, you know, that's what the assessment
25 did, and the directive, of course, drew heavily from the

1 scientific assessment.

2 Your Honor, I would also note the assessment cited 179
3 references, so it was based on extensive engagement with the --
4 with the evidence.

5 And, of course, the authors, Drs. Hoeg and Kulldorff,
6 are both highly qualified researchers with extensive experience
7 in vaccines, epidemiology, and public health, and, of course,
8 they also consulted with experts in CDC, FDA, NIH, and CNS, and
9 so I think just based on the face of the assessment, we see
10 ample support for the decision.

11 Of course, you know, starting next month, we're going
12 to start producing the administrative record, and we might see
13 more evidence there. We'll see more about what the agency
14 considered, you know, who talked to whom, what evidence was
15 considered.

16 But at least for now, just based on the scientific
17 assessment and the decision memo, we see the agency engaging
18 with the science, talking to experts, looking at safety and
19 efficacy data, looking at other countries' experiences, and
20 reaching a reasonable conclusion about how best to promote
21 vaccine trust and uptake.

22 Plaintiffs in their presentation, they said, well, the
23 agency didn't follow the ACIP process; they didn't follow the
24 GRADE or EtR frameworks, but nothing required CDC to follow the
25 same processes as ACIP did.

1 You know, we acknowledge that, you know, there are
2 ACIP procedures about, you know, what procedures to follow, but
3 nothing whatsoever required CDC, in issuing its own vaccine
4 recommendations, to follow the GRADE framework or the EtR
5 framework or to spend any particular amount of time on this
6 issue.

7 I would also note with regard to the amount of time,
8 Plaintiffs said, well, there's no way you could have made this
9 decision in the course of a month, but we don't know how long
10 was spent on this. I think when we compile the record, we will
11 see how long the agency spent on this, but, you know, it's
12 certainly possibly at this point that the agency spent much
13 more than a month on this issue.

14 But, of course, the important point is that there's no
15 requirement that CDC spend any particular amount of time or go
16 through any particular process or any particular reasoning in
17 order to reach its vaccine recommendations. In fact, as we
18 just discussed, it has extensive, and indeed unreviewable,
19 discretion in how it goes about making vaccine recommendations.

20 You know, something else that was talked about by
21 Plaintiffs was that, you know, they tried to make -- they tried
22 to argue these other countries are different, that the agency
23 didn't sufficiently consider the differences. I think one
24 point, which we already discussed, was that Plaintiffs
25 attempting to poke holes in the Denmark, Japan, and Germany

1 examples doesn't work because the agency relied on 20 peer
2 countries, not just those three.

3 But also, with regard to how America compares and,
4 kind of, the ability to compare America to those other 20
5 countries, the agency actually did consider whether it was
6 appropriate to compare America with those other countries.

7 What it said at page 16, the scientific assessment
8 acknowledged --

9 THE COURT: Page 16 of what? I'm sorry. Which
10 document?

11 MR. BELFER: This is ECF 185-19, page 16, which I
12 think is the scientific assessment.

13 THE COURT: 185-16.

14 MR. BELFER: 185-19.

15 THE COURT: 19. Thank you.

16 MR. BELFER: At page 16.

17 THE COURT: Thank you. I'm right with you.

18 MR. BELFER: And so there the assessment acknowledged
19 that countries differ in terms of both vaccine exposure and the
20 health care system, and the differences between countries'
21 immunization schedules sometimes reflect the unique
22 epidemiology of diseases in each region.

23 However, acknowledging that, what the assessment found
24 was that differences in immunization schedules more often arise
25 from uncertain science and knowledge gaps which lead to

1 inadequately informed assessments of risks and benefits that
2 are subject to differing interpretations.

3 And so the agency actually was considering whether
4 it's appropriate to look to these other countries and said,
5 yes, like, we acknowledge there are differences between
6 countries, differences in vaccine epidemiology, in public
7 health systems, we acknowledge that, but we, nonetheless,
8 conclude that it's appropriate to consider these other
9 countries because the differences are actually more likely due
10 to incomplete information and countries reaching different
11 interpretations based on that incomplete information.

12 Plaintiffs also argued that there is no new evidence
13 considered and that you needed to consider new evidence. Right
14 off the bat, that's incorrect. Many of the 179 references in
15 the scientific assessment were from 2025. There was a lot of
16 new information cited.

17 But even beyond that as a matter of law, there was no
18 requirement for the agency to consider, you know, evidence from
19 any particular point in time.

20 THE COURT: Right.

21 MR. BELFER: The question is just: Did you reasonably
22 consider the issues and reasonably explain your decision? And
23 as long as you consider evidence and reasonably explain why
24 that supports your decision, you can consider whatever evidence
25 you believe appropriate from, you know, whenever in time.

1 Plaintiffs have argued that we didn't follow the
2 practices of peer countries. They said, well, you should have
3 considered the process by which other countries reach vaccine
4 recommendations and you should look at, like, the committees
5 that the other countries used to inform vaccine
6 recommendations, but that was not required.

7 What the presidential memorandum from December 2025
8 said was, you know, I'm directing HHS and CDC to look at the
9 best practices of peer countries in setting immunization
10 schedules and the evidence behind those schedules, and if other
11 countries' practices are superior to America's, then you should
12 revise America's vaccine schedule to be consistent with that
13 with other countries. You should basically learn -- if other
14 countries are doing it better, you should learn from that.

15 And so what that meant is you should look to the
16 vaccine schedules of other countries and the evidence
17 supporting that which is exactly what the assessment did.

18 There was no need to, kind of, look at exactly the
19 process by which they reached those recommendations, it was
20 just look at other countries' recommendations and the evidence
21 supporting that and if you see better results in other
22 countries, then learn from that valuable information, and
23 that's what the agency did.

24 With regard to promoting trust, Plaintiffs contest --
25 they say, well, we should have had studies or surveys or data

1 showing that this approach, kind of, the more focused approach
2 would restore public trust.

3 In fact, we did that. We looked at other countries,
4 other peer countries. That data, we looked at the 20 peer
5 countries, and we said, look, you know, looking at those
6 countries, those countries tend to have a more focused vaccine
7 schedule, but they also have high levels of vaccine trust and
8 uptake because people trust the public health system and, thus,
9 they trust the vaccine schedule and they're getting vaccinated.

10 And so we did look at data in the form of how other
11 countries have focused vaccine schedules with high levels of
12 vaccine trust and uptake in contrast to America where we have a
13 much broader recommended for all children category, but there's
14 extensive data on the lack of trust and the lack of uptake.

15 For example, the measles outbreaks, the fact that
16 there is less uptake of the COVID-19 vaccine, there is ample
17 evidence that in America, we have more vaccines but low level
18 of trust and uptake compared to foreign countries,
19 peer-developed countries, that have a more focused schedule but
20 high levels of trust and uptake, so we did go through that
21 analysis.

22 And, you know, another thing that's informative, you
23 look at the Supreme Court's *State Farm* decision, the Court held
24 it is not infrequent that the available data does not settle a
25 regulatory issue, and the agency must, then, exercise its

1 judgment moving from the facts and probabilities on the record
2 to a policy conclusion. And, again, when an agency makes
3 predictions within its area of special expertise, a review in
4 court must generally be at its most differential, and that's
5 the *Baltimore Gas and Electric* Supreme Court case.

6 So, you know, even to the extent that there's
7 reasonable disagreement between Plaintiffs and the government
8 about how to best promote public trust, under the APA the
9 government must defer to the agency's reasonable analysis of
10 that question which is well within the agency's special
11 expertise.

12 And I think something else I'd like to point out with
13 regard to the public trust issue, I think one of the amicus
14 briefs is actually informative on this issue, and so this is --
15 let's see, this is the -- a brief of the American Association
16 of Immunologists, American Physicians Groups.

17 THE COURT: Do you have a docket number?

18 MR. BELFER: Yes, Docket Number 218, two one eight.

19 THE COURT: Give me one second. Okay. Go ahead.

20 MR. BELFER: Okay. So on page -- the top of page 9 of
21 that brief, it confirms the importance of trust in science and
22 vaccines. It says, "Reaching and maintaining herd immunity,
23 thus, requires trust in science, access to vaccines, and global
24 cooperation."

25 And then similarly, if you go to page 19 of that

1 brief, so this is the second paragraph on page 19.

2 THE COURT: Okay.

3 MR. BELFER: It acknowledges that there is a growing
4 trend of patients refusing vaccines and rejecting science even
5 before January 2026. It says -- and this is the second
6 sentence, "Even before the recent changes, vaccinations have
7 declined at troubling rates with childhood vaccination rates
8 some of the lowest in 10 years. More families are currently
9 refusing vaccines for preventable diseases such as measles,
10 mumps, and pertussis."

11 And then, you know, it predicts that HHS will
12 exacerbate vaccine hesitancy, which, again, is just a
13 disagreement with our approach.

14 But the critical thing is that these amici are
15 agreeing that there is a public trust problem. We have a real
16 problem in this country of a loss in public trust, in public
17 health infrastructure, including vaccine schedules and
18 decreased vaccine uptake. That's a real problem. And what the
19 government is trying to do in the January action is to address
20 that problem.

21 Plaintiffs may disagree with how we're doing it.
22 There may be a policy disagreement about the best vaccine
23 policy to promote public health, but there can be no doubt that
24 we are addressing a very real problem in a reasonable way.

25 And I just -- I would also note just on the next page

1 of that brief, it talks about the measles outbreaks, and,
2 again, that supports the January 2026 action because, if the
3 Court will recall, in the scientific assessment, it discussed
4 measles outbreaks. It said part of the harm to this loss in
5 trust is that people are not getting vaccinated; we're not
6 getting uptake of these consensus vaccines that help protect
7 against important and very harmful diseases like measles.

8 And so the -- what's motivating the assessment --
9 again, it's not anti -- being anti-vaccine; we're not trying to
10 discourage vaccines. In fact, we're saying the existence of
11 measles outbreaks is a problem. We're trying to solve that
12 problem.

13 And we think part of the problem is that there's a
14 decrease in vaccine trust and uptake, and so our -- you know,
15 under our policy judgment, we're going to address that problem
16 by having a more focused vaccine schedule focusing on consensus
17 vaccines because we think that will help increase vaccine
18 uptake for those consensus vaccines, again, while maintaining
19 access to all the other vaccines.

20 And so that was a reasonable policy judgment that
21 Plaintiffs cannot challenge under arbitrary and capricious
22 review. Again, if they disagree, they're free to express their
23 disagreement. They're free to publicize their own vaccine
24 schedules and advise their members on what they think is the
25 best approach to protecting their patients. That's all fine.

1 But that -- the fact remains that the agency made a
2 reasonable policy judgment about how to address real problems
3 in vaccine trust and uptake.

4 And I think, you know, Plaintiffs, they also argued in
5 their presentation that this was ipse dixit, that the agency is
6 just saying things about trust, but, again, that's wrong
7 because we actually do have data comparing the U.S. experience
8 and, you know, measles outbreaks and lower vaccine uptake in
9 the United States to the experience of 20 peer countries.

10 Okay. So I think we can turn to the question about
11 considering the relevant factors. So Plaintiffs argue that CDC
12 did not consider the relevant facts in reaching its decision.

13 Importantly, though, under the relevant statute,
14 42 U.S.C., Section 243(a), that statute does not establish any
15 specific factors for the agency to consider. The agency has
16 discretion how to go about helping states promote public
17 health. Indeed, the agency has discretion whether to issue
18 immunization schedules at all and even more discretion about
19 what to consider in issuing those schedules. And so here, the
20 agency acted well within its wide discretion under 42 U.S.C.,
21 243(a). Now, something just --

22 THE COURT: Aren't the factors assist in preventing
23 communicable diseases and improving public health?

24 MR. BELFER: That's the goal that the agency is
25 pursuing.

1 THE COURT: But they're not -- that is a
2 non-judicially reviewable factor. I can't consider it.

3 MR. BELFER: Well, I wouldn't say that that's a factor
4 for how you should go about making your decision. Like, for
5 example, like, one factor might be that the agency must use the
6 best available scientific evidence in reaching this conclusion,
7 you know. There are other cases that, like, are in the EPA
8 context --

9 THE COURT: Okay.

10 MR. BELFER: -- where there are statutes that are say,
11 you know, you have to consider the best available evidence in
12 reaching this environmental decision.

13 THE COURT: Okay.

14 MR. BELFER: That would be an example of a statute
15 constraining the agency's discretion because it's saying in
16 pursuing this environmental goal --

17 THE COURT: I see.

18 MR. BELFER: -- we're saying consider the best
19 available evidence guiding the agency and constraining this
20 question. There's nothing like that here. There's nothing
21 constraining the agency's discretion in how it goes about
22 pursuing those very broad public health goals.

23 And so something just to note upfront is that, again,
24 we haven't produced the record yet, and so we don't yet have a
25 full accounting for what the agency considered --

1 THE COURT: Right.

2 MR. BELFER: -- what factors it considered, but what
3 we do have is the January 2026 assessment -- scientific
4 assessment and decision memo. And from the face of those
5 documents, we can see that the agency actually did consider the
6 relevant factors.

7 So Plaintiffs say that we didn't consider evidence of
8 vaccine safety and efficacy. Not true. For example, we did
9 assess -- and this is ECF Number 185-19, I think, again, this
10 is the scientific assessment, and with regard to the influenza
11 vaccine, it says the influenza vaccine has been linked to
12 Guillain-Barre syndrome, that the Pandemrix influenza vaccine
13 was found to cause narcolepsy of unvaccinated children and
14 adolescents. It noted the scarcity of reliable safety data for
15 the influenza vaccine, and that reliable safety data is limited
16 to the hepatitis A vaccine.

17 It also quoted a study that found no convincing
18 evidence that vaccine -- I think it's influenza vaccines can
19 reduce mortality, hospital admissions, serious complications,
20 or community transmission of influenza, so there was
21 consideration of vaccine safety.

22 There was also consideration of vaccine efficacy, and
23 so this is at -- between pages 20 and 23 of the assessment. It
24 noted the lack of adequate placebo-controlled randomized trials
25 for the hepatitis A, meningococcal disease, and influenza

1 vaccines, and it found there's no convincing evidence that
2 vaccines can reduce mortality, hospital admissions, serious
3 complications, or community transmission of influenza. And so,
4 again, it is very expressly considering the state of the
5 evidence on vaccine safety and efficacy.

6 It also considered data regarding vaccine uptake and
7 trust. It considered peer countries' practices, so, again, it
8 was considering safety and efficacy data combined with other
9 data regarding trust and uptake and peer countries'
10 experiences.

11 You know, Plaintiffs argued that the assessment did
12 not consider epidemiological or economic data comparing the
13 U.S. to peer countries, but, as we just discussed, the
14 assessment actually did consider whether it's appropriate to
15 compare the U.S. to peer countries. It noted that there might
16 be differences in epidemiology, in disease prevalence, in
17 public health systems between the U.S. and other countries. It
18 acknowledged that.

19 But it said, nonetheless, based on our judgment, we
20 believe that those -- the differences in vaccine schedule are
21 more likely due to differences -- are based on uncertain
22 science and knowledge gaps which leads to inadequately informed
23 assessments of risks and benefits subject to different
24 interpretations, and so it considered the differences between
25 countries, but it explained why it was, nonetheless, comparing

1 the U.S. to these foreign countries.

2 And I think it's also important that the assessment
3 and the directive recognize the benefits of vaccines. They
4 recognize the vaccines can provide material benefits against
5 targeted disease. They recognize that when vaccine uptake dips
6 below a certain percentage, it may lead to transmission, and,
7 thus, we have, you know, measles outbreaks, but what it
8 observed is that peer countries achieve high vaccination rates
9 while preserving informed consent through trustworthy public
10 health authorities and use more focused vaccine schedules.

11 And so informed by the experience of other countries,
12 it explained that, you know, one way to restore trust is to
13 follow these other countries and focus our vaccine schedules on
14 the consensus vaccines in order to promote trust and uptake of
15 those consensus vaccines.

16 Something else Plaintiffs have argued is that we
17 didn't consider reliance and trust. They say that various
18 members of the public have relied on the existing vaccine
19 schedules and we should have considered that reliance in
20 changing the vaccine schedule.

21 But here's the problem, vaccine schedules change all
22 the time. They're not designed to be permanent. It's not like
23 this is a long-standing policy that was designed to remain in
24 place indefinitely and it was suddenly changed. To the
25 contrary, the vaccine schedule is updated all the time.

1 In fact, the -- you know, Plaintiffs note in their
2 brief on page 26, note 68, they concede that, with regard to
3 the hepatitis B vaccine, they say "Even after the first
4 universal recommendation, ACIP continued to assess and revise
5 HepB vaccination recommendations."

6 The ACIP charter, which is ECF Number 185-21,
7 recognizes that ACIP may revise recommendations over time as
8 information changes.

9 And so given that the vaccine schedule is designed to
10 change over time as new information comes about and as, you
11 know, democratically accountable policymakers pursue different
12 vaccine policies, that's baked into the vaccine
13 recommendations, so given that they change over time by design,
14 neither Plaintiffs nor anyone else had any reliance interests
15 in the recommendations remaining the same in perpetuity.

16 And, you know, we cite several cases including the
17 D.C. Circuit's *Bell Atlantic Telephone Company* case and the
18 Supreme Court's *Wages & White Lion* case to support that point.
19 There simply was no reliance interest here.

20 And, you know, Plaintiffs argue that, you know, we
21 didn't consider the effects on health insurance coverage and
22 cost sharing under the Affordable Care Act and also the Vaccine
23 For Children program.

24 But, as we've discussed, all the vaccines that were on
25 the schedule before are still on the schedule. They might have

1 moved from recommended for all children to recommended under
2 shared clinical decision-making, but that does not change
3 coverage under the Affordable Care Act or the Vaccines for
4 Children Program. They're all still covered, so there simply
5 was no change in terms of insurance coverage or the VFC
6 program.

7 And so, kind of, in sum what we see from the documents
8 before us is that CDC reasonably considered the relevant issues
9 and reasonably explained its decision.

10 Plaintiffs may disagree with the government's
11 assessment of the evidence, but that cannot overcome the high
12 level of deference given to the agency's scientific judgment
13 within its area of expertise and the Court cannot substitute
14 its judgment about vaccine policy for that of the agency.

15 The agency has discretion over how to set vaccine
16 policy to promote public health, and that's exactly what it did
17 here. Its decision is well within a zone of reasonableness.

18 So I think we can turn finally to FACA.

19 THE COURT: Before we just move on to that, you had
20 said that the CDC has discretion on whether or not to issue
21 immunization schedules at all, but there's lots of statutes,
22 many of which Mr. Oh walked us through, where Congress has
23 seemed to rely on the issuance of those vaccine schedules.

24 And so when you say the CDC has complete discretion
25 whether to issue a vaccine schedule or not, how do I marry that

1 assertion to the fact that Congress seems to be reliant upon
2 the issuance of such schedules across a whole wealth of other
3 areas?

4 MR. BELFER: So I think a lot of the statutes refer to
5 ACIP recommendations which are then approved by the CDC
6 director.

7 THE COURT: Right.

8 MR. BELFER: And so, again, I think if -- if the
9 government were to abolish ACIP entirely --

10 THE COURT: Can the government say -- could CDC say,
11 we're out of the vaccination game; we don't recommend anything,
12 not only -- not that -- maybe their recommendation is no
13 vaccines, can the CDC do that?

14 MR. BELFER: Under Section 243(a), yes.

15 THE COURT: So it's within -- under 243(a), it's
16 within the CDC's discretion to say, we don't believe in
17 vaccines; we don't recommend any.

18 MR. BELFER: Yes. Under 243(a), they have the
19 discretion not to issue vaccine recommendations at all.

20 THE COURT: Okay. And then --

21 MR. BELFER: But I think, you know, the Court doesn't
22 even really need to reach that issue because here no one is
23 saying we're not going to issue vaccine recommendations.

24 THE COURT: You've done a very good job of presenting
25 your argument, and I understand that that's not it. Don't get

1 me wrong. I was just making sure I understand the end point of
2 what -- where agency discretion might end.

3 MR. BELFER: Yeah. And, I guess, just to close the
4 loop on that, you know, I think Your Honor is right that there
5 are other statutes that reference ACIP recommendations.

6 And so I think if CDC were to say, like, we are no
7 longer going to consider ACIP recommendations at all, like,
8 ACIP, you can do what you want, but we're not going to adopt
9 them; we're not even going to consider them, like, that would
10 be a different case because there would be other statutes
11 implicated. Like, the statutes that reference ACIP
12 recommendations, those might be implicated if the government
13 said, we are just going to, kind of, ignore ACIP and pretend it
14 doesn't exist.

15 THE COURT: So Mr. Oh's argument was that, in those 13
16 statutes that he pointed to that referenced ACIP
17 recommendations, really what they meant was as adopted by the
18 CDC. Do you agree with that?

19 MR. BELFER: So I'm not familiar with, like, all of
20 those 13 statutes, but, like, for example, at least with regard
21 to, like, the Affordable Care Act --

22 THE COURT: Yeah.

23 MR. BELFER: Yes, the government's interpretation of
24 the Affordable Care Act is that when it refers to vaccine
25 recommendations from ACIP that are in effect, what it means is

1 vaccine recommendations from ACIP that have been adopted by
2 CDC.

3 THE COURT: Okay. So you all are in agreement on
4 that.

5 MR. BELFER: So, yes, we agree that -- like, at least
6 with the Affordable Care Act, that is referring to ACIP
7 recommendations adopted by CDC.

8 THE COURT: Okay.

9 MR. BELFER: And so I think if this were a different
10 case, if CDC were going to say, you know, we're just going to
11 ignore ACIP recommendations forever and pretend it doesn't
12 exist, you know; ACIP you can make a recommendation, we are
13 going to, like, adopt a policy where we, like, pretend it
14 doesn't exist, that would be a different case, and under the,
15 kind of, committed agency discretion analysis, that would be a
16 different analysis.

17 THE COURT: I understand.

18 MR. BELFER: Right. But, again, here, the existence
19 of ACIP is not at issue, and so all of those 13 statutes are
20 not relevant. What's relevant is 243(a) which governs how CDC
21 goes about assisting states in promoting public health.

22 THE COURT: Before you turn to FACA, can I -- can you
23 pause for just one minute? This would be a logical point to
24 take a 10-minute break just to give everyone a chance to
25 stretch their legs for a minute.

1 THE CLERK: All rise.

2 (The Honorable Court exited.)

3 (Brief break from 3:39 p.m. to 3:54 p.m.)

4 THE CLERK: All rise.

5 (The Honorable Court entered.)

6 THE CLERK: Please be seated.

7 THE COURT: Mr. Belfer, you're on to FACA, I believe.

8 MR. BELFER: Yes, Your Honor. I want to make a few
9 clarifications first.

10 THE COURT: Okay.

11 MR. BELFER: In my previous presentation, I think Your
12 Honor asked about the appropriate form of relief; if the Court
13 would agree with Plaintiffs, what sort of relief should be
14 issued, and I just want to clarify a couple things.

15 THE COURT: Sure.

16 MR. BELFER: I think I may have said that the Court
17 could vacate the January action. Upon discussion with my
18 colleagues, I realized the Court cannot vacate preliminarily.
19 That's something that happens on final judgment.

20 THE COURT: Right.

21 MR. BELFER: And so it wouldn't be vacatur, but what
22 the Court could do is the Court could enjoin those aspects of
23 the decision that are causing irreparable harm to Plaintiffs,
24 so it would be, like, a narrowly tailored decision enjoining
25 just those aspects that are causing irreparable harm, and

1 then --

2 THE COURT: Can I ask you -- I appreciate that. Were
3 you done with that thought, or were you moving on?

4 MR. BELFER: Well, I was going to go on to the relief
5 for FACA, which would basically just -- it's a similar point,
6 you know. I think -- I think what I said before was the Court
7 could remand for the agency to reconstitute FACA, but I think,
8 again, that's more of a final relief thing to do.

9 Preliminarily, on a PI, I think the relief would be,
10 again, just a narrowly tailored injunction enjoining those
11 aspects of the February meeting that the Court finds are
12 causing irreparable harm, so if there's a particular thing
13 about the meeting that the Court thinks is causing irreparable
14 harm, the Court could enjoin that, but that would be the nature
15 of any order.

16 THE COURT: Thank you. I think I actually said the
17 word vacatur, so I probably led you down the wrong path there,
18 but I appreciate that correction, and I think you're right.

19 You had said in response to one of my questions that
20 if the CDC had just said we -- we're ignoring ACIP, ACIP had
21 given a recommendation on January 2nd, and then the CDC
22 director had said, I'm not reading that; I'm issuing it on my
23 own, and you said that would be a different situation. Would
24 it be a different situation than not seeking the ACIP guidance
25 at all?

1 MR. BELFER: So I think what's clear from the statutes
2 Plaintiffs cited is that Congress recognizes that ACIP exists
3 and it has a function, that one pathway for making vaccine
4 recommendations starts with ACIP and then goes to CDC.

5 THE COURT: Right.

6 MR. BELFER: And so if the agency were to say that
7 process is done, like, we are going to cancel that process
8 going forward, then that would be a different case.

9 THE COURT: That is what happened in January; right?

10 MR. BELFER: Well, no. What happened in January was
11 the CDC issued its own vaccine recommendations, but it did not,
12 like, prevent ACIP from, like, ever meeting again. It's a fine
13 point, but I think it's an important distinction.

14 THE COURT: Apply it to the ACA, right, the ACA says
15 that immunizations that are routine, and it uses the -- it says
16 for routine use, and I'm not sure if routine use includes
17 shared clinical decision-making or not, but the ACA
18 specifically says it is referring to those recommendations that
19 are taken from the ACIP and adopted by the CDC.

20 MR. BELFER: Right.

21 THE COURT: It says ACIP recommendations finalized,
22 and then it defines finalized as -- or it says in effect
23 rather, not finalized -- and in effect is as adopted by the
24 director of the CDC.

25 So under the ACA, does the January guidance have any

1 force at all? And it is -- that's question 1. And question 2,
2 is shared clinical decision-making routine use?

3 MR. BELFER: So the answer to question 2 is yes.

4 THE COURT: Okay. What authority do you point to for
5 that?

6 MR. BELFER: The --

7 THE COURT: I'm not telling you you're wrong. I
8 genuinely don't know.

9 MR. BELFER: The agency has interpreted routine use
10 per the ACA to include shared clinical decision-making anything
11 that's on the schedule, and I think we have the regulatory
12 cites in our briefs.

13 THE COURT: Okay.

14 MR. BELFER: But, yes, anything that is on the
15 schedule including shared clinical decision-making is
16 considered routine use and thus covered by the Affordable Care
17 Act.

18 THE COURT: What about question 1, which is does --
19 since the ACA refers to only ACIP recommendations adopted by
20 the CDC, since there's no ACIP recommendation that predated the
21 January guidance, does the January guidance have any impact on
22 the ACA?

23 MR. BELFER: So the government's position is, yes, the
24 vaccines that are on the schedule from January 5th are still
25 covered by the Affordable Care Act, and so I think, you know,

1 we've taken that position publicly. It's on our website. It's
2 on the fact sheet. We've said that all the vaccines on the
3 schedule are still covered under the Affordable Care Act.

4 And no one is -- you know, Plaintiffs have certainly
5 not challenged that, so I think it's kind of -- it's undisputed
6 that the vaccines on the January 2026 schedule are still
7 covered under the Affordable Care Act.

8 THE COURT: Okay. Great. Thank you. I'm sorry to
9 redirect you, and I recognize that it's been a long day, so
10 I'll give you the floor on FACA.

11 MR. BELFER: Thank you.

12 And I guess before we get to FACA, Your Honor asked
13 about the *Braidwood* case.

14 THE COURT: Yes.

15 MR. BELFER: So I want to address that. And so this
16 is a case that was, I think, cited in an amicus brief, and I
17 think the context was the question whether the -- whether CDC
18 can make vaccine recommendations that are not based on ACIP,
19 and this amicus says that under *Braidwood*, you have to go
20 through ACIP, but *Braidwood* actually is in opposite.

21 THE COURT: It seems to say you can just -- well, my
22 takeaway from this case is you can just fire everyone and tell
23 them what the recommendation would be.

24 MR. BELFER: Well, so *Braidwood* was about the
25 appointments clause.

1 THE COURT: Right.

2 MR. BELFER: And what *Braidwood* held -- it addressed
3 this task force, and it said that the task force members were
4 inferior officers because the HHS secretary was able to remove
5 them at will and could block their recommendation, so it was
6 just this appointments clause case about whether the task force
7 members were inferior officers and whether they were adequately
8 supervised by the secretary.

9 But *Braidwood* did not address whether the secretary
10 could make recommendations on his own, that -- so the notion
11 whether the secretary can make recommendations on his own that
12 are not based on the task force was simply not at issue in
13 *Braidwood*.

14 THE COURT: I agree. I just read that case yesterday,
15 but thank you.

16 MR. BELFER: Okay. Okay. So -- and I guess just one
17 another point about *Braidwood* is the -- another reason why
18 that's distinguishable is that here the secretary's authority
19 to issue -- yeah, the CDC's authority to issue vaccine
20 recommendations is under Section 243(a) and so that's the
21 statutory basis for issuing vaccine recommendations, but that
22 statute was not at issue in *Braidwood*, so it's just a different
23 statute at issue.

24 THE COURT: Right. I appreciate that distinction.
25 Thank you.

1 MR. BELFER: Okay. So I think we can turn to FACA,
2 and I think we're getting close to the end. We have FACA and
3 then briefly standing, and I think we're done.

4 THE COURT: Okay.

5 MR. BELFER: And so on FACA, so let's start with the
6 fairly balanced requirement and then we can go to inappropriate
7 influence. So FACA --

8 THE COURT: Can I actually stop you for a moment,
9 please?

10 MR. BELFER: Sure.

11 THE COURT: So under -- I assume because of FACA, the
12 agency set up this -- the -- how they were going to constitute
13 the committee, and they set up a procedure for that. Does the
14 agency have unfettered discretion to disregard the procedure
15 they set up?

16 MR. BELFER: So I think Your Honor is referring to the
17 membership balance plan.

18 THE COURT: Right. I'm sorry. I had forgotten the
19 exact name. I appreciate that.

20 MR. BELFER: So the membership balance plan -- I
21 guess, the first question is, like, is that actually required?

22 THE COURT: Yeah. The procedure that they set out,
23 they -- I mean, the CDC submitted that document I assume; is
24 that correct?

25 MR. BELFER: Yeah. The agency created the document.

1 I'm not sure, like, who signed it, but, yes, the agency did
2 create --

3 THE COURT: So the CDC creates this document that
4 says, this is how we will constitute ACIP. It relies on the
5 ACIP -- I left that document on my desk -- but the ACIP
6 steering committee and that it lays out, this is how we're
7 going to constitute the committee members; we're going to
8 publish proposed members in the federal register; we're going
9 to do it at a meeting in November or December. There was seven
10 or eight different things.

11 They didn't happen. At least some of them didn't
12 happen. Certainly, I know they didn't meet in November or
13 December, and I know they didn't publish them in the federal
14 register before the appointment. Those procedures were set up
15 by the CDC, and then the CDC elected not to follow them.

16 I don't know that the CDC is required to follow those
17 procedures and what's the answer to that? Is the CDC required
18 to follow the procedures that it imposed on itself?

19 MR. BELFER: It is not required to follow the
20 membership balance plan. That does not constrain the
21 secretary.

22 So I guess a few points, so with regard to, kind of,
23 how the regulations deal with this issue, so that's -- there
24 was a change recently, I think it was in December 2025, the
25 regulation -- the FACA regulations changed, so they used to

1 require a membership balance plan, that agencies submit one,
2 but they no longer require that, so --

3 THE COURT: As of December of 2025?

4 MR. BELFER: My understanding is that in December of
5 2025, the FACA regulations changed to no longer require
6 agencies to submit a membership balance plan.

7 THE COURT: But does that matter?

8 MR. BELFER: Well, I mean, I think --

9 THE COURT: Because this all happened in June of 2025;
10 right?

11 MR. BELFER: The appointments -- I think they're
12 ongoing, but they --

13 THE COURT: Oh, right. Okay. But let's -- putting
14 aside that maybe things changed in December, let's talk about
15 pre-December when presumably they did have to have the
16 membership balance plan.

17 MR. BELFER: Sure. And I think, like, a relevant
18 consideration there is, kind of, even if there were a violation
19 of FACA under the APA, you have to consider harmless error.

20 And so, you know, here even if the Court were to find
21 that the agency needed to follow this particular procedure to
22 appoint ACIP members back in June, the secretary could just
23 reappoint them now because now you don't have to have a
24 membership balance plan, and so there's simply no harm there.

25 But let's turn to the question of whether -- as Your

1 Honor noted, the agency did create this plan, and so are they
2 required to follow it? And I think the answer there is still
3 no.

4 So the membership balance plan helps the agency comply
5 with the fair balance provision of FACA. It provides
6 procedures that would help the agency achieve that.

7 But FACA itself never requires a membership balance
8 plan. It does not require agencies to follow any particular
9 procedures. What FACA requires is just what's set out in the
10 statute. It requires fairly balanced and it requires guarding
11 against inappropriate influence.

12 So the Court can just apply FACA directly, and,
13 indeed, in the First Circuit in the *Union of Concerned*
14 *Scientists* case, that's what they did. They applied FACA
15 directly. They applied the fairly balanced, inappropriate
16 influence provisions directly.

17 And so, you know, I think the membership balance plan,
18 it exists to kind of help the secretary and help the agency
19 comply with FACA, but the particular procedures in the
20 membership balance plan, they do not constrain the secretary's
21 discretion to appoint ACIP members.

22 Okay. And, again, I think also, you know, the ACIP
23 charter, I know that, like, one of the issues was the steering
24 committee, but, again, like, that's not -- that's not required
25 by the ACIP charter. That's just, kind of, a component of the

1 membership balance plan, which, again, exists to help the
2 agency comply with the statute, but the procedures in the
3 membership balance plan are not mandatory. They don't
4 constrain the secretary's discretion in appointing ACIP
5 members.

6 And another thing that's helpful is that, you know, if
7 you look at FACA, FACA does not regulate the process for
8 appointing advisory committee members. Instead, it regulates
9 the composition of the committee, and so --

10 THE COURT: Can't I look -- so your argument is heard
11 and well made in that the membership balance plan is not a
12 required part of FACA, so not following it doesn't ipso facto
13 mean you violated FACA.

14 But if I'm looking for whether or not the ACIP is
15 reasonably balanced, can't I look at whether or not the agency
16 followed the membership balance plan to infer whether or not
17 the result is a balanced committee?

18 MR. BELFER: I don't think so because really what the
19 Court has to do is look at the membership, you know. We know
20 who the members are. They've all -- they've been selected.
21 They have bios online.

22 THE COURT: Yeah.

23 MR. BELFER: You can look at the background, the
24 credentials, the experience of the members on ACIP, and just
25 looking at that, who's on the committee, the current committee

1 composition, and ask, is this committee fairly balanced, and I
2 think that's what the Court should do.

3 I think the procedure that was reached to appoint
4 them, that's simply not relevant to the fairly balanced
5 requirement. The fairly balanced requirement is just focused
6 on, what is the current membership and is that membership
7 fairly balance?

8 THE COURT: It seems like it would be a much more
9 conservative use of judicial discretion, rather than trying to
10 inject myself into the qualifications of the individuals, to
11 review whether or not the procedure that led to the appointment
12 of those individuals was fair and balanced.

13 I am very reluctant, as a judge, to say I'm going to
14 look at the credentials and say whether or not this
15 epidemiologist is sufficiently qualified in the world of
16 epidemiology to be on the committee versus looking at the plan
17 itself and saying, as a judge, the only thing I can look at is
18 whether or not you followed a procedure that led to a
19 reasonable balance of people.

20 MR. BELFER: And I think Your Honor's hesitation is
21 borne out by the case law, and so, for example, if you look at
22 the First Circuit's *Union of Concerned Scientists* case, what
23 the First Circuit said is that FACA does not require an
24 advisory committee to be split exactly evenly on one side of an
25 issue or the other. You don't need an exact even split, but

the FACA preserves wide agency discretion in striking a balance among committee members.

The First Circuit said 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 committee.

And then if you look at -- we cited the D.C. Circuit opinion of Judge Edwards in the *Public Citizen* case, and what he said is "The fairly balanced requirement falls short of mathematical precision and application and involves some balancing of interest by the agency. The difficulty in determining what precisely constitutes a fair balance may incline Courts to be differential in reviewing the composition of advisory committees and may defeat a plaintiff's claims in a given case."

And then another judge in that case, Judge Friedman, confirmed, "The determination of how the fairly balanced membership advisory committee in terms of the points of view represented and the functions that the committee is to perform is to be achieved necessarily lies within the discretion of the official who appoints the committee."

And so I think Your Honor is right, there is a wide discretion of the appointing official to determine fair balance. It's not a matter of just counting numbers. It's not a matter of exact even numbers on any kind of an issue.

1 There's a lot of discretion here.

2 And so, you know, I think under *Union of Concerned*
3 *Scientists*, I think the appropriate approach is to look at
4 committee membership. It's really not about procedure.

5 It really is about the composition of the committee,
6 but when the Court does that, it should be done with high
7 levels of discretion given that this is -- you know, there's a
8 lot of gray here; there's a lot of room for discretion.

9 And so, you know, ultimately Plaintiffs have the
10 burden on a PI, so let's look at what Plaintiffs argue in terms
11 of fair balance.

12 So what Plaintiffs have argued is that 10 of the 14
13 current ACIP members hold what Plaintiffs call anti-vaccine
14 views. That is both legally irrelevant and false.

15 It's legally irrelevant, because, again, from the
16 *Public Citizen* case, that explained that Congress intended
17 balance to be judged by the members' employment status and
18 background, not their professed personal opinions.

19 Nothing in the act or its legislative history even
20 slightly indicates that Congress intended the presence or
21 absence of balance to turn on an inquiry into the opinions of
22 individual members.

23 And so what that case is saying is, you know, again,
24 don't try and characterize each person's viewpoints and
25 opinions, look at their background, look at their experience,

1 and see if in light of all that, there's a fair balance on this
2 committee.

3 And here, the ACIP members have a wide variety of
4 employment backgrounds, a wide variety of experiences which
5 does satisfy the fair balance requirement.

6 But, you know, even if you were -- so I think that's
7 one point. Another point is that the notion that 10 members
8 are anti-vaccine -- kind of categorically anti-vaccine is just
9 not true, and you can tell that by looking at the actual
10 meetings, look at how they voted.

11 In the June 2025 meeting, ACIP -- which is -- you
12 know, the newly reconstituted ACIP recommended that adults and
13 children receive seasonal influenza vaccines in single-dose
14 formulations that are free of thimerosal as a preservative. It
15 didn't say don't get this vaccine. It said you should get this
16 vaccine, but we're going to tweak it so you don't have this
17 particular ingredient that we're concerned about.

18 In September, they voted unanimously to recommend the
19 COVID-19 vaccine based on shared clinical decision-making. And
20 in December, they voted to recommend the hepatitis B vaccine
21 based on shared clinical decision-making for certain infants.

22 And so what all these votes show is that they're not
23 categorically rejecting vaccines. They have not recommended
24 against any vaccine. They have not recommended any vaccine be
25 removed from the schedule. They've kept all the vaccines on

1 the schedule. They've just tweaked certain recommendations in
2 light of their concerns with particular vaccines or particular
3 vaccine ingredients.

4 The September meeting summary which we cite in our
5 brief, page 88, one of the ACIP members noted the committee's
6 discussions clearly demonstrate the members are not opposed to
7 vaccines and that the robust scientific debate, mutual respect
8 among members, and inclusion of external experts reflect a
9 thoughtful, open-minded approach rather than any predetermined
10 stance. And so I think that shows that this, kind of, gross
11 characterization of all -- of 10 ACIP members as just
12 categorically anti-vaccine is not true.

13 And then a final point on that, you know, even if you
14 were to accept that their personal opinions are relevant and
15 even if you agree with Plaintiffs that they are anti-vaccine,
16 that would mean there's a 10/4 split, but even such a split is
17 within the agency's wide discretion in striking a balance among
18 ACIP members.

19 Again, the agency has wide discretion. It's not a
20 mathematical exact even balancing. There's some, you know,
21 play in the joints. There's room for the agency to exercise
22 discretion, and so even if there were, like, a 10/4 split as
23 Plaintiffs characterize it, that would not show a violation of
24 FACA.

25 And something else to note, there are still unfilled

1 positions, you know. There are 19 authorized slots, and so
2 there's still, you know, people to be appointed. There's still
3 room to balance FACA, you know. Even if FACA's not balanced
4 now, which we don't agree, but even if the Court thinks
5 there's, kind of, more to be done to balance FACA, you know,
6 we're still in the process of appointing FACA members -- we're
7 still in the process of appointing ACIP members.

8 THE COURT: I follow you.

9 MR. BELFER: ACIP members. Okay.

10 So I think -- so that, kind of, covers the point of
11 view issue.

12 Then another part of fair balance is that you have a
13 balance that is relevant to the agency's function, so making
14 sure that the ACIP members have backgrounds and experience that
15 are balanced so that they can be successful in achieving the
16 agency's functions and operation, and here, that's easily met.

17 If you look at the bios of the ACIP members -- and we
18 go through this in our brief; I don't need to belabor it
19 here -- but if you look at their bios, there is extensive
20 experience relevant to vaccine recommendations from a wide
21 range of clinical and research backgrounds, you know. All the
22 members have an M.D., Ph.D., or Pharm.D., and, again, they have
23 extensive experience in epidemiology, in research, in clinical
24 practice related to vaccines.

25 And indeed, when the secretary appointed the ACIP

1 members, he explained there was no reference to, you know,
2 trying to skew the pro- or anti-vaccine component of ACIP.

3 What the secretary said was, I want to appoint people
4 who will exercise independent judgment and follow the evidence,
5 and that's what he did. Okay.

6 So we talked about their qualifications. We talked
7 about the membership balance plan. And so I think that covers
8 it for the fairly balanced requirement, so I think we can turn
9 to the inappropriate influence requirement.

10 And so here in 5 U.S.C., 1004 Section (b) (3) and (c),
11 FACA provides that in creating an advisory committee, agency
12 heads shall ensure there are appropriate provisions to assure
13 that the advice and recommendations of the advisory committee
14 will not be inappropriately influenced by the appointing
15 authority or by any special interest but will instead be a
16 result of the advisory committee's independent judgment, and
17 the regulations refer to develop procedures to assure the
18 committee's recommendations will not be inappropriately
19 influenced.

20 What the First Circuit explained in *Union of Concerned*
21 *Scientists* is that FACA preserves wide agency discretion both
22 in fairly balanced and in protecting against inappropriate
23 influence.

24 Now, Plaintiffs do not argue that when ACIP was
25 originally created or when the secretary appointed members that

1 there were inadequate provisions or procedures in place to
2 protect against inappropriate influence.

3 What they argue, they say that there are various
4 anti-vaccine people in the committee, but even if Plaintiffs
5 are right that a certain number of ACIP members have anti --
6 quote, anti-vaccine views, that doesn't show there are not
7 appropriate provisions or procedures in place to ensure against
8 inappropriate influence.

9 One thing they argue, they say four ACIP members are
10 members or otherwise affiliated with openly anti-vaccine
11 organizations. Even if that were true, though, it doesn't show
12 the absence of appropriate provisions or procedures to guard
13 against inappropriate influence.

14 And I think, you know, helpful here is the *Public*
15 *Citizen* case that we've discussed before, I think that
16 elaborates on what inappropriate influence means.

17 And so the *Public Citizen* case, this is actually
18 quoting the relevant house report from the legislative history
19 of FACA. It says, "The inappropriate influence requirement is
20 designed to protect against the danger of allowing special
21 interest groups to exercise undue influence upon the government
22 through their dominance of advisory committees which deal with
23 matters in which they have vested interest." So the concern is
24 dominance. Do special interests dominate the committee?

25 For example, are all the members of a committee part

1 of industry? Are they all members of certain -- of a certain
2 kind of advocacy group? That sort of dominance would violate
3 the inappropriate influence provision.

4 And in *Public Citizen*, there -- the committee there
5 had 18 members. Six of the 18 were employed by industry, but
6 the Court found that six of 18 employed by industry did not
7 show inappropriate influence.

8 Here, we have, I think, four out of 14, similarly does
9 not show -- four people out of a committee of 14 are allegedly
10 affiliated with anti-vaccine groups does not show any dominance
11 of the committee.

12 And something else that's relevant is that, you know,
13 there's a presumption that government employees exercise their
14 duties in good faith and in accordance with law, you know, the
15 presumption of regularity.

16 Here, ACIP members are considered special government
17 employees under the ACIP charter, and so there's a presumption
18 that they have properly discharged their duties and have
19 exercised their independent judgment in advising CDC in making
20 recommendations.

21 And to overcome that presumption of regularity, the
22 presumption that government employees act in good faith and
23 properly discharge their duties, Plaintiffs' burden is to
24 present clear evidence to the contrary, and they simply have
25 not shown any clear evidence of inappropriate influence.

Simply alleging that some ACIP members have anti-vaccine views, maybe they're members of anti-vaccine organizations, that is not clear evidence overcoming the presumption of regularity.

In their presentation, Plaintiffs also -- they said, well, there have been anti-vaccine speakers at ACIP meetings, but the mere fact that some of the speakers at a meeting hold anti-ACIP views -- sorry -- hold anti-vaccine views does not show the committee's being inappropriately influenced.

You can flip it. What if some of the speakers at an ACIP meeting held pro-vaccine views? What if they were members of AAP? Would having, you know, speakers at an ACIP meeting that were pro-vaccine and members of AAP be inappropriate influence? Of course not, so simply saying, well, a few members have anti-vaccine viewpoints does not show inappropriate influence. I think that covers it for FACA.

So I think we can probably move on to the final topic, which is standing. Plaintiffs argue at the end of their presentation that we didn't address the *Diamond Alternative Energy* case. The reason why we didn't address that in our brief is that that case was not about organizational standing.

The *Alliance* case from the Supreme Court, that is the law on organizational standing, and so we cited *Alliance* rather than *Diamond Alternative Energy* because *Alliance* is the case that provides the relevant standard on organizational standing.

And so, you know, turning to *Alliance*, I think -- you

1 know, we explained in our brief why we think Plaintiffs do not
2 have standing under *Alliance*.

3 And so, you know, we understand the Court reached a
4 different conclusion in resolving our motion to dismiss, and so
5 we don't need to belabor the point here, but I think suffice to
6 say for the reasons discussed in our brief, we would
7 respectfully submit that the theory of organizational standing
8 and diversion of resources that Plaintiffs are alleging were
9 squarely rejected by the unanimous Supreme Court in *Alliance*
10 *for Hippocratic Medicine*.

11 With regard to associational standing, and so this is
12 the injuries to Plaintiffs' members, so I think a very, you
13 know, telling omission, as discussed earlier, was that, you
14 know, Plaintiffs now admit that there are insurance billing
15 codes; there are CPT codes for being reimbursed for shared
16 clinical decision-making, and so even if Plaintiffs' members,
17 those doctors, are spending time on shared clinical
18 decision-making, that is not an injury because they could be
19 reimbursed for that time.

20 And to the extent an insurance company chooses not to
21 reimburse, that's the independent decision of an insurance
22 company, not fairly traceable to the government.

23 And then the final question is, you know, Plaintiffs
24 make this new argument about being denied participation in ACIP
25 work groups. They say that gives them standing to challenge

1 ACIP's composition.

2 But I think if the Court looks at what Plaintiffs are
3 actually challenging, they're not actually challenging, in
4 their complaint, either the third amended complaint or the
5 proposed fourth amended complaint, they're not challenging the
6 involvement of liaison organizations in work groups.

7 What they're challenging is the secretary's
8 appointment of voting members, and so because the composition
9 of work groups is not the challenged action, you know, any
10 alleged injury not being involved in the work groups is not
11 fairly traceable to the challenged action which is the
12 appointment of voting members, nor is it addressable by any
13 action addressing that alleged injury.

14 Also notable is the fact that liaison organizations
15 can still participate in ACIP meetings. They are no longer
16 involved with work groups meetings, but they still can and
17 still do participate in ACIP meetings including the September
18 ACIP meeting.

19 And, you know, similarly, the ACIP charter, while it
20 provides for liaison representatives to ACIP, it does not say
21 that they have to participate in work groups. And, in fact,
22 the work group operating procedure says the work groups may
23 include ACIP liaison organizations.

24 And so I think for all of those reasons Plaintiffs do
25 not have standing, and we think that their claims are simply

1 not viable for all of the reasons we discussed, and, of course,
2 we also think they have failed to show irreparable harm or that
3 the public interest favors an injunction.

4 Absent any other questions, I think we'll rest at our
5 submission.

6 THE COURT: Thank you very much, Mr. Belfer. I
7 appreciate your argument.

8 Mr. Oh, you have a very few minutes for rebuttal. I
9 have a couple quick questions for you first. This began with a
10 conversation about whether or not the VFC was affected by the
11 January guidance or the February meeting, and Mr. Belfer said
12 it was not contradicting the affidavit submitted by the
13 Dr. Kelsey -- I think -- Kressly -- sorry. Will the January
14 guidance -- the supposition by Dr. Kressly about what would
15 happen in February affect the VFC?

16 MR. OH: Yes, it will, Your Honor.

17 THE COURT: How will it do so?

18 MR. OH: And I'd like to direct your attention to
19 Dr. Kressly's declaration and Dr. Berman's declaration that
20 haven't yet been filed on the record.

21 THE COURT: So if that's the answer, I appreciate that
22 answer. I've read this. Mr. Belfer, there's a disagreement on
23 this point, and it seems relevant to me, so if this is what
24 fashioned your response, which I think we gave you until next
25 Wednesday, that is my question, will the VFC be affected by the

1 January guidance or the February meeting as predicted by
2 Dr. Kressly?

3 MR. OH: And so perhaps Mr. Belfer should address
4 paragraph 11 in Dr. Kressly's declaration, and then --

5 THE COURT: Well, Mr. Belfer can address whatever he'd
6 like.

7 MR. OH: Okay.

8 THE COURT: My second question is the -- what are the
9 legal consequences of the January guidance?

10 MR. OH: The legal consequences of the January
11 guidance.

12 THE COURT: The issue that he -- Mr. Belfer argued
13 there's no -- it is not final agency action because no legal
14 consequences flow from it. What legal consequences flow from
15 the January guidance?

16 MR. OH: Well, for one --

17 THE COURT: I wouldn't call it guidance, the
18 January -- whatever you want to call it -- directive.

19 MR. OH: The potential -- this creates a dynamic of
20 "do I follow CDC guidance or HHS guidance" or "do I follow the
21 standard of care and, thereby, expose myself to potential
22 liability?" That is one legal consequence that does flow from
23 that, Your Honor.

24 THE COURT: This is -- you're referring to the
25 statement Kennedy made about whether or not you'd still be

1 protected.

2 MR. OH: Yes. Yes.

3 THE COURT: Okay.

4 MR. OH: There are -- I mean, I don't know necessarily
5 what the full definition is and what all the case law says
6 about legal consequences, but there are contractual
7 relationships that providers, some have -- either do or do not
8 enter into as a result of the issue of whether or not they need
9 to stock certain vaccines.

10 And so one of the issues with VFC here is that under
11 the program, there are providers who do not actually have to
12 stock vaccines that are classified as shared clinical
13 decision-making.

14 THE COURT: Right. No. I get the affidavit. There
15 was a disagreement about whether or not it's true, so I just
16 wanted to highlight that that is something that I'm considering
17 so Mr. Belfer can choose to respond as he'd like.

18 Mr. Oh, I'll give you 10 minutes to respond to the
19 rest of the presentation.

20 MR. OH: Oh, man. I have, like, seven points I'd like
21 to make.

22 THE COURT: I know, but it is Friday at 4:30. I did
23 say I'd give you all day and you took me up on it.

24 MR. OH: So I will -- you asked the question: Is
25 there a case that addresses the membership balance plan?

1 THE COURT: Okay.

2 MR. OH: There is. It is *Western Organization of*
3 *Resource Councils versus Bernhardt*, 412 F. Supp. 3rd 1227,
4 District of Montana 2019.

5 And in that particular case, there is an actual
6 section that is entitled "Membership Balance Plan," and the
7 agency's final decision as to membership falls within the realm
8 of agency discretion must provide a rational basis for its
9 decision. The failure to do so was arbitrary and capricious in
10 violation of the APA because it didn't follow a membership
11 balance plan.

12 And the Court's conclusion there was because the
13 committee was established in violation of FACA, it should not
14 be permitted to meet further.

15 THE COURT: Was that decision taken to an appellate
16 Court?

17 MR. OH: It was not as far as I know. I don't think
18 it was.

19 THE COURT: 412 F. Supp. 1227.

20 MR. OH: 412 F. Supp. 3rd 1227.

21 And then I'd also like to address your attention to
22 *Alabama-Tombigbee*, T-O-M-B-I-G-B-E-E, *Rivers Coalition versus*
23 *Department of Interior*, 26 F.3rd 1103 1994. It's an Eleventh
24 Circuit case, and in that particular case --

25 THE COURT: 22nd F.3rd.

1 MR. OH: 26 F.3rd 1103.

2 THE COURT: Okay.

3 MR. OH: 1994, Eleventh Circuit. And in that
4 particular case, the federal advisory committee issued a report
5 that wasn't in compliance with FACA and the APA, and the
6 District Court permanently enjoined the defendants from
7 publishing, employing, and relying upon the advisory committee
8 report that it issued and the Eleventh Circuit affirmed.

9 THE COURT: Great. I will read both of those this
10 evening.

11 MR. OH: I did quickly want to mention the speech
12 issue, and I would note that the ACIP members are special
13 governmental employees, and under *Garcetti versus Ceballos*,
14 547 U.S. 410, it's a Supreme Court case, 2006, restricting
15 speech that owes its existence to a public employee's
16 responsibilities does not infringe on any liberties the
17 employee might have enjoined as a private citizen.

18 And when they're speaking as special government
19 employees at a public ACIP meeting, they don't have First
20 Amendment protection. With regard --

21 THE COURT: I understand that, and I do -- Mr. Belfer
22 was careful to say First Amendment -- you had a nice phrase to
23 it. I've forgotten. Because you didn't say First Amendment
24 rights. You said.

25 MR. BELFER: First Amendment, like, values or --

1 THE COURT: Yes. I thought Mr. Belfer was quite
2 careful on that point to not say that they were infringing on
3 their First Amendment rights.

4 MR. OH: One other point about the case of *Department*
5 *of Commerce versus New York*, I often like it when my opposing
6 counsel relies on a case that goes in my favor.

7 And in this particular case and, quite frankly, from
8 the beginning of this case, I thought that this case was pretty
9 darn similar to this one because of the facts and because of
10 the pretextual reasons that the secretary of commerce gave to
11 put a citizenship question on the census.

12 And in this particular case -- let me see here --
13 agency -- we do not hold that the agency's decision was
14 substantively invalid, but agencies must pursue their goals
15 reasonably. Reasoned decision-making under the APA calls for
16 an explanation for agency action. What was provided here was
17 more of a distraction.

18 So I would commend your court -- the Court to take a
19 look at *New York Department of Commerce versus Trump*, and
20 actually, the -- that was a case that involved a fair amount of
21 extra record discovery because there was significant evidence
22 of bad faith.

23 With regard to committed to agency discretion, Your
24 Honor, and *Braidwood* -- so *Braidwood* was a question of
25 principal versus inferior officers.

1 THE COURT: Yeah.

2 MR. OH: And the ACIP was mentioned in one footnote.
3 If you read the district Court and the appellate Court
4 decisions and even the briefing in that case, the ACIP was
5 discussed more in-depth, and to the point of because they don't
6 have the final decision-making authority, they make
7 recommendations, and they operate under authority from the --
8 that starts with the secretary who then delegates to the CDC
9 director who then delegates to -- and controls, essentially,
10 the ACIP in terms of whether or not to adopt or not their
11 decision, that made them inferior officers. That's not the
12 question here, of course.

13 THE COURT: Right.

14 MR. OH: But *Braidwood*, in my mind, is -- and that's
15 one reason why we, in our statement of request for relief, we
16 did not ask Your Honor to appoint members if you found that the
17 membership appointments should be vaccinated, because that is
18 within the discretion of the secretary under *Braidwood*.

19 It is the secretary's discretion to appoint members to
20 a federal advisory committee. They serve at will, and that's
21 how the secretary can control the -- any advisory committee
22 because they know that they're answering to a higher authority.

23 THE COURT: Right.

24 MR. OH: But that's really kind of as far as that case
25 goes for purposes of this particular case. Now, to the point

1 that you -- I think you said the way you read *Braidwood*, and,
2 believe me, it took me about 10 times to read it to try and
3 understand it, that case doesn't give the secretary unfettered
4 discretion, unreviewable discretion to do anything he wants,
5 which seems to be what the government is arguing here.

6 And even if the secretary or the CDC director has the
7 authority, which we don't think they do, to change the CDC's
8 immunization schedule unilaterally, that's still reviewable
9 under the APA. That is still a final agency action that is
10 justiciable and reviewable under the APA, because, let's not
11 forget, the APA has a basic presumption of judicial review for
12 one suffering a legal wrong because of agency action, and here,
13 the government has not rebutted that presumption. It's a very
14 narrow exception.

15 And then I think I've addressed harm. And I've
16 addressed injunctive relief. And did you have any other
17 questions about harm?

18 THE COURT: I don't.

19 MR. OH: Okay. So one -- I'm not sure that this is
20 the best subject to end on, but the whole question of restoring
21 trust, that is based on a fallacy. The whole -- the
22 government's argument that we need to restore trust, and,
23 therefore, we should change the CDC's schedule is based on the
24 fallacy of there's peer nations here and their best practices
25 are superior to yours, and when you base a decision on a

1 fallacy, that makes the end result incorrect and legally wrong.

2 So I've -- this is a good book. It's called Logic for
3 Lawyers. It's a guide to clear thinking by a former senior
4 appellate court judge from the Third Circuit by the name of
5 Ruggero J. Aldisert.

6 And I pulled that out when I was trying to make heads
7 or tails of their brief, and it's -- this is the third edition.
8 I've been using it for decades, quite frankly.

9 And on the subject of fallacies, "Fallacies are
10 dangerous because they are false conclusions or interpretations
11 resulting from thinking processes that claim or appear to be
12 valid but fail to conform to the requirements of logic. A
13 fallacy can, therefore, be defined as any argument that seems
14 conclusive to the normal mind that proves, upon examination,
15 not to establish alleged conclusion or more succinctly a form
16 of argument that seems to be correct that proves upon
17 examination not to be so."

18 This is at page 142 of this book, and so not legal
19 authority, but it's from a very distinguished, very
20 well-respected judge.

21 And then you want me to say one more thing, which is
22 what?

23 Finally, under FACA, and then the membership balance
24 plan, let's remember what the sequence is. The FACA regs
25 require a membership balance plan. It's in 41 CFR.

1 The membership balance plan was not complied with in
2 many ways and not just the vacancy, the appointments, but the
3 factors for balance that are laid out in the membership balance
4 plan.

5 And even if the membership balance plan were not
6 required, the cases are all aligned that the tests the Court
7 must apply is, does the balance reflect the function, the
8 purpose, and objective of the committee? And I think the
9 evidence is pretty clear that it does not.

10 And so we think that Your Honor has a good -- we think
11 we have a good set of facts for Your Honor to conclude that the
12 January 5 schedule change was arbitrary and capricious and that
13 you have the authority and the authority and also other case
14 law authority that would support a decision to restrain the
15 next ACIP meeting until there are further -- there's further
16 adjudication in this case.

17 THE COURT: Thank you, Mr. Oh.

18 MR. OH: Did I get that done in 10 minutes?

19 THE COURT: Well, you were in the ballpark.

20 MR. OH: Close enough.

21 THE COURT: Mr. Belfer, I'll give you the last word.

22 MR. BELFER: Thank you, Your Honor.

23 Yeah. I think -- just to be very brief, I think
24 the -- you know, Plaintiffs ended on public trust, and they
25 said that, you know, our argument is based on a fallacy, but I

1 think that just goes to -- you know, there is a disagreement in
2 this case about what the evidence shows, about how you evaluate
3 the evidence of vaccine trust and uptake in America versus
4 foreign countries. There's a reasonable disagreement about
5 what the facts show and about what vaccine policy you should
6 make in light of those facts.

7 But under the APA and under our construction,
8 democratically accountable elected officials and, you know,
9 presidentially appointed, Senate-confirmed officials have
10 authority and discretion to make policy judgments and to
11 resolve evidence.

12 The Court has to defer to the agency's reasonable
13 evaluation of the evidence in areas within their expertise, and
14 so I think fundamentally this case is about a policy
15 disagreement. It's about a disagreement about how you evaluate
16 the evidence, but that does not support an APA claim, and it
17 certainly does not support preliminary relief.

18 THE COURT: Thank you, Mr. Belfer. Thank you, all.
19 It's been a full day. I appreciate your effort both in your
20 briefing and in your oral argument today, so thank you for
21 everything. It's made -- I wouldn't say it's made the decision
22 easy. It's made the decision hard, but that means you've done
23 a great job, so thank you, all.

24 THE CLERK: All rise.

25 (The Honorable Court exited.)

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(Adjourned at 4:46 p.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

I, Jennifer M. Vaillancourt, do hereby certify that the foregoing is a correct transcript from the record of proceedings taken on February 13, 2026, in the above-entitled matter to the best of my knowledge, skill, and ability.

/s/ Jennifer M. Vaillancourt 20th day of February, 2026

Jennifer M. Vaillancourt, RPR, CSR Date
Official Court Reporter

APPENDIX

VOLUME III OF III

(App. 643–860)

United States Court of Appeals for the First Circuit

No. 26-1503

American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al.

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Order on Motion for Preliminary Injunction (ECF 291)	App. 816

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

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

Defendants.

Civil Action No.

1:25-cv-11916-BEM

ELECTRONIC ORDER

(Docket No. 269 — Entered February 27, 2026)

Judge Brian E. Murphy: ELECTRONIC ORDER entered. The parties are directed to submit supplemental briefing of no more than ten pages on the applicability of the Federal Advisory Committee Act (FACA) to the Advisory Committee on Immunization Practices (ACIP) by Thursday, March 5, 2026. In *Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748 (2025), the Supreme Court stated that the U.S. Preventive Services Task Force (PSTF), a comparable “entity within the Department of Health and Human Services, [which] issues public recommendations about preventive healthcare services,” *id.* at 753, “ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act [“ACA”] and empowered the Task Force to issue binding recommendations,” *id.* at 766 n.3 (internal quotation marks omitted). The ACA provisions granting authority to PSTF and ACIP are similar, *see* 42 U.S.C. § 300gg-13(a)(1)-(2), and the *Braidwood* Court appeared to discount ACIP’s subsequently issued regulation, requiring adoption of its recommendations, *see* 45 C.F.R. § 147.130(a)(1)(ii), as a relevant distinction, *see* 606 U.S. at 767 & n.4 (concluding that the ACA did not violate the Appointments Clause, in part, because “the Secretary can use his rulemaking authority... to establish a formal review process,” like the one applicable to ACIP, even though the Secretary had not done so). Given the Supreme Court’s characterization of PSTF’s authority (and, by extension, ACIP’s authority) as the power “to issue binding regulations,” *Braidwood*, 606 U.S. at 766 n.3, the Court is uncertain as to whether ACIP continues to “perform primarily... advisory [as opposed to ‘operational’] functions” for purposes of FACA. *See Nat. Res. Def. Council v. EPA*, 806 F. Supp. 275, 276 (D.D.C. 1992) (quoting 42 C.F.R. § 101-6.1004(g) [sic] (1992), current version at 41 C.F.R. § 102-3.40(j) (2025)).

Entered: February 27, 2026 (MBM).

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

**Defendants' Second Memorandum in Opposition to Plaintiffs' Motion for
Preliminary Injunction**

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INTRODUCTION

This opposition addresses the remaining four actions challenged in Plaintiffs’ preliminary injunction motion: (1) the May 2025 Secretarial Directive regarding COVID-19 vaccines for children and pregnant women, (2) the Advisory Committee on Immunization Practices’s (“ACIP”) June 2025 vote recommending that children and adults be administered thimerosal-free influenza vaccines, (3) ACIP’s September 2025 vote to recommend shared clinical decision-making for pediatric and adult COVID-19 vaccines, and (4) ACIP’s December 2025 vote to recommend shared clinical decision-making for the hepatitis B vaccine for certain infants. Plaintiffs are not entitled to preliminary relief from any of these actions.

To start, there is no likelihood of success on the merits. Plaintiffs offer no evidence of a cognizable injury specifically traceable to any of the four challenged actions and thus lack standing. Even if Plaintiffs could establish standing, the Court lacks jurisdiction over their Administrative Procedure Act (“APA”) claims because the Secretarial Directive and the Centers for Disease Control and Prevention’s (“CDC”) decisions to adopt the ACIP recommendations are committed to the agency’s discretion and outside the APA’s ambit. Regardless, on the merits, Plaintiffs have not shown these actions were arbitrary and capricious; Plaintiffs merely disagree with the current policies. That will not do under the APA.

Plaintiffs also have not established they will suffer irreparable harm absent extraordinary relief. Again, the analytical window is narrow: the few months before the Court rules on the merits. Plaintiffs do not clearly show irreparable harm in that short period for all the reasons in Defendants’ first opposition plus several more that are specific to the four challenged actions addressed here. Plaintiffs’ months-long delay in challenging the June 2025 ACIP vote about thimerosal precludes any claim of irreparable harm. And they seek to preliminarily enjoin a variety of actions by various individuals over the course of several months—the Secretarial

Directive and three ACIP recommendations, as adopted by CDC—without bothering to break down how any particular action causes immediate, irreparable harm. Instead, Plaintiffs improperly mix everything together under the generic labels of “Non-ACIP Actions” and “ACIP Actions” and thereby fail to demonstrate how any challenged action would cause any specific harm that cannot be redressed after summary judgment.

Lastly, the public interest strongly disfavors Plaintiffs’ attempt to force HHS to espouse immunization recommendations that it no longer agrees with. Plaintiffs cannot substitute their preferred vaccination policies for those adopted by HHS leadership—appointed by the President and confirmed by the U.S. Senate—and in the exercise of discretionary, statutory authority. Nor is the public served by the whiplash a preliminary injunction would inflict by temporarily reinstating recommendations that HHS does not support. Plaintiffs’ motion should be denied.

BACKGROUND

I. CDC’s Immunization Recommendations

In the United States, vaccine regulation occurs at both the federal and state levels. Before vaccines are distributed and marketed, they must be approved by the Food and Drug Administration (“FDA”). 42 U.S.C. § 262(a). But the rules for prescribing and administering a particular vaccine are generally made at the state and local level through the exercise of police powers. *See Zucht v. King*, 260 U.S. 174, 176 (1922); *e.g.*, Mass. Gen. Laws Ann., ch. 111, §§ 6, 181, ch. 76, § 15 (2024); *Preston v. United States*, No. CV 19-11034-MPK, 2022 WL 3093235, at *19 (D. Mass. May 25, 2022).

Relatedly, Congress directed the Secretary of Health and Human Services to “assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters” and to “advise the several States on matters relating to the preservation and improvement of the public health.” 42 U.S.C. § 243(a).

One way the Secretary (through CDC) has done so is by publishing non-binding schedules of vaccines recommended for children and adults. *See, e.g.*, ECF Nos. 185-13 and 185-14 (recommended schedules for adults and children as of October 2025). The schedules generally contain three types of recommendations: (1) immunizations recommended for everyone in an age group, (2) immunizations recommended for certain high-risk groups or populations, and (3) immunizations recommended based on shared clinical decision-making. *See* ECF Nos. 185-13 and 185-14. CDC also sometimes makes no recommendation. *See* ECF No. 185-14, at 4 (“No Guidance/Not Applicable” category).

“Shared clinical decision-making” means the decision whether to vaccinate is “individually based and informed by a decision process between the health care provider and the patient or parent/guardian.” CDC, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), <https://perma.cc/QE5B-D8WU>. A health care provider is “anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.” *Id.* There “is not a prescribed set of considerations or decision points in the decision-making process,” and the decision “may be informed by” factors including “the individual’s characteristics” and “the health care provider’s clinical discretion.” *Id.* Cost, however, is not a factor. Vaccines administered through shared clinical decision-making, when that is recommended by CDC, “generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible).” *Id.* (citing 42 U.S.C. § 300gg-13; 26 C.F.R. § 54.9815-

2713(a)(1)(ii); 29 C.F.R. § 2590.715-2713(a)(1)(ii); 45 C.F.R. § 147.130(a)(1)(ii)).¹

II. The May 2025 Secretarial Directive

On May 27, 2025, Secretary Kennedy issued the Directive. ECF No. 185-1.² The Secretary noted that HHS “continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available [FDA] approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.” *Id.* After reviewing a new recommendation from FDA and National Institutes of Health (NIH) officials regarding COVID-19 vaccines for “healthy U.S. children ages six months to 17 years,” the Secretary weighed the risks and benefits of COVID-19 vaccines for such children. *Id.* Based on this analysis, the Secretary rescinded two Secretarial Directives from June 2022 agreeing with CDC recommendations that all healthy U.S. children ages six months to 17 years receive the COVID-19 vaccine. *Id.*

The Secretary also reviewed an FDA official’s recommendation regarding COVID-19 vaccines for pregnant women. *Id.* Based on that analysis, the Secretary “determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby.” *Id.* The Secretary therefore rescinded CDC’s “recommendation that pregnant

¹ See CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), <https://perma.cc/SD3P-G2V7> (“Like routine recommendations, individual-based-decision-making allows for immunization coverage through all payment mechanisms including entitlement programs such as the Medicare, Medicaid, Children’s Health Insurance Program, and the Vaccines for Children Program, as well as insurance plans regulated by the Affordable Care Act.”); Centers for Medicare & Medicaid Services, *Affordable Care Act Implementation FAQs - Set 12*, Question 8 (last modified Sept. 10, 2024), <https://perma.cc/NL2N-3W9D>.

² An initial version of the Directive was mistakenly dated May 19, 2025, despite being executed on May 27, 2025. However, the Secretary executed another copy correctly dated May 27, 2025.

women receive the COVID-19 vaccine.” *Id.*

Over the summer, CDC implemented the Directive. ECF No. 103-2 (rev. Aug. 7, 2025); ECF No. 103-3 (same). The Recommended Child and Adolescent Immunization Schedule was revised to recommend “shared clinical decision-making” between “the health care provider and the patient or parent/guardian” about administration of the COVID-19 vaccine to healthy children. ECF No. 103-2 at 5. That meant where “the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances.” *Id.* CDC also revised the entry for the COVID-19 vaccine for pregnant women in the pediatric and adult immunization schedules to indicate “No Guidance/Not Applicable.” ECF No. 103-2 at 4; ECF No. 103-3 at 3.

III. The ACIP Recommendations of June, September, and December 2025

“[I]n connection with any of” the Secretary’s “functions,” such as advising states on the prevention and suppression of communicable diseases, he may “appoint such advisory councils or committees . . . as he deems desirable . . . for the purpose of advising him.” 42 U.S.C. § 217a(a). Exercising that discretion, the Secretary established the ACIP to advise the CDC Director “regarding use of vaccines and related agents for effective control of vaccine-preventable diseases.” ECF No. 185-21, at 2. ACIP recommendations are reviewed by the CDC Director, who has discretion whether to adopt them as official CDC/HHS recommendations. *Id.*

In June 2025, Secretary Kennedy removed the then-serving ACIP members. HHS, *HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP* (June 9, 2025),

<https://perma.cc/C5YC-Q7ZA>. He has since appointed 16 new ACIP members,³ 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 relevant expertise, and represent a wide range of clinical and research backgrounds. *See* CDC, *ACIP Membership Roster* (Jan. 14, 2026), <https://perma.cc/74CV-D3NT>. Four seats on ACIP remain vacant.

Three ACIP votes are at issue here. **First**, 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>. HHS adopted the recommendation to remove thimerosal, a “mercury-based preservative,” in July 2025.⁴ HHS, *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines* (last revised July 28, 2025), <https://perma.cc/4UFD-HXZ4>.

“The effort to remove mercury from childhood vaccines,” HHS explained, “began in 1999 when the U.S. Public Health Service, the American Academy of Pediatrics (AAP), and vaccine manufacturers jointly agreed that any potential risk from mercury warranted its removal as soon as possible.” *Id.* “[B]y voting to remove mercury entirely from all influenza vaccines,”

³ HHS announced the appointment of two new ACIP members on February 27, 2026. HHS, *Secretary Kennedy Appoints Two Physicians to CDC's Advisory Committee on Immunization Practices* (Feb. 27, 2026), <https://perma.cc/AR66-A574>. Additionally, one of the ACIP members the Secretary had appointed, Dr. Kulldorff, is no longer a member of the ACIP.

⁴ At the time, the office of CDC Director was vacant, so the ACIP's recommendation was adopted by the Secretary.

ACIP had “broke[n] with long-standing inaction” and “align[ed] U.S. policy with that of Europe, which phased out mercury additives years ago.” *Id.* Further, “[v]accine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted.” *Id.* Thus, HHS believed this recommendation would “restore trust with Americans” and “enhanc[e] public confidence in vaccines” by “removing risk while sustaining access to vaccines.” *Id.*

Second, in September 2025, the ACIP voted to recommend the COVID-19 vaccine for children and adults based on shared clinical decision-making (also referred to as individual-based decision-making). ACIP, September 18-19, 2025, ACIP Meeting Summary, at 88–89, <https://perma.cc/Q5AE-PN4R>. For “[i]ndividuals 6 months to 64 years,” the ACIP emphasized “that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.” *Id.* at 87–88; *see* HHS, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-Making* (last revised Sept. 19, 2025), <https://perma.cc/BP2T-97ZS>.

In October 2025, CDC adopted these recommendations and updated its child and adult immunization schedules accordingly. *See* ECF Nos. 185-13 and 185-14. The agency explained that the prior recommendation of COVID-19 vaccines for all children and adults had “deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent.” CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), <https://perma.cc/SD3P-G2V7>. It noted that “just 23% of adults followed the CDC’s most recent seasonal [COVID-19] booster recommendation” and that “[t]he booster shots prompted

widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic following population-wide immunity acquired during the pandemic” and Operation Warp Speed. *Id.*

Third, in December 2025, the ACIP voted to recommend 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* (Dec. 5, 2025), <https://perma.cc/qq8p-dvnq>. The ACIP recommended that “parents and health care providers should consider whether there are infection risks such as a household member who has hepatitis B or frequent contact with persons who have emigrated from areas where hepatitis B is common.” *Id.* The ACIP further recommended that “[f]or those infants not receiving the birth dose, . . . the initial dose be administered no earlier than two months of age.” *Id.* CDC adopted these recommendations, explaining that they “reflect[] ACIP’s rigorous review of the available evidence” and “restor[e] the balance of informed consent to parents whose newborns face little risk of contracting hepatitis B.” CDC, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025), <https://perma.cc/6R3R-E2HJ>.

IV. Procedural History

Plaintiffs moved for a preliminary injunction on January 26, 2026. ECF No. 183. On January 30, 2026, the Court bifurcated proceedings on Plaintiffs’ motion. ECF No. 190. The first phase addressed two of the challenged actions: CDC’s January 2026 changes to certain childhood and adolescent immunization recommendations, and the ACIP meeting scheduled for February 25–27, 2026 (which has been rescheduled to March 18–19, 2026). *Id.* Defendants filed an opposition regarding those actions on February 9, 2026, ECF No. 232, and the Court heard

argument on February 13, 2026, ECF No. 241.

Now, in the second phase, Defendants address the remaining four actions challenged in Plaintiffs’ preliminary injunction motion: (1) the May 2025 Secretarial Directive regarding COVID-19 vaccines for children and pregnant women, (2) the ACIP’s June 2025 vote recommending that children and adults be administered thimerosal-free influenza vaccines, (3) the ACIP’s September 2025 vote to recommend shared clinical decision-making for pediatric and adult COVID-19 vaccines, and (4) the ACIP’s December 2025 vote to recommend shared clinical decision-making for the hepatitis B vaccine for certain infants.

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

Like their claims addressed in Defendants’ first opposition, Plaintiffs’ challenges to the

Secretarial Directive and the June, September, and December ACIP recommendations ask the Court to intrude into complex questions of science and health policy on which reasonable minds might disagree. These are questions for scientists and policymakers—not judges—and Plaintiffs cannot use the APA to impose their policy preferences on the country. Plaintiffs lack standing, and their claims are not cognizable under the APA because vaccine advice from the Secretary, the ACIP, or CDC to states and localities is committed to agency discretion. If the Court reached the merits of Plaintiffs’ claims, those claims still fail because the challenged actions are not arbitrary and capricious. Even on the limited record available in reviewing Plaintiffs’ preliminary injunction motion, it is plain that HHS “reasonably considered the relevant issues and reasonably explained [its] decision[s].” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

A. Plaintiffs Lack Standing

Defendants incorporate their standing arguments from their first opposition, ECF No. 232 at 30–36, which apply equally to the four challenged actions covered by this brief. Additionally, Plaintiffs’ attempt to show standing for these four actions has several further, fatal deficiencies.

1. ACIP’s June 2025 Thimerosal Recommendation

Plaintiffs have not offered evidence of their alleged injury from the ACIP’s June 2025 thimerosal recommendation, as adopted by HHS. *See Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (requiring plaintiffs to “make a ‘clear showing’” that they are “‘likely’ to establish each element of standing” at the “preliminary injunction stage” (quoting *Winter*, 555 U.S. at 22)). Generalized allegations of harm from the allegedly “final agency actions challenged herein,” ECF No. 245, ¶ 105, or the “ACIP Actions,” PI Mem., ECF No. 237, at 22, are insufficient because Plaintiffs must show a cognizable injury traceable to each “challenged action,” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). After all, a litigant who may have “standing to challenge one government action” cannot “challenge other governmental actions that did not injure” them.

DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 353 n.5 (2006). Thus, under the requisite “claim-by-claim” analysis, *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016), Plaintiffs have failed to show standing to challenge the thimerosal recommendation.

That failure is hardly surprising because *AAP has supported removing thimerosal* from vaccines because of its mercury content. In 1999, “the U.S. Public Health Service, [AAP], and vaccine manufacturers jointly agreed that any potential risk from mercury warranted its removal [from vaccines] as soon as possible.” *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, *supra*. Today, only about 4–5% of influenza vaccine doses are in thimerosal-containing multi-dose vials. ACIP, June 25-26, 2025, ACIP Meeting Summary, at 69, <https://perma.cc/WEP5-K2LD>. “Vaccine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted.” *Id.* Thus, Plaintiff have not—and cannot—show any injury from the challenged thimerosal recommendation.

2. The May 2025 Secretarial Directive, ACIP’s September 2025 COVID-19 vaccine recommendation (as adopted by CDC), and ACIP’s December 2025 Hepatitis B vaccine recommendation (as adopted by CDC)

To have standing to “seek[] prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of *future* injury.” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024) (emphasis added). And the future is assessed as of February 17, 2026, the date the Fourth Amended Complaint was filed. *See Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 473–74 (2007); ECF No. 245.

Plaintiffs lack standing to challenge the Secretarial Directive, ACIP’s September 2025 COVID-19 vaccine recommendation, and ACIP’s December 2025 hepatitis B vaccine recommendation because those actions have no future effect and so cannot cause Plaintiffs any future injury. CDC adopted a new immunization schedule in January 2026, including

recommendations for the COVID-19 and hepatitis B vaccines. ECF No. 185-18. Although the January 2026 decision memorandum mentioned the ACIP recommendations for those vaccines, it was not contingent on those recommendations, as adopted by CDC, but simply considered them along with other relevant information, such as peer countries’ practices regarding the COVID-19 and hepatitis B vaccines. *Id.* at 6, 8. In other words, CDC’s operative recommendations for the COVID-19 and hepatitis B vaccines date from the January 2026 decision, not the September and December 2025 ACIP votes. Thus, Plaintiffs cannot show any “future injury” caused by the challenged Secretarial Directive and September and December 2025 ACIP votes. *All. for Hippocratic Med.*, 602 U.S. at 381; *see Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

For the same reasons, Plaintiffs cannot show their alleged injuries are “likely to be redressed” by an order vacating the Secretarial Directive, ACIP’s September 2025 COVID-19 vaccine recommendation, and ACIP’s December 2025 hepatitis B vaccine recommendation. *Spokeo*, 578 U.S. at 338. Such an order would not affect the operative January 2026 immunization schedule because the January 2026 action was not contingent on the Secretarial Directive or the September and December 2025 ACIP recommendations, as adopted by CDC. Thus, if the Court vacated the actions challenged here, the shared clinical decision-making recommendations for the COVID-19 and hepatitis B vaccines on the January 2026 schedule would remain in place.

The same analysis shows why Plaintiffs’ challenges to the Secretarial Directive and the ACIP’s September and December 2025 recommendations are moot. The January 2026 immunization schedule has “overtaken” these actions, *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 6 (1st Cir. 2021), and Plaintiffs “lack a legally cognizable interest in the outcome” of their

challenges to those actions because an order vacating them would not change the operative January 2026 schedule, *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotation omitted).

B. The Challenged Actions Are Unreviewable Because CDC’s Immunization Recommendations Are Committed to Agency Discretion by Law

Each of Plaintiffs’ claims arises 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).⁵

The four challenged actions occurred under the Secretary’s authority 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” the Secretary, the ACIP, or CDC “should exercise its discretion.” *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The statute does not mention immunization recommendations—much less require them—and contains no “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 make immunization recommendations

⁵ Although this issue was not raised in Defendants’ motion to dismiss the Third Amended Complaint, Plaintiffs’ 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).

and, if the agency so chooses, their “form and content.” *Dep’t of Com. 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 Secretarial Directive and CDC’s adoption of the challenged June, September, and December 2025 ACIP votes 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. 25–34. That, of course, would reduce the exception to a nullity. Instead, the necessary 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 (emphasis added) (quoting *Union of Concerned Scientists*, 954 F.3d at 21). Here, they do not.

Although certain statutes and regulations reference the ACIP’s immunization recommendations and CDC’s potential adoption of those recommendations, *e.g.*, 42 U.S.C. § 300gg-13(a)(2); 26 C.F.R. § 54.9815-2713(a)(1)(ii), they do not prescribe how the ACIP should formulate a recommendation or CDC should determine whether to adopt it. *See Marasco & Nesselbush*, 6 F.4th at 171 n.26 (the court needs a “set of statutory or regulatory *requirements* to guide [it] in assessing the propriety of” the challenged actions (emphasis added) (quoting *Union of Concerned Scientists*, 954 F.3d at 21)). Moreover, as relevant to the Secretarial Directive, although these statutes and regulations acknowledge the existence of a process whereby ACIP makes immunization recommendations that CDC may adopt, they say nothing about whether CDC may also follow other processes to make immunization recommendations, such as making recommendations that are not based on ACIP’s. Thus, these statutes and regulations do not constrain the Secretary’s broad and unreviewable discretion under 42 U.S.C. § 243(a) to “assist”

and “advise” States about preventing communicable diseases and preserving public health, including through the ACIP and CDC.

The absence of meaningful standards for the Secretarial Directive and issuance of immunization recommendations by the ACIP and CDC stands in contrast to 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 [agency] 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” the Secretary, the ACIP, or 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 the . . . exercise of discretion” in making immunization recommendations, *id.* at 17 (quotations omitted), such actions are “committed to agency discretion by law,” 5 U.S.C. § 701(a)(2). Thus, all the actions challenged here are unreviewable under the APA.

C. The Challenged Actions Are Not Final Agency Action

For the reasons set out in Defendants’ first opposition, ECF No. 232, at 13–15, the four additional actions challenged here are not final agency actions subject to APA review—but instead recommendations without concrete legal effects on Plaintiffs. Plaintiffs have not met

their burden to show otherwise.⁶ Indeed, their brief (PI Mem. 23–24) does not even analyze whether each specific action they challenge satisfies the Supreme Court’s test for final agency action, in light of the “unique constellation of statutes and regulations that govern the action at issue.” *Sierra Club v. EPA*, 955 F.3d 56, 61 (D.C. Cir. 2020) (quotation omitted).

Plaintiffs’ continued attempt to challenge these four actions—on top of the two addressed in the last round of briefing—illustrates that, at its core, this litigation is not about the sort of “discrete” final agency action reviewable under the APA at all. Instead, it amounts to a programmatic challenge to HHS’s vaccine policy writ large that is not cognizable under the APA. As the Supreme Court has explained, an APA challenge may “proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*.” *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). “These limitations rule out several kinds of challenges,” including “the kind of broad programmatic attack” raised here. *Id.* Plaintiffs may firmly disagree with HHS’s views on vaccination policy, but they “cannot seek wholesale improvement of this program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made.” *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 875 (1990). The Court should thus decline Plaintiffs’ invitation to effectively serve as a special monitor indefinitely overseeing the federal government’s vaccination recommendations.

D. The Challenged Actions Were Reasonable and Reasonably Explained

Under the APA’s standard of review, 5 U.S.C. § 706(2)(A), the court has “only a narrow

⁶ Plaintiffs also cannot compensate for this failure by falsely asserting Defendants “waived any contention that the Challenged Actions are not final agency actions.” PI Mem. 23. As we stated previously, “Plaintiffs’ quotations of Defendants’ counsel’s comments do not concede anything on finality.” ECF No. 232, at 14. And arguments about a lack of final agency action—a species of failure to state a claim—may be raised at any time through trial. *See* Fed. R. Civ. P. 12(h)(2).

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.” *Prometheus Radio Project*, 592 U.S. at 423. 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), *cert. denied*, 144 S. Ct. 1117 (2024) (mem.) (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 May 2025 Secretarial Directive and the ACIP recommendations from June, September, and December 2025, as adopted by CDC, were arbitrary and capricious. For each of these actions, however, the agency “reasonably considered the relevant issues and reasonably explained the decision.” *Prometheus Radio Project*, 592 U.S. at 423. The agency’s full reasoning will be set out in the administrative records for these decisions, which have not yet been produced, but even considering just the publicly available documents, the challenged decisions plainly were well “within a zone of reasonableness.” *Id.*

1. The May 2025 Secretarial Directive Was Reasonable

The Secretarial Directive and the scientific assessments on which it is based provide ample support for the Secretary’s decision to rescind the recommendation that all children and pregnant women receive the COVID-19 vaccine. Regarding the recommendation for children, the Secretary’s decision was supported by a scientific assessment from the Principal Deputy Director of NIH, Matthew Memoli, M.D., M.S., and the Principal Deputy Commissioner of

FDA, Sara Brenner, M.D., M.P.H. Ex. A⁷ at 1. This assessment explained that in June 2022, then-Secretary of Health and Human Services Xavier Becerra issued Secretarial Directives “recommending that children between the ages of 6 months and 17 years receive the COVID-19 vaccine.” *Id.* But “after a review of relevant existing data,” including 39 scientific references and “new studies unavailable to Secretary Becerra when he issued his Directives” in June 2022, Drs. Memoli and Brenner found “no clear evidence that the benefits of vaccination for COVID-19 outweigh the risk of harm in children under 18 years of age.” *Id.*

The Memoli-Brenner assessment began by considering the risks to children from COVID-19. It found that “[t]he risks associated with SARS-COV-2 infection, and subsequent clinical disease known as COVID-19, in children under 18 has been extremely low since the novel virus emerged in 2019.” *Id.* at 2. For example, “the mortality from SARSCoV-2 infection among children without underlying health conditions is much less than one per million, which is significantly less than from RSV or influenza,” and “there is no clear evidence that vaccination plays a role in preventing these exceedingly rare deaths.” *Id.* “Hospitalization rates of children from COVID-19 are also extremely low and have decreased since 2019,” and in fact are “substantially lower than for influenza and RSV in the United States.” *Id.* Additionally, “Multi-Inflammatory Syndrome in Children (MIS-C)” and “[l]ong COVID” in children are “exceedingly rare,” and no reliable evidence shows “a reduction in risk of th[ese] condition[s] due to vaccination.” *Id.* at 3.

The Memoli-Brenner assessment next considered the risks of COVID-19 vaccination. It found that “[p]ost-vaccination myo- and pericarditis are well-established side effects of COVID-

⁷ References to “Ex. A” and “Ex. B” refer to exhibits to the Declaration of Isaac C. Belfer, filed with this brief.

19 vaccination identified in adolescent boys and girls” and that “[p]ost-vaccination myocarditis can be severe and may have lasting consequences in children and young adults” and may even result in death. *Id.* at 3–4. Although “myocarditis can be a consequence of SARS-CoV-2 infection in children and young people, the risk from vaccination appears to be significantly higher,” and “no robust evidence has shown vaccination to reduce post-COVID-19 myocarditis risks.” *Id.* at 4. “Additional risks that have been associated with mRNA vaccination”—and COVID-19 mRNA vaccines—include “seizures, Bell’s palsy, transverse myelitis, clotting disorders, strokes, heart attacks, and acute kidney injury,” as well as “non-COVID-19 lower respiratory tract infection.” *Id.*

The Memoli-Brenner assessment then noted “the past and current true efficacy of the COVID-19 vaccines remains unclear.” *Id.* at 5. “The initial clinical trials in children and adolescents included less than 2,500 children and were unable to determine efficacy against severe COVID-19,” and there have not been “[m]ore recent randomized placebo-controlled trials of original and/or updated vaccine formulations . . . to evaluate the safety or efficacy of any COVID-19 vaccines.” *Id.* Beyond these deficiencies in the existing safety and efficacy data, “the ever-changing nature of the SARS-COV-2 viral antigens makes it unlikely that the current vaccination strategy will provide durable immunity against COVID-19.” *Id.* Ultimately, Drs. Memoli and Brenner concluded that “currently available data and published studies do not provide sufficient clinical and scientific evidence to broadly recommend COVID-19 vaccination for those under 18 years of age.” *Id.* Rather, “[g]iven the low risk of infection to those under the age of 18, the known risks of vaccination outweigh any small potential benefit.” *Id.*

Turning to COVID-19 vaccination for pregnant women, the Secretary’s decision was based on a scientific assessment from Tracy Beth Høeg, MD, PhD, an advisor to the FDA

Commissioner, which cited 11 scientific references. Ex. B. The Høeg assessment explained there was “[a] lack of high-quality data on the safety of mRNA Vaccines during pregnancy.” *Id.* at 1. Vaccine manufacturer “Novavax has thus far not sought authorization of their vaccine in pregnancy as they lacked safety data,” and “Pfizer and Moderna also lack high quality, randomized trial safety data—specifically, there was one insufficiently powered (very small) randomized study of the Pfizer COVID-19 vaccine and no randomized trial pregnant women has been done of the Moderna COVID-19 vaccine.” *Id.*

Thus, the Høeg assessment explained, “our knowledge about the safety of COVID vaccination during pregnancy relies on lower quality data including findings from pharmacovigilance systems and on retrospective observational studies.” *Id.* at 1–2. “There are numerous issues with relying on these datasets and analyses,” including that “pharmacovigilance data tends to be vastly underreported” and “observational studies are prone to multiple potential biases.” *Id.* at 2. Dr. Høeg also observed that “the COVID-19 mRNA vaccines have been shown . . . to cross the placenta,” that “mRNA vaccination has also been linked to multiple types of blood clots,” and that “[p]lacental blood clots can decrease oxygen to the fetus, cause birth defects, growth restriction, miscarriage and other pregnancy complications.” *Id.* at 3.

In addition to these safety questions, the Høeg assessment found that “the current benefit of mRNA COVID-19 vaccination against severe disease is uncertain” given “widespread immunity from prior infection and a lack of randomized placebo control trials looking at clinical outcomes in this setting.” *Id.* Furthermore, “vaccine efficacy in our current circumstances has been deduced from observational data and immunobridging data,” and “the applicability of the initial randomized controlled trials to today’s epidemiological circumstances” and a population that has been exposed to the SARS-CoV-2 virus is not “well defined.” *Id.* Thus, Dr. Høeg

concluded that “[d]ue to a lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy and some basis for concern, it would be wise to err on the side of caution and recommend against . . . vaccination in pregnancy until there is certainty the benefits of vaccination are likely to outweigh potential risks to the mother and developing baby.” *Id.* Although the Secretary declined to recommend against vaccination in pregnancy, he did rescind the routine recommendation that all pregnant women receive the COVID-19 vaccine because “the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby.” ECF No. 185-1.

As the above summary illustrates, the Secretary “reasonably considered the relevant issues and reasonably explained the decision.” *Prometheus Radio Project*, 592 U.S. at 423. Contrary to Plaintiffs’ assertion that the Secretarial Directive was not based on safety and efficacy data, PI Mem. 32, the scientific assessments from FDA and NIH conducted an evidence-based balancing of the risks (i.e., safety) and benefits (i.e., efficacy) of COVID-19 vaccination.⁸ And Secretary Kennedy “ha[d] discretion to rely on the reasonable opinions of [his] own qualified experts.” *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). Even if the Court disagrees with how the agency weighed the evidence, it cannot “substitute its judgment for that of the agency.” *State Farm*, 463 U.S. at 43 (citation omitted); *see Dist. 4 Lodge*, 18 F.4th at 45–47. Indeed, the Court should “be at its most deferential” because vaccine evaluations are

⁸ Plaintiffs claim the Secretarial Directive did not consider “new data or evidence-based analysis” regarding the vaccine’s safety or efficacy. PI Mem. 33. As an initial matter, the agency was not required to consider “new” information—just to “reasonably consider[] the relevant issues and reasonably explain[] the decision.” *Prometheus Radio Project*, 592 U.S. at 423. Regardless, the scientific assessments cited multiple “new” references from 2024 and 2025. Ex. A at 7–10; Ex. B at 5.

“scientific determination[s]” within the agency’s “area of special expertise.” *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *see, e.g., Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626, 629-30 (D.C. Cir. 2025) (deferring to FDA where its analysis turned “squarely on the FDA’s expertise in evaluating the clinical significance of drug studies, which we will not lightly second-guess”); *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)).

Plaintiffs argue that the change to COVID-19 vaccine recommendations for pregnant women is inconsistent with data presented by government officials regarding the risks of COVID-19 to pregnant women. PI Mem. 10–11, 29 (citing ECF No. 180-1, ¶ 98). There is no inconsistency: Neither Dr. Høeg’s assessment nor the Secretarial Directive suggested there was no risk to pregnant women from COVID-19. The Secretary merely rescinded his predecessor’s blanket recommendation that all pregnant women get vaccinated, based on “the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination.” ECF No. 185-1. Plaintiffs also cite data regarding child deaths and hospitalizations from COVID-19, PI Mem. 11, but the Memoli-Brenner assessment explained why the data likely overestimate the true incidence of such events, Ex. A at 2–3. Likewise, the Memoli-Brenner assessment did not solely consider the risks to children from COVID-19, but the broader evidence regarding the COVID-19 vaccine’s safety and efficacy.⁹

Plaintiffs’ remaining arguments are equally meritless. Plaintiffs criticize the Secretarial

⁹ Having reasonably considered the state of the evidence on the vaccine’s safety and efficacy, the agency was not required to consider as well the various factors Plaintiffs identify, such as “changes to practice guidelines published by Plaintiffs or other professional organizations.” PI Mem. 32; *see also* 42 U.S.C. § 243(a) (leaving it to the agency’s discretion to determine which factors to consider in advising states and localities on public health).

Directive for making changes to the immunization schedules that were not based on an ACIP vote. PI Mem. 28. But HHS has wide, unreviewable discretion to make vaccine recommendations and is not required to base them on an ACIP vote or on any particular methodology. *See supra* pp. 13–15; ECF No. 232 at 15–17. Indeed, HHS has previously deviated from the ACIP’s recommendations. *See* Feb. 13, 2026, Hearing Tr. 46:10–47:17.

Finally, Plaintiffs had no “reliance interests” in the CDC’s COVID-19 vaccine recommendations for children and pregnant women that were in place before the Secretarial Directive. *Contra* PI Mem. 33–34. Vaccine recommendations are never permanent. *See* PI Mem. 26 n.68 (noting how “[e]ven after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations”). Indeed, the potential for revision or withdrawal of an immunization recommendation is baked into the ACIP Charter. *See* ECF No. 185-21, at 3. Thus, Plaintiffs have no “*reasonable* reliance interests” in any particular iteration of a vaccine recommendation. *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 569 (2025) (emphasis added); *see Bell Atl. Tel. Cos. 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”).

2. The June 2025 Thimerosal Recommendation Was Reasonable

The ACIP’s June 2025 recommendation to administer thimerosal-free influenza vaccines, as adopted by the CDC, was also “within a zone of reasonableness.” *Prometheus Radio Project*, 592 U.S. at 423. At its June 2025 meeting, the ACIP received a presentation titled *Thimerosal as a Vaccine Preservative* from Lyn Redwood RN, MSN. <https://perma.cc/J8EA-MCK5>; *see* CDC, *ACIP Meeting Materials: June 25-26, 2025, Meeting* (June 24, 2025), <https://perma.cc/DP2D-BH7C>. The presentation noted several safety concerns with thimerosal, which is about “49.6%

mercury by weight.” Lyn Redwood, *Thimerosal as a Vaccine Preservative*, at 10–20 (June 2025), <https://perma.cc/J8EA-MCK5>. It further observed that, in 1999, the U.S. Public Health Service and AAP had jointly recommended that “thimerosal-containing vaccines should be removed as soon as possible.” *Id.* at 3 (quotations omitted). The Institute of Medicine had concurred. *Id.* at 4, 20. Consistent with these recommendations and the cited evidence, the presentation recommended removing thimerosal from influenza vaccines and noted that “[w]e currently have enough thimerosal free flu vaccines” for “all pregnant women, infants and children.” *Id.* at 20.

This issue was thoroughly discussed at the June 2025 ACIP meeting. ACIP, June 25–26, 2025, ACIP Meeting Summary, *supra*, at 64–74. For example, Drs. Kulldorff and Malone expressed concerns with cumulative mercury exposure from multiple sources, including annual influenza vaccination. *Id.* at 67. Dr. Kulldorff noted that “removing mercury-containing preservatives from vaccines could also help build public confidence” in vaccines, given “the consumer rejection of mercury in other products, such as food.” *Id.* Dr. Levi discussed ways to ensure vaccine integrity without using thimerosal. *Id.* And Dr. Hoeg, representing FDA, reported that only about 4–5% of influenza vaccine doses in the 2024–2025 season “were thimerosal-containing multi-dose vials” and that “there does not appear to be a limitation in supply if a shift were made to using only single-dose formulations.” *Id.* at 69. Based on this analysis, the ACIP recommended that adults and children “receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.” *Id.* at 72–74.

The Secretary adopted this recommendation in July 2025, explaining that it would “restore trust with Americans” and “enhanc[e] public confidence in vaccines” by “removing risk while sustaining access to vaccines.” *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, *supra*. He explained there had been “more than two decades of

delay” since the 1999 recommendation to remove thimerosal from vaccines and that his adoption of the ACIP’s recommendation “fulfills a long-overdue promise to protect our most vulnerable populations from unnecessary mercury exposure.” *Id.* “Injecting any amount of mercury into children when safe, mercury-free alternatives exist defies common sense and public health responsibility.” *Id.* This action “mark[ed] the final step to remove mercury from all vaccines given to Americans” and “align[ed] U.S. policy with that of Europe, which phased out mercury additives years ago.” *Id.* Moreover, “[v]accine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted.” *Id.*

Plaintiffs argue HHS should have “explained why [the ACIP] did not apply the GRADE approach, utilize the EtR framework, or consult with ACIP Work Groups to examine relevant data before adopting” the thimerosal recommendation. PI Mem. 28. But regardless of any past application of the GRADE approach or the EtR framework, the ACIP was not required—whether by statute, regulation or other source of law—to follow these internal operating procedures for thimerosal. *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*, 663 F.3d 476 (D.C. Cir. 2011). And because the internal procedures Plaintiffs demand were “not required,” the agency was not required to explain why it did not follow those procedures in making the thimerosal recommendation. *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).

Even if the ACIP were required to explain why it did not use the GRADE, EtR, and workgroup processes, any error was harmless. *See* 5 U.S.C. § 706. Plaintiffs do not challenge the ACIP recommendation itself, just HHS’s adoption of it. *See* ECF No. 245, ¶ 170. And the Secretary properly exercised his unreviewable, unconstrained discretion to adopt the ACIP’s recommendation regardless of which internal procedures ACIP followed. *See supra* pp. 13–15.

Plaintiffs’ remaining arguments are unavailing. The agency was not required to consider “new data,” PI Mem. 17, 33, but simply to “reasonably consider[] the relevant issues and reasonably explain[] the decision,” which it did, *Prometheus Radio Project*, 592 U.S. at 423; *see supra* n.8. HHS also was not required to cite data (PI Mem. 31) in support of its explanation that removing thimerosal from season influenza vaccines would “restore trust with Americans” and “enhanc[e] public confidence in vaccines” by “removing risk while sustaining access to vaccines.” *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines, supra*. As Dr. Kulldorff observed, it is common sense that “removing mercury-containing preservatives from vaccines could . . . help build public confidence” in vaccines, given “the consumer rejection of mercury in other products, such as food.” June 25-26, 2025, ACIP Meeting Summary, *supra*, at 67.

Finally, Plaintiffs had no “reliance interests” in CDC’s past position on the use of thimerosal in seasonal influenza vaccines. *See supra* p. 23; *contra* PI Mem. 33–34. That is confirmed by Plaintiffs’ six-month delay in challenging the recommendation (*i.e.*, from HHS’s adoption of ACIP’s recommendation in July 2025 to filing the Fourth Amended Complaint in January 2026). If the recommendation had harmed Plaintiffs by disrupting their reliance interests, surely Plaintiffs would have exercised greater diligence in challenging it.

3. The September 2025 Shared Clinical Decision-Making Recommendation for the COVID-19 Vaccine

The ACIP’s September 2025 recommendation regarding the COVID-19 vaccine, as adopted by the CDC, was also “within a zone of reasonableness.” *Prometheus Radio Project*, 592 U.S. at 423. At the September meeting, the ACIP received numerous scientific presentations about the COVID-19 vaccine from experts in the field, including CDC subject matter experts and members of the ACIP’s COVID-19 Immunization Work Group:

- An introductory presentation from the ACIP COVID-19 Immunization Work Group Chair Retsef Levi, Ph.D., Professor of Operations Management at MIT Sloan School of Management;
- “Updates to COVID-19 epidemiology” by Arjun Srinivasan, MD, from CDC’s National Center for Immunization and Respiratory Diseases;
- “COVID-19 Vaccination Implementation” by Dr. Srinivasan;
- “Updates to COVID-19 Vaccine Effectiveness” by Dr. Srinivasan;
- “Vaccine safety signal detection and evaluation” by John Su from the CDC Immunization Safety Office;
- “Workgroup Safety Uncertainties of mRNA COVID Vaccines” by ACIP COVID-19 Immunization Work Group members Wafik El-Deiry, MD, PhD, FACP, Director of the Legorreta Cancer Center and Associate Dean of Oncologic Sciences at the Warren Alpert Medical School of Brown University; and Charlotte Kuperwasser, PhD, Director of the Tufts Convergence Laboratory of Biomedical, Physical, and Engineering Sciences and Professor of Developmental, Molecular & Chemical Biology at Tufts University School of Medicine;
- “Genomics of Vaccine-Induced Myocarditis” by ACIP COVID-19 Immunization Work

Group member Bruce Carleton, Pharm.D., Professor of Pediatrics, Medical Genetics, Pharmaceutical Sciences, and Population and Public Health at the University of British Columbia;

- “Economic Analysis of COVID-19 Vaccination” by Dr. Srinivasan on behalf of the University of Michigan;
- Updates from COVID-19 vaccine manufacturers;
- “COVID-19 Vaccine Discussion Framing, 2025-2026” by Dr. Levi;
- “Additional Workgroup Considerations in COVID-19 Vaccination Policy and Practice” by ACIP COVID-19 Immunization Work Group members Henry Bernstein, DO MHCM, Professor of Pediatrics at Zucker School of Medicine at Hofstra/Northwell; Mitchell Miglis, MD, Clinical Associate Professor of Adult Neurology and Psychiatry and Behavioral Sciences at Stanford University School of Medicine; and Stanley Perlman, MD, PhD, Professor of Microbiology and Immunology and Professor of Pediatrics at the Carver College of Medicine at the University of Iowa.

CDC, *ACIP Presentation Slides: September 18-19, 2025, Meeting* (Sept. 18, 2025), <https://perma.cc/F4MW-2YE4>.

During the meeting, the ACIP members and other participants thoroughly discussed the safety and efficacy of COVID-19 vaccines, as well as other considerations such as public trust and confidence in the vaccines. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94. They also discussed the proposal to recommend shared clinical decision-making. The COVID-19 Immunization Work Group Chair, Dr. Levi, explained that work group “[m]embers debated whether vaccination guidance should be based on population-level recommendations or individual clinical decisions.” *Id.* at 85. He reported that “[t]he majority

supported an individual-based approach, concluding that COVID-19 vaccines should be prescribed by a clinician rather than administered under standing orders.” *Id.* Dr. Levi explained that “[t]his approach would allow for personalized discussions between patients and healthcare providers about prior infections, immune response, comorbidities, and the balance of risks and benefits.” *Id.* He “noted that this level of individual consideration is more appropriate now that the situation is no longer an emergency.” *Id.* After Dr. Levi’s presentation, Dr. Bernstein shared the view of a “minority of [work group] members” that shared clinical decision-making “create[s] unnecessary barriers to vaccination” and “can lead to confusion.” *Id.* at 85–86.

ACIP member Dr. Hibbeln said “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.” *Id.* at 88. He affirmed that “understanding the risks and benefits of vaccines is essential to the committee’s work, acknowledging the difficulty of quantifying these factors.” *Id.*

The ACIP also considered whether a shared clinical decision-making recommendation would have implications for insurance coverage. Dr. Kulldorff explained “the recommendation ensures coverage with zero cost-sharing under [the Children’s Health Insurance Program (“CHIP”)], [Affordable Care Act (“ACA”)] plans, and Medicare Part B for all individuals aged six months and older, including children up to age 18.” *Id.* at 88. Thus, he explained, “there would be no insurance restrictions on receiving the vaccine.” *Id.*

Following this discussion, the ACIP voted to recommend the COVID-19 vaccine for children and adults based on shared clinical decision-making. *Id.* at 88–89. The ACIP further recommended that, for “[i]ndividuals 6 months to 64 years,” shared clinical decision-making

“emphasi[ze] that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.” *Id.* The ACIP also rejected a proposal to recommend that COVID-19 vaccines be available only by prescription. *Id.* at 93.

When CDC adopted the shared clinical decision-making recommendation in October 2025, it explained that the prior recommendation of COVID-19 vaccines for all children and adults had “deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent.” *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, *supra*. It further observed that “just 23% of adults followed the CDC’s most recent seasonal [COVID-19] booster recommendation” and that “[t]he booster shots prompted widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic.” *Id.*

The ACIP’s deliberations, together with CDC’s reasoning in adopting the ACIP’s recommendation, show that the agency “reasonably considered the relevant issues,” including the COVID-19 vaccine’s safety and efficacy, impacts on insurance coverage, and concerns about vaccine trust and confidence, and “reasonably explained the decision” to recommend the vaccine based on shared clinical decision-making. *Prometheus Radio Project*, 592 U.S. at 423; *contra* PI Mem. 32. These deliberations were based on scientific evidence and input from the ACIP COVID-19 Immunization Work Group, other ACIP members, and CDC experts. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94; *contra* PI Mem. 17 (incorrectly claiming ACIP “did not consult with the Covid Work Group prior to the vote”). And in adopting the ACIP’s recommendation, CDC permissibly relied on “the reasonable opinions of [ACIP’s] qualified experts.” *Marsh*, 490 U.S. at 378.

Plaintiffs merely rehash their debunked arguments in opposition. The ACIP was not required to consider “new data.” PI Mem. 33; *see supra* n.8. In any event, the committee *did consider* recent data from 2024 and 2025. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94. There were no “reliance interests” the agency needed to consider. *See supra* p. 23; *contra* PI Mem. 33–34. And the ACIP was not required to explain why it did not follow the GRADE and EtR frameworks—or if it was, this procedural foot fault was harmless. *See supra* pp. 25–26; *contra* PI Mem. 28.

4. The December 2025 Shared Clinical Decision-Making Recommendation for the Hepatitis B Vaccine

Finally, the ACIP’s December 2025 recommendation regarding the hepatitis B vaccine, as adopted by the CDC, was also well “within a zone of reasonableness.” *Prometheus Radio Project*, 592 U.S. at 423. Although the minutes from the December 2025 meeting have not yet been posted, the publicly available presentations from the meeting and CDC’s adoption of the ACIP’s recommendation suffice to show that the agency “reasonably considered the relevant issues and reasonably explained the decision.” *Id.*

At the December meeting, the ACIP received multiple scientific presentations about the hepatitis B vaccine from CDC, the Centers for Medicare & Medicaid Services (“CMS”), and the Childhood/Adolescent Schedule Workgroup:

- “Hepatitis B Virus Vaccine Birth Dose” by ACIP member and Childhood/Adolescent Schedule Workgroup Chair Vicky Pebsworth, PhD, RN;
- “Burden of disease” by Dr. Nevison from CDC;
- “Safety Review of Hepatitis B Birth Dose Vaccination” by Mark F. Blaxill, MBA, from the Office of the CDC Director;
- A presentation from hepatitis B vaccine manufacturers by Drs. Robinson, Goveia, and

Chit;

- A presentation on the Childhood/Adolescent Schedule Workgroup’s process and findings by Dr. Pebsworth;
- “VFC Resolution Update: Hepatitis B Vaccine” by Dr. Santoli of the CDC National Center for Immunization & Respiratory Diseases;
- “Overview of Vaccine Coverage” by Mr. A. Johnson from CMS.

CDC, *ACIP Presentation Slides: December 04-05, 2025, Meeting* (Dec. 5, 2025),

<https://perma.cc/N7NQ-46GT>.

Dr. Pebsworth’s second presentation noted that the Childhood/Adolescent Schedule Workgroup met seven times between October 17 and November 24, 2025, and received “12 presentations by CDC staff, workgroup members, and invited ad hoc experts that covered clinical ethics, non-specific vaccination effects, aluminum adjuvant exposures, clinical practice challenges and solutions, and the Alaska Hepatitis B vaccine trials.” Vicky Pebsworth, *Summary of Information*, at 5 (Dec. 4, 2025), <https://perma.cc/GS4X-5X79>. Dr. Pebsworth reported “Full/Nearly Full Agreement” among the workgroup for the following findings:

- Although hepatitis B “is a serious disease[] and can be prevented by vaccination with the HBV vaccine,” there is uncertainty about incidence rates and “whether all three recommended doses are needed to acquire protection.”
- “There are gaps in evidence and limitations related to evidence of safety (per GRADE quality of safety evidence is poor).”
- Pregnant mothers should be screened for hepatitis B, and “[i]nfants born to mothers who test positive for [hepatitis B] should continue to be vaccinated with [the hepatitis B] vaccine and receive hepatitis B immunoglobulin soon after birth.”

- “Infants born to mothers who test negative for [hepatitis B] have extremely low risk of horizontal infection during childhood and particularly in first months of life and therefore, do not need to be routinely vaccinated with the [hepatitis B] vaccine at birth.”

Id. at 6–7.

Dr. Pebsworth reported that the workgroup favored shared clinical decision-making (also known as individual-based decision-making) for the hepatitis B vaccine for infants born to mothers who test negative. *Id.* at 9. The presentation discussed the advantages of a shared clinical decision-making approach and potential concerns with that approach. *Id.* at 10–13. Ultimately, the workgroup decided to recommend shared clinical decision-making because, among other reasons, it “[p]rovides for a return of decision-making to parents in collaboration with the health care provider” and allows providers “to recommend a flexible schedule and . . . tailor care to individual needs, risks and preferences.” *Id.* at 12. The presentation also considered vaccine safety concerns and the risk of hepatitis B infection. *Id.* at 10. Its discussion of vaccine safety was consistent with the Blaxill presentation. Mark F. Blaxill, *Safety Review of Hepatitis B Birth Dose Vaccination* (Dec. 4, 2025), <https://perma.cc/GE6J-ZVF5>. Finally, Dr. Pebsworth provided the workgroup’s rationale for recommending that infants who do not receive the birth dose receive the initial dose no earlier than two months of age. *Summary of Information, supra*, at 12.

Having considered these presentations, along with other information discussed at the meeting, the ACIP voted to recommend 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,” and it identified infection risks to consider. CDC, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test*

Negative for the Virus (Dec. 5, 2025), <https://perma.cc/QQ8P-DVNQ>. The ACIP further recommended that “[f]or those infants not receiving the birth dose, . . . the initial dose be administered no earlier than two months of age.” *Id.*

CDC adopted these recommendations, explaining that they “reflect[] ACIP’s rigorous review of the available evidence” and “restor[e] the balance of informed consent to parents whose newborns face little risk of contracting hepatitis B.” *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus*, *supra*. In addition to the “[v]ery low incidence of perinatal hepatitis B transmission in the U.S. due to existing prevention systems,” CDC noted the “[h]igh reliability of prenatal hepatitis B screening, which identifies nearly all hepatitis B infections during pregnancy.” CDC, *Fact Sheet Hepatitis B Immunization* (Dec. 16, 2025), <https://perma.cc/T927-DBYV>. When “maternal hepatitis B status is confirmed negative,” CDC determined that “[f]amilies and providers should be afforded flexibility.” *Id.* Finally, CDC explained that it would “[d]evelop materials to support clinicians in discussing vaccination timing with families.” *Id.*

Plaintiffs’ arguments against this decision are meritless. Again, the ACIP was not required to consider “new data.” PI Mem. 33; *see supra* n.8. In any event, the committee *did consider* recent data from 2024 and 2025. *See, e.g., Safety Review of Hepatitis B Birth Dose Vaccination, supra; Summary of Information, supra*, at 5 (noting that the Childhood/Adolescent Schedule Workgroup received 12 expert presentations on medical and scientific issues at its meetings in October and November 2025). There were no “reliance interests” the agency needed to consider. *See supra* p. 23; *contra* PI Mem. 33–34. And the ACIP was not required to explain why it did not follow the GRADE and EtR frameworks, *see supra* pp. 25–26; *contra* PI Mem. 27–28, though Dr. Pebsworth’s second presentation at least partially applied the GRADE framework, *see*

Summary of Information, supra, at 6.

In sum, the ACIP and CDC “reasonably considered the relevant issues,” including the hepatitis B vaccine’s safety and efficacy, impacts on insurance coverage, and the advantages and potential disadvantages of a shared clinical decision-making recommendation, and “reasonably explained” their recommendations. *Prometheus Radio Project*, 592 U.S. at 423; *contra* PI Mem. 18, 32. These deliberations were based on scientific evidence and input from the ACIP Childhood/Adolescent Schedule Workgroup and CDC experts. *See ACIP Presentation Slides: December 04-05, 2025, Meeting, supra*; *contra* PI Mem. 18 (incorrectly claiming “[n]o Work Group presented at this ACIP meeting on HepB”). And in adopting the ACIP’s recommendations, CDC permissibly relied on “the reasonable opinions of [ACIP’s] qualified experts.” *Marsh*, 490 U.S. at 378.

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

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. We maintain (and reassert) all arguments against irreparable harm from our initial opposition brief, *see* ECF No. 232, at 37-43, and discuss herein only our additional arguments specific to the May 2025 directive and the ACIP votes from June, September, and December.

Off the bat, Plaintiffs’ substantial delay in challenging the June 2025 ACIP vote about thimerosal precludes any claim of irreparable harm. *See Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 163 (1st Cir. 2004) (“[D]elay between the institution of an action and the filing of a motion for preliminary injunction, not attributable to intervening events, detracts from the movant’s claim of irreparable harm.”). “If [Plaintiffs] were genuinely at risk of irreparable harm” from the June recommendation (as adopted by HHS in July), they “presumably” would not have waited six months before moving to add this vote to the case. *Doe v. Trs. of Dartmouth*

Coll., 597 F. Supp. 3d 511, 514 (D.N.H. 2022). This months-long delay strongly “militates against a finding of irreparable harm.” *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016); *see Doe*, 597 F. Supp. 3d at 514-15 (finding no irreparable harm based on a delay of several months). And of course, Plaintiffs “cannot delay the initiation of litigation and then use an ‘emergency’ created by [their] own decisions concerning timing to support a motion for preliminary injunction.” *Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V. v. Whitehead Inst. for Biomedical Rsch.*, 650 F. Supp. 2d 114, 123 (D. Mass. 2009).

Furthermore, despite seeking to preliminarily enjoin four distinct actions—the Secretarial Directive and three ACIP votes—Plaintiffs do not explain how *each* “challenged conduct causes some harm that cannot be adequately redressed” after summary judgment. *Nagle v. Gerry*, No. 08-CV-432-SM, 2009 WL 702798, at *5 (D.N.H. Mar. 13, 2009). Rather, they lump everything together under general labels like “the ACIP Actions.” PI Mem. 43. That does not suffice where, as here, each challenged action has a distinct subject and effect. *City of Lowell v. Enel N. Am., Inc.*, 705 F. Supp. 2d 116, 120 (D. Mass. 2010) (finding no irreparable harm when city addressed only “the *overall* risk of massive flooding, not to the increased flood risk based upon the [challenged] use of five-foot flashboards”).

For example, to enjoin the June ACIP “vote to remove thimerosal from all influenza vaccines distributed in the United States,” ECF No. 183-1, at 2, Plaintiffs must establish why this vote, in particular, will likely cause them irreparable harm. That requires addressing factors like AAP’s past support for “remov[ing] mercury from childhood vaccines” and vaccine manufacturers’ confirmation that “they have the capacity to replace multi-dose vials containing mercury, ensuring the [VFC] program and adult vaccine supplies will remain uninterrupted.” *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*,

supra. The evidence on these points will necessarily differ from that which would purportedly show irreparable harm from the Secretary’s May instruction “to remove the recommendations from CDC immunization schedules that pregnant women and children [routinely] receive the Covid vaccine.” ECF No. 183-1, at 2. Yet Plaintiffs ignore all these distinctions, offering only generalized statements of harm in the aggregate. Thus, Plaintiffs fail to carry their burden of showing how they will likely suffer irreparable harm from each action they seek to enjoin. *See, e.g., City of Lowell*, 705 F. Supp. 2d at 120.

III. 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. “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.

Plaintiffs are trying to substitute their preferred policies for those adopted by senior, democratically accountable federal officials. However, Congress directed “[t]he Secretary” of Health and Human Services—not Plaintiffs—to “assist States . . . in the prevention and suppression of communicable diseases and with respect to other public health matters” and to “advise the several States on matters relating to the preservation and improvement of the public health.” 42 U.S.C. § 243(a). And Congress authorized the Secretary to establish the ACIP, *see id.* § 217a(a), to advise the CDC Director “regarding use of vaccines and related agents for effective control of vaccine-preventable diseases,” ECF No. 185-21, at 2. The ACIP, the CDC Director,

and the Secretary then must remain free to “select the views that [they] want[] to express” about vaccine recommendations and protection of the public health. *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)). And these officials may share their views “in the hopes of persuading others to follow [their] lead.” *Id.* at 188.

Furthermore, Plaintiffs’ desired preliminary injunction would create the very “state of confusion” they decry. PI Mem. 54. Over the past months, the current Administration has developed and released its immunization recommendations. To suddenly revert to the previous advice through a preliminary injunction would subject the public and healthcare practitioners to whiplash and create confusion about the actual position of CDC and HHS. And if Defendants prevail on the merits and the preliminary injunction is dissolved, more whiplash will occur as the current recommendations are restored. The public interest is significantly disserved by such ambiguity about the current, actual recommendations of those democratically accountable officials charged with advising and assisting States to protect the public health.

CONCLUSION

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

February 27, 2026

Respectfully submitted,

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Counsel for Defendants

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 27, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

**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

Declaration of Isaac C. Belfer

Pursuant to 28 U.S.C. § 1746, I, Isaac C. Belfer, declare as follows in support of Defendants’ Second Memorandum in Opposition to Plaintiffs’ Motion for Preliminary Injunction:

1. I am a trial attorney in the Federal Programs Branch, Civil Division, U.S. Department of Justice, and am representing Defendants in this matter. The purpose of this declaration is to authenticate and enclose the exhibits cited in Defendants’ Second Memorandum in Opposition to Plaintiffs’ Motion for Preliminary Injunction.

2. Attached hereto as **Exhibit A** is a true and correct copy of the May 12, 2025, Memorandum to Secretary of Health and Human Services Robert F. Kennedy, Jr. from Matthew Memoli, M.D., M.S., Principal Deputy Director of NIH, and Sara Brenner, M.D., M.P.H., Principal Deputy Commissioner of FDA, titled, “Medical and Scientific Assessment of Secretary Becerra’s Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age.”

/s/ Isaac C. Belfer
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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 27, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

Exhibit A

MEMORANDUM TO THE SECRETARY

**THROUGH: HEATHER MELANSON, CHIEF OF STAFF
CORTNEY MCCORMICK, EXECUTIVE SECRETARY**

**FROM: MATTHEW MEMOLI, M.D., M.S., PRINCIPAL DEPUTY DIRECTOR, NIH
SARA BRENNER, M.D., M.P.H., PRINCIPAL DEPUTY COMMISSIONER,
FDA**

**SUBJECT: Medical and Scientific Assessment of Secretary Becerra's
Determination Recommending COVID-19 Vaccination of Children
Less Than 18 Years of Age**

DATE: May 12, 2025

On June 18 and June 24, 2022, Secretary of Health and Human Services Becerra issued "Secretarial Directives" recommending that children between the ages of 6 months and 17 years receive the COVID-19 vaccine. At this time, after a review of relevant existing data, including new studies unavailable to Secretary Becerra when he issued his Directives on June 18, 2022, and June 24, 2022, there is no clear evidence that the benefits of vaccination for COVID-19 outweigh the risk of harm in children under 18 years of age.

Vaccines are products designed to be given to individuals to stimulate immunity against a certain pathogen thereby preventing disease and its sequelae. A departmental recommendation of any vaccination should be based on a careful evaluation of probable benefits weighed against risks and potential harms. The benefits and risks of vaccination should be clearly established using randomized controlled trials prior to a recommendation. Vaccination of any population should only be recommended when it is clear, based on the best available evidence from these trials, that the benefits are likely to outweigh the known and potential risks of the vaccines. Once a recommendation is made, reevaluation of the recommendation is regularly required, as new data will continue to emerge as a vaccine is used in a population and as a pathogen evolves.

Risks of COVID-19 to Children

Mortality

The risks associated with SARS-COV-2 infection, and subsequent clinical disease known as COVID-19, in children under 18 has been extremely low since the novel virus emerged in 2019. A review using death certificates in countries with widespread COVID-19 testing found that deaths were over-attributed to COVID-19 by as much as 40-50% early in the pandemic and possibly as high as 60-70% after the emergence of Omicron (Friis, 2023). This type of over-attribution led to widespread misunderstanding among the U.S. population about the mortality attributable to COVID-19 in children due to CDC's public dashboard on COVID-19 deaths, COVID Data Tracker, which consistently overstated the number of deaths attributed to COVID-19 in children by 20% or more compared with the CDC's standard and more carefully adjudicated National Center for Healthcare Statistics database (Krohnert, 2023). A clearer picture of the low risk in children emerged in multiple studies, including a landmark study from 2020-2021 of over 750,000 healthy children ages 5-17 infected with SARS-CoV-2. This study identified no deaths due to the virus in their cohort (Sorg, 2022). This study was performed early in the pandemic when death rates were highest from COVID-19 and prior to the current widespread immunity and evolution of milder SARS-COV-2 variants. A subsequent study found the omicron subvariants later in the pandemic posed even lower risk to children with an over 3-fold reduction in infection mortality rate in children and young people compared to early in the pandemic (Hani, 2023), while some of the few overall deaths observed occurred in vaccinated children. By the end of 2023, CDC reported a death rate in children under 18 of 0.5 per million cases (<https://data.cdc.gov/Public-Health-Surveillance/Rates-of-COVID-19-Cases-or-Deaths-by-Age-Group-and/54ys-qyzm>) with that number likely an over-estimate given unreliable denominators (total number of actual infections was higher than captured in the data) and has been decreasing even further since. These data together suggest that the mortality from SARS-CoV-2 infection among children without underlying health conditions is much less than one per million, which is significantly less than from RSV or influenza. Furthermore, there is no clear evidence that vaccination plays a role in preventing these exceedingly rare deaths.

Hospitalization

Hospitalization rates of children from COVID-19 are also extremely low and have decreased since 2019; they are now substantially lower than for influenza and RSV in the United States. Similar to COVID-19 deaths, starting early in the pandemic, hospitalization rates of children due to SARS-CoV-2 in the U.S. were likely overestimated by at least 40% (Beck, 2021). This suggests that nearly half or more of the children who had been reported to be hospitalized from COVID-19 were hospitalized either due to other illness or injury, or unnecessarily hospitalized due to fear of COVID-19. This again gave the public an inaccurate sense that hospitalization due to

severe COVID-19 was common in children. This also likely led to an inflated perceived effect of vaccination on hospitalization, as the vaccine availability calmed some of these fears.

Multi-Inflammatory Syndrome in Children (MIS-C)

An additional condition of potential risk related to COVID-19 in children is a post-infection inflammatory condition, named Multi-Inflammatory Syndrome in Children (MIS-C). This condition was rare, but is now exceedingly rare with less than 80 total cases nationwide in 2024. To date, no randomized controlled trials have demonstrated a reduction in risk of this condition due to vaccination. Observational data assessing effectiveness of COVID-19 vaccines against MIS-C are likely unreliable due to underlying biases (Høeg, 2024).

Long COVID

Long COVID is a diagnosis which suffers from broad and imprecise case definitions (Høeg, 2024). However, the most well-conducted studies indicate that infection-related lasting symptoms in children are exceedingly rare (Selvakumar, 2023; Høeg, 2023). Randomized studies have also not assessed the efficacy of vaccination against Long COVID (Munro, et al.). One study among Norwegian children found vaccination to be an independent risk factor for more severe fatigue following SARS-CoV-2 infection (Selvakumar, 2025) suggesting a possible worsening of Long COVID associated symptoms, but observational studies have been mixed and prone to multiple biases when evaluating the relationship between vaccination and Long COVID. (Høeg, 2023; Høeg, 2024).

Vaccination Risks

Post-Vaccination Myocarditis and Pericarditis, Including Sudden Cardiac Death and Sequelae

Post-vaccination myo- and pericarditis are well-established side effects of COVID-19 vaccination identified in adolescent boys and girls (Krug, 2022; Kracalik, 2023). About 1 in 2,700 boys vaccinated with a second dose of Pfizer were hospitalized with myo- and/or pericarditis according to a prospective study from Hong Kong (Chua, 2022). Post-vaccination myocarditis can be severe and may have lasting consequences in children and young adults (Kracalik, 2023). In that study, about 1 in 5 children were admitted to intensive care for the condition. At 90 days follow up, over 30% had still not been cleared for physical activity and about 25% were still being prescribed medications. Rates of subclinical myo- and pericarditis, and associated long term health outcomes, have yet to be fully characterized.

Deaths post-vaccination due to myocarditis appear to be rare but have been reported in young people (Mevorach, 2021). A nationwide Korean study (Cho, 2023) attributed 21 total deaths to vaccination-induced myocarditis, corresponding to a death rate of 1-2 per million primary series mRNA vaccinations given in the 12–44-year-old age group, consistent with a nationwide study from Qatar (Butt, 2023). In these two studies together, there was one death and three

fulminant cases in those under 21, highlighting a serious risk of vaccination that should be weighed with a lack of certainty of vaccination benefit and an exceedingly low rate of death among children—well below 1 per million infections in healthy children.

While myocarditis can be a consequence of SARS-CoV-2 infection in children and young people, the risk from vaccination appears to be significantly higher. A study performed in 2021 (Karlstad, 2022) that included 23 million residents of Norway, Sweden, Denmark, and Finland ages 12 and older found no cases of post-COVID myocarditis in children between 12–15 years of age, but did find cases in 16–24-year-olds. However post-vaccination myocarditis was at least six times more common than myocarditis post-COVID infection among both males and females (details in supplement). Furthermore, no robust evidence has shown vaccination to reduce post-COVID-19 myocarditis risks.

Additional Safety Signals and Potential Risks of Vaccination in Children

Additional risks that have been associated with mRNA vaccination include but are not limited to seizures, Bell’s palsy, transverse myelitis, clotting disorders, strokes, heart attacks, and acute kidney injury (Faskova, 2024; Dag Berild, 2022; Lim 2025; Hu, 2024; Hwang, 2025). Analysis of the randomized trials in children suggests there may be an increased risk of non-COVID-19 lower respiratory tract infection (Hoffman, 2023). The potential benefit in healthy children of vaccination is very small given the low risk of severe disease and, based on existing data, may not outweigh the risks of vaccination. This is most likely the reason why, as mentioned during the 2025 ACIP meeting on April 15, 2025, the U.S. is currently a global outlier in recommending yearly routine vaccination of children under 18 for COVID-19. The WHO European Nations, Australia, Canada, and the UK do not currently recommend routine vaccination of non-high-risk children. Denmark notably does not offer the COVID-19 vaccine to anyone under the age of 65 unless they have certain underlying medical conditions and children <18 may not receive a COVID-19 vaccine unless they have a chronic illness and have been assessed by a pediatrician who recommends vaccination for them. Notably, the Director General of the Danish Health Authority, Søren Brostrøm, stated in the summer of 2022 that “it was a mistake” (det var in fejl) to vaccinate children for COVID-19. Furthermore, updated versions of COVID-19 vaccines, which claim to provide protection against severe illness due to infection with new subvariants, may have additional, new, and/or unknown risks. The clinical efficacy of updated vaccines has also not been established on the basis of randomized controlled trials and health outcomes data; and similarly, comprehensive adverse event data has yet to be captured and fully analyzed for these new products, leading to an incomplete benefit/risk analysis. An example of this in another setting was the 2009 inactivated influenza vaccine, Pandemrix, manufactured by Glaxo Smith Klein which caused narcolepsy in children (Buonocore, 2022). Well over 1,000 children were affected by the time this link was made with the vaccine the following year (Doshi, 2018) as well as additional serious safety concerns. This is a good example of why continued consideration and evaluation of vaccine recommendations must be done regularly.

Lack of Clear Evidence of Vaccination Benefit

As described above, there is insufficient evidence based on clinical outcomes data to render a positive benefit risk assessment for vaccinating children at this time. The initial clinical trials in children and adolescents included less than 2,500 children and were unable to determine efficacy against severe COVID-19 (Frenck, 2021; Ali, 2021; Walter, 2022; Creech, 2022; Anderson, 2022; Muñoz, 2023). Any purported protection against symptomatic disease identified in epidemiological data appears modest and wanes rapidly (Munro, 2024; Chemaitelly, 2022). More recent randomized placebo-controlled trials of original and/or updated vaccine formulations have *not* been conducted to evaluate the safety or efficacy of any COVID-19 vaccines. This is especially relevant and necessary in the setting of current widespread population immunity (as understood from seroprevalence studies) or against the new subvariants in children or adults. What makes this even more concerning is that by the time a new formulation is manufactured and released based on currently circulating variants, the virus has evolved away from the variant the vaccine was designed against, likely reducing efficacy and again altering the benefit/risk calculation.

To estimate efficacy, randomized placebo-controlled trials of boosters and updated vaccination formulas have thus far measured neutralizing antibody response to re-vaccination. However, the clinical correlate of protection to this response among children and adults who have previously had SARS-CoV-2 infection one or multiple times has not been established (Zhang, 2025). Further the ever-changing nature of the SARS-COV-2 viral antigens makes it unlikely that the current vaccination strategy will provide durable immunity against COVID-19. Observational data are largely unreliable to assess vaccine efficacy due to multiple biases; one of the most significant being the “Health Vaccinee Bias” that reflects better underlying health among vaccinated populations (Høeg, 2023, Fürst, 2024, Chemeitelly, 2024). For this reason, the past and current true efficacy of the COVID-19 vaccines remains unclear.

Conclusions

In conclusion, currently available data and published studies do not provide sufficient clinical and scientific evidence to broadly recommend COVID-19 vaccination for those under 18 years of age. No clear benefit of vaccination in children under 18 has been established with current formulations of COVID-19 vaccines against current circulating variants, especially given the widespread immunity from prior infection(s) that currently exists in the population. Given the low risk of infection to those under the age of 18, the known risks of vaccination outweigh any small potential benefit. It is HHS’s priority to ensure the health and safety of this vulnerable population—whether risk comes from a disease or a treatment/vaccine. We have a duty to set a gold standard for scientific review of products that are recommended to Americans and that those products, including vaccines, must have clearly defined benefits that outweigh the risks. Ultimately, decisions regarding risk and benefit must be tailored to the individual and made through shared decision making between patients and their physicians.

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Exhibit B

Subject: COVID-19 vaccine safety in pregnant women

Because of the above issues, our knowledge about the safety of COVID vaccination during pregnancy relies on lower quality data including findings from pharmacovigilance systems and

Memorandum

on retrospective observational studies. There are numerous issues with relying on these datasets and analyses.

First, pharmacovigilance data tends to be vastly underreported. (Shumabukuro, 2015) Pregnant women or their obstetricians may not consider the vaccine as a cause of common or non-rate pregnancy outcomes such as miscarriage or fetal abnormality. Also, even if reported to a phamacovigilance database, small percentage increases (such as a couple of percentage points) in conditions such as fetal loss may not be found to be statistically significant from baseline rate but may still impact many women.

Second, observational studies are prone to multiple potential biases, of which *healthy vaccinee bias* (where people who get vaccinated tend to be healthier at baseline than those who do not get vaccinated) is potentially the most important. This bias has been thoroughly documented for the COVID-19 and the influenza vaccine in numerous countries across the world (Høeg, 2023; Fürst, 2024; Chemeitelly, 2024; Reidmann, 2025 Remschmidt, 2015). Women who have better underlying health are also less likely to have pregnancy complications. This may cause us to miss real safety issues if the unvaccinated are more prone to pregnancy complications.

Furthermore, another important bias, selection bias, stems of the fact only a few observational studies have looked at COVID vaccination during early stages of pregnancy, when the risk of toxicity leading to miscarriage or developmental defect is the highest. Most observational studies have not found a significant association between vaccination and adverse outcomes in pregnancy.

Potential safety concerns

However, a large study from Ontario did find a higher rate of fetal loss among women vaccinated prior to week 20. (Velez, 2023) This associations disappeared when excluding induced abortions. However, it is unclear if these were truly elective or recommended due to impending fetal loss. Furthermore, this study adjusted for time of year, which was likely to be inappropriate given the rapid timing of the vaccination rollout in Ontario in this age group.

Memorandum

Another study from Israel (Dick, 2022), where the population was almost exclusively vaccinated with the Pfizer mRNA vaccine found that women vaccinated in the second trimester had a 1.9% higher rate of preterm birth and this was highly significant. This signal persisted after adjusting for multiple potential confounders.

Additionally, another small study of women who underwent *in vitro* fertilization found a 50% higher clinical pregnancy loss rate among COVID-19 vaccinated women compared with unvaccinated (Aharon, et al. 2022), however this was not found to be statistically significant and again, observational studies are subject to multiple biases.

Importantly, the COVID-19 mRNA vaccines have been shown in a study in the American Journal of Obstetrics and Gynecology to cross the placenta (Lin, 2024). mRNA vaccination has also been linked to multiple types of blood clots (Faskova, 2024). Placental blood clots can decrease oxygen to the fetus, cause birth defects, growth restriction, miscarriage and other pregnancy complications.

Uncertainty about vaccine efficacy

In the setting of widespread immunity from prior infection and a lack of randomized placebo control trials looking at clinical outcomes in this setting, the current benefit of mRNA COVID-19 vaccination against severe disease is uncertain. This is because vaccine efficacy in our current circumstances has been deduced from observational data and immunobridging data and the applicability of the initial randomized controlled trials to today's epidemiological circumstances and in a non-immune naïve population is not well defined.

Conclusion

Due to a lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy and some basis for concern, it would be wise to err on the side of caution and recommend against during vaccination in pregnancy until there is certainty the benefits of vaccination are likely to outweigh potential risks to the mother and developing baby.

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Memorandum

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

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; *et al.*,

Defendants.

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

**PLAINTIFFS' SUPPLEMENTAL BRIEF REGARDING
THE APPLICABILITY OF THE FEDERAL ADVISORY COMMITTEE ACT TO THE
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES**

I. INTRODUCTION

The Court has questioned whether the Advisory Committee on Immunization Practices (“ACIP”) functions as an advisory committee, such that it is governed and subject to the requirements of the Federal Advisory Committee Act (“FACA”). The answer is yes. Congress enacted FACA to regulate committees providing advice or recommendations to federal agencies. The ACIP does just that. From inception, the ACIP has consistently provided advice and recommendations regarding the control of vaccine-preventable diseases for the consideration and approval by the Centers for Disease Control and Prevention (“CDC”) Director. Unlike the U.S. Preventive Services Task Force (“PSTF”) at issue in *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), which issued “A” and “B” ratings that on their own compelled insurance coverage determinations, the ACIP’s recommendations are not self-effectuating and only trigger coverage determinations when subsequently adopted by the CDC Director. That Congress has recognized this well-embedded two-step process for vaccine recommendations—the ACIP

recommendation followed by CDC endorsement—in various statutes does not convert the longstanding purpose of the ACIP from primarily advisory in function to operational. *Braidwood* does not alter the ACIP’s status as an advisory body subject to FACA nor did it address the question of FACA applicability.¹

II. UNLIKE PSTF, THE ACIP IS AN ADVISORY COMMITTEE WITHIN THE MEANING OF AND SUBJECT TO FACA.

There are multiple reasons why the ACIP qualifies as an advisory committee subject to FACA and that *Braidwood*’s analysis of the PSTF does not apply to the ACIP.

First, the ACIP and PSTF occupy entirely different roles within the Public Health Service. The PSTF is established by Congress in a specific statute, 42 U.S.C. § 299b-4, which explicitly mandates that its members and their recommendations shall be “independent and, to the extent practicable, not subject to political pressure”. In contrast, the ACIP was created through a delegation of the Secretary’s general authority under 42 U.S.C. § 217a(a) to establish “advisory councils or committees.” Congress provided that the Secretary may “delegate to [the ACIP] such advisory functions . . . as [he] determines to be appropriate.” 42 U.S.C. § 217a(c).

This distinction between the congressionally established PSTF and the ACIP, established pursuant to explicit “advisory committee” authority, is further codified in the Affordable Care Act’s preventive coverage requirement itself. While the PSTF is referenced in its own right, the ACIP is further characterized as “of the Centers for Disease Control and Prevention”. *See* 42 U.S.C. § 300gg-13(a)(1–2). This phrasing, consistent with other prior statutes referencing ACIP,

¹ Plaintiffs anticipate that the Government may rely on Footnote 3 of the *Braidwood* decision to argue that ACIP is no longer “advisory.” *See Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748, 766 n.3 (2025) (observing that “the [PSTF] ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act and empowered the [PSTF] to issue binding recommendations. [PSTF] members are officers because, by operation of the ACA, their ‘A’ and ‘B’ recommendations are not purely advisory.” (citation modified)). While the Court described the PSTF’s role under the Affordable Care Act as “not purely advisory,” this same description cannot automatically apply to the ACIP, and this Court should reject such a broad reading.

confirms that Congress views ACIP as a subordinate advisory arm of the CDC rather than as an independent decision-maker.²

Second, Congress expressly made FACA inapplicable to the PSTF, and there is no comparable exclusion of the ACIP. Thus, when enacting the very statutory framework at issue in *Braidwood* (42 U.S.C. § 300gg-13(a)), Congress simultaneously provided, in 42 U.S.C. § 299b-4(a)(5), an express exclusion of the PSTF from FACA. It did not similarly exempt the ACIP.

This silence is dispositive. Congress demonstrated that it knew exactly how to exempt an entity from FACA’s requirements. It chose not to do so with respect to the ACIP. Under the canon of *expressio unius est exclusio alterius*, the decision to exempt the PSTF while remaining silent on ACIP serves as a definitive legislative recognition that the ACIP remains an advisory committee. The PSTF was granted a unique, independent status that Congress saw fit to expressly exempt from FACA. The ACIP, however, was maintained as a traditional advisory body, fully subject to the public’s right to oversight. It is a fundamental principle of statutory interpretation that Congress is presumed to act intentionally and purposely when it includes particular language in one section of a statute but omits it in another.³

² See, e.g., 42 U.S.C. § 300gg-13(a)(2) (“immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices **of the Centers for Disease Control and Prevention** with respect to the individual involved” (emphasis added)); 42 U.S.C. § 1396d(a)(13)(B) (“with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting **through the Director of the Centers for Disease Control and Prevention**)” (emphasis added)); 42 U.S. Code § 1396s(e) (“The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting **through the Director of the Centers for Disease Control and Prevention**).” (emphasis added)); 38 U.S. Code § 1701(10) (“The term ‘recommended adult immunization schedule’ means the schedule established (and periodically reviewed and, as appropriate, revised) by the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services and **delegated to the Centers for Disease Control and Prevention**.” (emphasis added)).

³ See *Russello v. United States*, 464 U.S. 16, 23 (1983) (observing that “[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)); see also *United States v. Wooten*, 688 F.2d 941, 950 (4th Cir. 1982). This “short answer”—that “Congress did not write the statute that way,” *United States v. Naftalin*, 441 U.S. 768,

Third, FACA defines an “advisory committee” as any group established or utilized by an agency “in the interest of obtaining advice or recommendations”. 5 U.S.C. § 1001(2). The core question as to FACA’s applicability is whether ACIP performs “primarily advisory” functions. ACIP remains a primarily advisory body because its functions are deliberative rather than executive. Under long-standing FACA jurisprudence, the legal distinction between “advisory” and “operational” functions rests on whether the committee itself is the final decider or whether its output is a recommendation used by a separate executive actor. *See Jud. Watch, Inc. v. Clinton*, 76 F.3d 1232, 1233 (D.C. Cir. 1996) (limiting FACA to advice directed to government policy). “[T]he most important inquiry for FACA purposes is whether it is asked to render advice or recommendations.” *Pub. Emps. for Env’t Resp. v. Nat’l Park Serv.*, 605 F.Supp.3d 28, 52–53 (D.D.C. 2022) (citation modified).

The ACIP’s charge upon inception was “the responsibility of **advising** the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control.”⁴ Today, it continues to fulfill this fundamental purpose in providing recommendations to the Director of the CDC.

FACA regulations exempt “[a]ny committee established to perform primarily operational as opposed to primarily advisory functions . . . such as making or implementing Government decisions or policy.” 41 C.F.R. § 102-3.40(j); *See also Nat’l Res. Def. Council v. Env’t Prot. Agency*, 806 F.Supp. 275, 276 (D.D.C. 1992) (quoting 42 C.F.R. § 101-6.1004(g) [sic] (1992)

773 (1979)—applies with full force to the ACA’s preventive-services framework. While Congress explicitly provided that “the Federal Advisory Committee Act shall not apply to the [PSTF],” 42 U.S.C. § 299b-37(a)(6), it conspicuously omitted any such exemption for the ACIP. Following the Supreme Court’s instruction in *Russello*, this Court should “refrain from concluding” that the presence of an express FACA exemption for the [PSTF] and the absence of one for the ACIP was a “simple mistake in draftsmanship.” 464 U.S. at 23. Rather, it must be presumed that Congress intended for the ACIP to remain subject to the transparency mandates of FACA.

⁴ Jean Clare Smith et al., *History and Evolution of the Advisory Committee on Immunization Practices — United States, 1964–2014*, 63 MORBIDITY AND MORTALITY WKLY. REP. (MMWR) 955, 955–58 (Oct. 24, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm> [<https://perma.cc/PFX4-M8JL>] (emphasis added).

(current version at 41 C.F.R. § 102-3.40(j) (2025))). This includes any committee for which “operational responsibilities give rise to or beget its advisory duties,” or for which “its advisory duties are paramount to its mission and a culmination of its operational duties.” *Emmerich Newspapers, Inc. v. Mississippi River Comm’n*, 2025 WL 1223098, at *10 (S.D. Miss. 2025) (slip opinion).

Operational bodies generally perform direct governmental services—such as adjudicating claims, managing public lands, or issuing binding regulations—none of which the ACIP performs.⁵ The ACIP does not manage the budget for vaccine procurement, nor does it enforce insurance mandates or possess the power to penalize non-compliance; rather, it provides the scientific basis for decisions made by others. ACIP recommendations do not automatically impose legal requirements. Instead, the CDC is “utilizing” the group for advice, not delegating final executive power.

The ACIP was not established to be an operational entity. The ACIP was established as an advisory committee under a statute authorizing the creation of advisory committees—42 U.S.C. § 217a. It neither makes nor implements government decisions or policy, nor do its members have any authority to implement any recommendation issued by the committee. Those final agency decisions belong to the Secretary or the CDC Director, while the responsibility to implement those recommendations rests with the CDC. Neither the ACA nor *Braidwood* alter the ACIP's advisory status.

Even if the Court were to adopt the flawed logic that the ACA mandate is an “operational” function, that single function cannot “de-FACA” the entire ACIP. A committee’s status under FACA is determined by its *primary* function. For the ACIP, that primary function remains

⁵ See, e.g., *Jud. Watch*, 76 F.3d at 1235 (holding that “operational” functions involve “actual management or operation of federal programs” rather than the mere provision of “advice and recommendations”).

providing expert clinical and scientific guidance to the CDC Director. The insurance coverage trigger at issue in *Braidwood* is a closely connected legislative consequence of that advice, not the “operation” of the committee itself.

III. The ACIP Has Continuously Operated as an Advisory Committee Subject to FACA.

The ACIP’s establishment as an advisory committee in 1964 predated the passage of FACA. Since FACA’s enactment in 1972, the ACIP has been chartered accordingly. The ACIP’s formal charter has long explicitly acknowledged its status as a FACA-governed body, stating that “The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.”⁶ Moreover, following *Braidwood*, the Department of Health and Human Services (“HHS”) chose not to reorganize the ACIP as an operational unit, instead maintaining its existing FACA-compliant structure and processes.

The ACIP has continuously operated pursuant to all provisions of FACA, which include conducting meetings that are open to the public, publishing public notice of meetings in the Federal Register, maintaining a functional and regularly renewed charter, providing an opportunity for public comment and public involvement during meetings, and recording detailed minutes of all meetings.⁷

Indeed, the significant good faith efforts of the CDC and the ACIP to comply with FACA provide further proof of the ACIP’s advisory status. Unlike the PSTF, which operates with a degree of statutory independence, the ACIP is inextricably managed by a Designated Federal Officer (“DFO”), a role required by FACA. *See* 5 U.S.C. § 1009. The DFO for the ACIP has consistently and rigorously carried out FACA’s statutory mandates outlined above as well as approving the

⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, *Amendment to the Charter of the Advisory Committee on Immunization Practices* (signed Dec. 1, 2024; filed April 1, 2026), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/E8LM-QFVT>].

⁷ *See id.*; 5 U.S.C. § 1009.

ACIP’s agenda, attending meetings of the ACIP, and ensuring the ACIP’s transparency through the publication of meeting agenda, minutes, and other materials.

The CDC’s continued employment of a DFO to manage the ACIP is a functional admission that the committee remains advisory. If the ACIP were truly an operational body, the DFO’s role would be legally unnecessary and structurally inappropriate.

IV. In Renewing the ACIP’s Charter, Secretary Kennedy Explicitly Affirmed FACA’s Application to the ACIP.

The most compelling evidence that the ACIP remains subject to FACA is found in Secretary Robert F. Kennedy Jr.’s execution of a recent amendment to the ACIP’s charter, which retains the language stating that “[t]he Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.”⁸ If it were the belief of the Secretary that the rules and regulations of FACA do not apply to the ACIP, the Secretary could have removed this description of how the ACIP is governed. In renewing the ACIP’s charter, however, and keeping this explicit statutory reference to FACA, the Secretary concedes, explicitly affirms, and legally ratifies the applicability of FACA to the ACIP.

V. BRAIDWOOD DOES NOT EXEMPT THE ACIP FROM FACA.

In *Braidwood*, the Court observed that “the [PSTF] ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act and empowered the [PSTF] to issue binding recommendations. [PSTF] members are officers because, by operation of the ACA, their ‘A’ and ‘B’ recommendations are not purely advisory.” 606 U.S. at 766 n.3 (citation modified).

⁸ CTRS. FOR DISEASE CONTROL & PREVENTION, *Amendment to the Charter of the Advisory Committee on Immunization Practices* (signed Dec. 1, 2024; filed April 1, 2026), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/E8LM-QFVT>]. This amendment was signed on December 3, 2025 by Secretary Kennedy with April 1, 2026 specified as the filing date, the date on which the former ACIP Charter was set to expire.

The ACIP is different. As the district court noted in rejecting the argument that the ACIP's role violated the Appointments Clause, the ACA "contains no language removing or modifying the Secretary's background authority over ACIP." *Braidwood Mgmt. Inc. v. Becerra*, 627 F.Supp.3d 624, 640 (N.D. Tex. 2022).

The plain language of the ACA statute at issue in *Braidwood* also affirms that the ACIP remains in a purely advisory role by referencing only the PSTF under 42 U.S.C. § 300gg-13(a)(1), but then qualifying the ACIP as "of the Centers for Disease Control and Prevention" in the very next subparagraph. *See* 42 U.S.C. § 300gg-13(a)(2). The ACA's implementing rules are consistent with this distinction. Where 45 CFR § 147.130(a)(1)(i) references only the PSTF, the following subparagraph parrots the statutory "of the CDC" language *and* further states that an ACIP recommendation is "considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention." *See* 45 CFR § 147.130(a)(1)(ii). *Braidwood* took specific notice of this rule and stated hypothetically that similar rules could be promulgated and applied to PSTF recommendations.⁹ This, however, does not *de facto* erase the ACIP's advisory status for the foregoing reasons.

a. Braidwood Did Not Consider Whether the ACIP is Exempt from FACA.

The question of whether the ACIP remains an "advisory committee" under FACA was not before the Supreme Court in *Braidwood*. The district court had disposed of the questions concerning the ACIP and its interaction with the Appointments Clause without consideration of FACA. In so doing, it observed differences in the functions and operations of the ACIP and PSTF that led it to differing conclusions under their Appointments Clause analyses. Specifically, the district court observed that features such as the subsequent ratification of the ACIP's

⁹ *See Braidwood*, 606 U.S. at 767 n.4.

recommendations by the CDC Director or by the Secretary avoided the Appointments Clause problem it found with respect to the PSTF.¹⁰

b. *Braidwood* Cannot Be Read to Exempt the ACIP from FACA.

Braidwood's grant of certiorari was limited to the constitutional challenge to the PSTF under the Appointments Clause. Because the ACIP “was not before [the Court], [the Court] did not consider it.” See *United States v. L. A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 38 (1952) (noting that a decision is not a binding precedent on an issue not raised or argued). It would, therefore, be inappropriate to read the *Braidwood* decision so broadly as to implicitly repeal or override the statutory mandates of FACA. It is a settled rule that the Court does not “decide questions of a constitutional nature unless absolutely necessary to a decision of the case.” *Burton v. United States*, 196 U.S. 283, 295 (1905). To interpret a footnote limited to discussing the PSTF as a *sub silentio* reclassification of the ACIP’s statutory status would violate the principle that the Court does not normally decide any issues not presented. See *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 34 (1993).

c. *Braidwood*’s Applicability is Confined to PHSA § 2713.

Even if this Court were to find that *Braidwood* has implications for FACA’s applicability to the ACIP, such an impact must be strictly confined to the ACIP’s role under the ACA’s preventive services coverage requirement. The *Braidwood* litigation solely concerned that mandate. The Court, therefore, did not address, nor did it have occasion to address, the myriad other roles the ACIP plays within the federal government.

¹⁰ See *Braidwood Mgmt., Inc. v. Becerra*, 627 F.Supp.3d at 639–40. The court observed that ACIP is “under the supervision and direction of the Secretary,” 42 U.S.C. § 202, and its “vaccine recommendation . . . is considered in effect after it has been adopted by the Director of the [CDC],” 45 C.F.R. § 147.130(a)(1)(ii). Because the Secretary maintains the “power to superintend,” which includes the “right to judge and direct” the ACIP’s output, the Secretary’s “ratification of the challenged ACIP provisions remedies any appointment defects.” *Id.* (citation modified).

The ACIP’s responsibilities are far broader than simply triggering insurance coverage. It fulfills a broad advisory role by providing clinical guidance on vaccine administration, contraindications, and schedules that are relied upon by medical and public health professionals nationwide—functions that are purely advisory in nature and contemplated by Congress under PHSa § 222 (42 U.S.C. § 217a). Beyond this broad role and separate from the role Congress contemplated under the ACA, the ACIP has been prescribed roles under multiple other federal statutes previously brought to this Court’s attention, including but not limited to the Vaccine for Children (“VFC”) program under Section 1928 of the Social Security Act (42 U.S.C. § 1396s). *Braidwood* did not consider the ACIP’s operation under these other statutorily contemplated roles.

The public interest necessitates that the ACIP remain subject to FACA because its recommendations carry immense consequences for the health and economic well-being of every American. Shielding such influential advice from public scrutiny would allow vaccine policy to be formulated in private, resulting in the exact “shadow government” scenario that Congress enacted FACA to prevent and which this very action challenges.

VI. CONCLUSION

For the foregoing reasons, this Court should conclude that *Kennedy v. Braidwood Management, Inc.* does not undermine FACA’s applicability to the ACIP. The ACIP performs primarily advisory functions for purposes of FACA. Congress has repeatedly treated the ACIP as an advisory committee across multiple statutory schemes and has never exempted the ACIP from FACA, even while expressly exempting PSTF. The Court therefore should apply FACA’s requirements accordingly.

Dated: March 4, 2026

Respectfully submitted,

By: /s/ Richard H. Hughes IV

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**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

Defendants’ Response to the Court’s February 27, 2026, Order

Defendants hereby respond to the Court’s February 27, 2026, order directing the parties to “submit supplemental briefing . . . on the applicability of the Federal Advisory Committee Act (FACA) to the Advisory Committee on Immunization Practices (ACIP)” in light of *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025). ECF No. 269.

The ACIP was established under the authority of the Secretary of Health and Human Services to “appoint such advisory councils or committees . . . , for such periods of time, as he deems desirable . . . for the purpose of advising him in connection with any of his functions.” 42 U.S.C. § 217a(a); *see* ECF No. 185-21, at 2. The ACIP Charter provides that the ACIP “is governed by the provisions of [FACA].” ECF No. 185-21, at 2. That’s because the ACIP’s functions are “advisory,” not “operational.” 41 C.F.R. § 102-3.40(j). In other words, the committee does not “mak[e] or implement[] Government decisions or policy.” *Id.* The ACIP advises the CDC Director “regarding use of vaccines and related agents for effective control of vaccine-preventable diseases.” ECF No. 185-21, at 2. But the CDC Director retains full discretion whether to adopt the ACIP’s recommendations as official CDC/HHS

(2018 ed., Supp. IV)).

The ACIP is fundamentally different from the U.S. Preventive Services Task Force. Whereas the Task Force’s recommendations become “binding” if the Secretary does not block them, *id.*, the ACIP’s recommendations are “in effect” for purposes of the ACA’s insurance coverage requirements only when adopted by the CDC Director, ECF No. 185-21, at 2; 42 U.S.C. § 300gg-13(a)(2); 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 whereas the ACA expressly says “the Task Force is not subject to” FACA, 606 U.S. at 766 n.3 (quoting 42 U.S.C. § 299b-4(a)(5) (2018 ed., Supp. IV)); *see* Pub. L. No. 111-148, § 4003, 124 Stat. 119, 541-43 (Mar. 23, 2010), there is no similar FACA exemption for the ACIP, *see Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 452 (2002) (“It is a general principle of statutory construction that when Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”) (cleaned up). The Task Force and the ACIP also differ in how they were established. The creation of the Task Force was mandated by statute. *See* 42 U.S.C. § 299b-4(a)(1) (“The Director shall convene an independent Preventive Services Task Force . . . to be composed of individuals with appropriate expertise.”). Not so for the ACIP, which exists pursuant to the Secretary’s discretionary authority to “appoint such advisory councils or committees . . . , for such periods of time, as he deems desirable . . . for the purpose of advising him in connection with any of his functions.” 42 U.S.C. § 217a(a).

Braidwood does not compel a contrary conclusion. *Braidwood* did not analyze the ACIP; it merely observed, in a footnote, that a recommendation from the ACIP is “not ‘considered in effect’ until ‘it has been adopted by’” the CDC Director. 606 U.S. at 767 n.4 (quoting 45 C.F.R.

§ 147.130(a)(1)(ii)). Because the Secretary could promulgate a similar regulation for the Task Force, the Court explained, he “‘ha[s] the *discretion* to review decisions rendered by’ the Task Force,” which makes Task Force members inferior officers under the Appointments Clause. *Id.* at 767–68 (quoting *United States v. Arthrex, Inc.*, 594 U.S. 1, 27 (2021)). Critically, the question of whether Task Force members are inferior officers is wholly separate from whether the Task Force qualifies as an advisory committee. Whereas the Appointments Clause inquiry asks whether the Secretary has the *discretion* to prevent the Task Force recommendations from being binding on their own, *id.*, the “advisory committee” inquiry asks whether the Task Force’s recommendations can, *in fact*, be binding on their own, *id.* at 766 n.3. On the latter question, the Task Force’s recommendations *can* be binding on their own, and thus the Task Force is not an advisory committee. By contrast, the ACIP’s recommendations have no legal effect unless and until they are adopted by the CDC Director. Thus, the ACIP remains an advisory committee.

March 5, 2026

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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.

March 5, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF	)	
PEDIATRICS, ET AL.,	)	
	)	
Plaintiffs,	)	
	)	No. 1:25-cv-11916-BEM
v.	)	
	)	
ROBERT F. KENNEDY, JR.,	)	
ET AL.,	)	
	)	
Defendants.	)	

BEFORE THE HONORABLE BRIAN E. MURPHY
UNITED STATES DISTRICT JUDGE

Motion Hearing

March 4, 2026
9:05 a.m. - 11:41 a.m.

John Joseph Moakley United States Courthouse
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P R O C E E D I N G S

THE CLERK: All rise.

(The Honorable Court entered.)

THE CLERK: This Honorable Court is now in session.
Judge Brian Murphy presiding. You may be seated.

Civil Action Number 25-11916, American Academy of
Pediatrics, et al. versus Kennedy, et al.

If counsel could please identify yourselves starting
with Plaintiffs' counsel?

MR. OH: Good morning, Your Honor. James Oh on behalf
of the plaintiffs.

THE COURT: Good morning, Mr. Oh.

MS. MCEVOY: Good morning, Your Honor. Elizabeth
McEvoy also on behalf of the plaintiffs.

THE COURT: Good morning, Ms. McEvoy.

MR. HUGHES: Good morning, Your Honor. Richard Hughes
on behalf of the plaintiffs.

THE COURT: Good morning, Mr. Hughes.

MS. LEE: Good morning, Your Honor. Daniella Lee on
behalf of the plaintiffs.

THE COURT: Good morning, Ms. Lee.

MS. COSTELLO: Good morning, Your Honor. Gianna
Costello on behalf of the plaintiffs.

THE COURT: Good morning, Ms. Costello.

1 MR. WALTERS: Good morning, Your Honor. Will Walters
2 on behalf of the plaintiffs.

3 THE COURT: Good morning, Mr. Walters.

4 MR. BELFER: Good morning, Your Honor. Isaac Belfer
5 for the Department of Justice for the government. I'm joined
6 by James Harlow for the Department of Justice and Katrina
7 Hodges for the Department of Health and Human Services.

8 THE COURT: Good morning to you, all. Thank you, all,
9 for being here.

10 MR. OH: I might as well make some introductions
11 again, or --

12 THE COURT: Sure.

13 MR. OH: -- I'll at least acknowledge some --

14 THE COURT: Go ahead.

15 MR. OH: -- people in the courtroom. We do have
16 members of the American Academy of Pediatrics and the
17 Massachusetts Chapter of the American Academy of Pediatrics. I
18 won't make you stand up. Okay.

19 And I also would just like to point out that one of my
20 new best friends is here in the back of the courtroom. His
21 name is Rick Jaffe. He is counsel for Children's Health
22 Defense who's -- who filed the motion to intervene.

23 THE COURT: To intervene, yes.

24 MR. OH: We had a nice chat.

25 THE COURT: Good morning to you.

1 Thank you, all. So you are -- we're here for further
2 argument on the additional items that you've both briefed.
3 I've reviewed your briefing very carefully, and so during oral
4 argument, please don't feel the need to walk through it.

5 We are limited to an hour a side. I'll give you the
6 floor first, Mr. Oh. During that -- during your presentation,
7 I want you to briefly address the issue of the additional
8 declarations.

9 I understand -- Mr. Belfer, I understand you're
10 opposing it, but I don't think we have a written opposition
11 from you yet; right?

12 MR. BELFER: That's right. We didn't have time.

13 THE COURT: No. I understand. I wasn't faulting you,
14 but you can feel free to address it orally. I can tell you my
15 initial position.

16 I need -- to be honest, need a little more time to
17 review the declarations and so I can't say -- obviously, I
18 can't fault you for not having opposed them since I have not
19 managed to fully read them all, but my inclination would be to
20 allow them in and to give you -- you can think about the amount
21 of time you would want, if you want to file any opposition to
22 the substance of them.

23 I don't, upon my initial review, think that they're
24 going to move the needle in terms of resolving the preliminary
25 injunction substantially, but I'll give you an opportunity to

1 be heard on that.

2 In addition, I know that your briefing is not due
3 until tomorrow on whether or not ACIP is an advisory committee
4 or not, and I know this was not an issue that was briefed
5 before coming before me.

6 But you -- you saw the order that I issued on your
7 briefing. That issue I think is pretty central to at least how
8 this case is resolved on a preliminary fashion, and so I would
9 encourage you to address that as well.

10 With that, Mr. Oh, I'll give you the floor first. You
11 have an hour. So by way of planning, we will take a break at
12 10:10. Mr. Belfer, so you can put your thoughts together,
13 we'll take a break for 10 minutes, and then I'll hear from you.

14 MR. OH: Thank you, Your Honor.

15 Let me get my computer to start. So at the last
16 hearing, Your Honor --

17 THE COURT: Strong start.

18 MR. OH: Yes. And since brevity is the soul of wit
19 and tediousness the limbs and outward flourishes, I will be
20 brief. I will say I will try to be brief. That's from Hamlet
21 Act 2, Scene 2, Lines 90 to 92.

22 And, Your Honor, do you know what the next line is
23 after "I will be brief"?

24 THE COURT: I do not.

25 MR. OH: It is, "Your noble son is mad," and I'd like

1 the record to reflect that I am not referring to anyone in
2 particular in this case.

3 So I thought I'd start off with a presumption of
4 reviewability under the APA. As you know, it's a very narrow
5 exception. It is a strong presumption of reviewability.

6 And, essentially, the government's position in this
7 case is that Secretary Kennedy's actions cannot be reviewed.
8 That, I don't think, is the law, and it should not be the law.

9 And we did find a case that I think addressed one of
10 the questions you had last time around is -- is an agency
11 required to follow its own rules, not necessarily regulations
12 or law, but its own rules.

13 And *INS versus Yang*, 519 U.S. 26, an agency can limit
14 the scope of its own discretion, quote, by rule -- there's a
15 typo, sorry -- by rule or by subtle course of adjudication, a
16 general policy by which its exercise of discretion will be
17 governed, end of quote.

18 Once an agency so acts, quote, an irrational departure
19 from the policy, paren, as opposed to an avowed alteration of
20 it, closed paren, could constitute action that must be
21 overturned as arbitrary and capricious or an abuse of
22 discretion, end of quote, and I do not have the pinpoint cite
23 for you.

24 There are many different types of actions. Well,
25 actually, there aren't. There are a few types of actions that

1 are typically regarded as committed to agency discretion. This
2 is not one of them.

3 This isn't an enforcement -- a decision to enforce
4 something. This isn't a decision -- a pure judgment call on
5 how money should be spent.

6 And this case is very well grounded in many different
7 laws, and there are meaningful standards to be applied, and so
8 I think that we should readily overcome the presumption that --
9 or readily overcome the narrow exception to the presumption of
10 reviewability.

11 So before I get into the May directive, I thought I'd
12 take stock of where we are right now. So February 13th of
13 2026, when we were last here, that actually happened to be the
14 one-year anniversary of the date that Secretary Kennedy was
15 confirmed, so now we're about a year and two weeks after that.

16 And as you know, the last two elements of the
17 preliminary injunction standard, balance of equities and public
18 interest, they do kind of merge.

19 I kind of wish the First Circuit had more of a sliding
20 scale approach when looking at preliminary injunction motions,
21 because in this particular case, those two factors, balance of
22 equities and public interest, are so important, and the
23 evidence is so strong that the public interest is being
24 damaged.

25 And because I only have an hour, I wanted to make sure

1 I got this in because when you start talking about pretty
2 esoteric and arcane legal concepts under the Administrative
3 Procedure Act, arbitrary and capricious, committed to
4 discretion by law, we get into some of the facts, and you're
5 talking about membership balance plans and -- and the EtR
6 process, you can get down into the weeds and forget that in any
7 litigation, there's always a human element to a case, right.

8 And in this particular case, the human element to
9 this, you can easily lose sight of when you have some very
10 difficult kind of ambiguous standards to apply, and you can get
11 down in the weeds in the case law and forget or maybe just it's
12 not top of mind that there are real dramatic human interests at
13 stake here.

14 And so I just wanted -- I know you said you've read
15 the briefs, but I thought that the last two pages of our brief
16 captured this very well, and so I'm just going to read a couple
17 paragraphs from the last two pages of our brief, then I'm going
18 to move on.

19 This is on page 53 of ECF 184. It says page 60 of 64
20 on the ECF stamp. Quote, Courts have consistently held there's
21 a strong interest -- public interest in health and safety
22 citing the NIH case. More critically, there is no public
23 interest in the perpetuation of unlawful agency action and a
24 strong public interest in having governmental agencies abide by
25 the federal laws, citing cases.

1 That public interest is directly implicated here.
2 Plaintiffs have demonstrated that the defendants failure to
3 follow the customary evidence-based framework for vaccine
4 recommendations has destabilized America's public health
5 infrastructure and forced Plaintiff organizations, clinician
6 members, and patients into a state of confusion, uncertainty,
7 and perpetual crisis response mode.

8 By altering the CDC immunization schedule without ACIP
9 evidence-based review or through an improperly constituted
10 advisory committee, Defendants have replaced evidence-based
11 recommendations with unexplained departures that have sown
12 confusion and distrust among public health organizations,
13 medical associations, providers, and patients alike.

14 These disruptions materially increase the risk of
15 outbreaks of vaccine-preventable diseases including HepB and
16 RSV, and we should have added measles in there. Such harms
17 cannot be remedied after the fact.

18 The defendants here are not preventing public health
19 harm. They are creating it. Where unlawful government action
20 undermines disease-prevention systems and leaves public health
21 professionals unable to anticipate or contain outbreaks, the
22 public interest weighs decisively in favor of injunctive
23 relief. So after a year and a couple weeks of Secretary
24 Kennedy being in office, that is an accurate description of
25 where we are with regard to public health.

1 So now I'm going to go back to the beginning. I'll be
2 going through -- I won't be going through the January 5
3 schedule change, but I did want to put up this little timeline
4 here --

5 THE COURT: Okay.

6 MR. OH: -- just to demonstrate that there's been an
7 inconsistent use of process to change vaccine recommendations
8 over the past year.

9 You start with the secretarial directive, unilateral
10 decision, bypassing the ACIP, then fires the ACIP, and then
11 their first vote in June, which we -- you saw in our status
12 report we're withdrawing our question for preliminary relief on
13 the June vote, goes to the September ACIP vote to downgrade the
14 COVID-19 vaccine recommendation, then December 5 there's an
15 ACIP vote to remove the HepB birth dose recommendation, but it
16 flips back to a unilateral action through a decision memo very
17 similar to the original directive that started this all.

18 And it's interesting that when the government filed
19 their opposition late on Friday night, I saw that it was filed.
20 It was a little bit too late for me to -- like, oh, I'm going
21 to read this tomorrow.

22 And then lo and behold, there are these two decision
23 memos dated May 12th of 2025 that we hadn't seen before, didn't
24 know if anything existed to support the May directive, and it's
25 interesting to note that the play there, I think, served as the

1 playbook for the decision memo, because, as you recall with the
2 childhood schedule of January 5, they supported it through a --
3 an assessment by Martin Kulldorff and Tracy Beth Hoeg to
4 justify the change to the schedule, and then they changed the
5 schedule.

6 One week before the directive is dated, apparently,
7 the secretary got memos from FDA and NIH and then from FDA to
8 justify the changes that they made to the COVID recommendations
9 through the directive.

10 In my view, it looks like there was a conclusion
11 reached, and then they said draft us some memos that will
12 support that conclusion.

13 So Plaintiffs believe that we are likely to succeed on
14 the merits on the May 19 secretarial directive, and I'm going
15 to run through the case law and the standards set forth in the
16 case law. And, first, they failed to engage in reasoned
17 decision-making by failing to follow the ACIP process.

18 Now, I've already played this May 27th video for you.
19 Do you want to see it again, Your Honor, or just skip it?

20 THE COURT: I remember it.

21 MR. OH: Okay. Oh, sorry.

22 THE COURT: But it's your time, I mean.

23 MR. OH: It's only 58 seconds long.

24 So this is the directive dated May 19th, 2025, that is
25 the decision that instructs the CDC to remove the

1 recommendations on COVID regarding pregnant women and children.

2 And so when we first saw this directive, if you look
3 at the third paragraph on the bottom, "based on a review of the
4 recommendation of the FDA and National Institutes of Health,"
5 and then the next paragraph is based on a review of the
6 recommendation of the FDA, you know, we thought that, oh, it
7 must have been Doctors Makary and Bhattacharya advising the
8 secretary.

9 And then because on the second one it said only the
10 FDA, we thought, oh, maybe Bhattacharya doesn't agree with
11 the -- with the recommendation with regard to pregnant women,
12 but it turns out that there were -- apparently, that was a
13 reference to these two memos.

14 So I just note that in our first CMC in this case well
15 before you may have even known about this case existing, there
16 was one action being challenged then. It was the May
17 directive.

18 And Judge Young said, I wouldn't think that the
19 administrative record in support of that changed recommendation
20 is extensive or hard to ferret out. I'm a little bit surprised
21 that we got these memos the Friday before the -- this PI
22 hearing.

23 And to address the motion for leave, I mean, we
24 scrambled over the weekend and found three declarants who know
25 the process, two of whom were involved in the process last

1 year, Dr. Fiona Havers, who gave her presentation at the ACIP
2 meeting in April, and Dr. Goldman who was on the COVID-19 work
3 group. Neither of them had seen these memos before. And
4 Dr. Jose Romero, a former ACIP chair, when he saw these memos,
5 he was like, this is highly irregular.

6 So the irregularity of the process they followed here
7 can be shown just by looking at the memorandum of -- the
8 caption of the memorandum.

9 So there's Tracy Beth Hoeg who had been at FDA for all
10 of a month by then. She was initially hired as a special
11 consultant, and then for some reason, she's been, kind of,
12 working her way up.

13 And she gave a memo about the safety issues allegedly
14 with the COVID-19 vaccine for pregnant women. She, at this
15 particular time, I believe, was still a consultant in the FDA.

16 And then there's a memo from two individuals, one from
17 NIH, one from FDA, regarding the recommendation for children
18 less than 18 years of age.

19 That in and of itself shows arbitrariness and
20 capriciousness. It does not follow the well-accepted process
21 of how you make changes to recommendations to the CDC schedule.

22 So the declarations that we were able to procure since
23 Saturday, so Dr. Fiona Havers, she resigned on June 16th
24 because she could, quote, no longer continue with the health
25 secretary Robert F. Kennedy, Jr. -- while the health secretary

1 Robert F. Kennedy, Jr., dismantled the careful processes that
2 helped formulate vaccination standards in the U.S. She's been
3 at the CDC for 13 years, up to that point very involved with
4 the ACIP, and she didn't know about the memos, and she is
5 confident that no career CDC officials knew about these memos
6 until well after the fact.

7 Dr. Goldman had been on the COVID-19 work group since
8 inception. He never saw, received, discussed, or was informed
9 of these memos.

10 And the former ACIP chair finds these memos to be,
11 quote, highly irregular, inappropriate, and a striking
12 departure from the procedure that had been uniformly followed
13 for decades.

14 No mention at all of the ACIP in these memos. No
15 explanation at all for anyone as to why the ACIP process was
16 bypassed.

17 And the ACIP process, it provides a structured,
18 transparent, evidence-based review process for engaging in a
19 reasoned evaluation of the relevant factors.

20 And that process is what these doctors and the 67,000
21 other members of the AAP have relied on for years. It has been
22 a transparent process. It's been open. It has been credible.
23 It's been thoughtful, and it's been a process followed in good
24 faith.

25 And given explanation, this is not just, we don't like

1 the government's policies; this is, we don't like that you are
2 leaving us in the dark; you're not being transparent; you're
3 not explaining, as you're supposed to do under the law, why you
4 are jettisoning and departing from a process that we have all
5 around this country grown to know and trust. They failed to
6 provide a satisfactory explanation.

7 In the video, the secretary makes the conclusory
8 assertion that healthy kids and healthy pregnant women don't
9 need the COVID vaccine.

10 Question, how do you define who's a healthy kid and a
11 healthy pregnant woman? Does that mean zero underlying
12 conditions? Does that mean one? Does that mean that when you
13 get the COVID vaccine, you shouldn't have the flu?

14 This is -- it's simply a conclusory, unsupported
15 assertion that they don't need it. It's like, hey, I am the
16 secretary of Health and Human Services, trust me, but that is
17 not the way that -- and the process by which vaccine
18 recommendations have been or should be made in this country.

19 And so the explanation fails under the APA because
20 it's merely conclusory. *Association of American Universities*
21 *versus Department of Defense*, 792 F. Supp. 3rd 143, and the NIH
22 case 770 F. Supp. 3rd. 277 support that proposition.

23 Now, if we had played the video, you would have heard
24 the secretary say, there's a lack of any clinical -- he says,
25 "lack of any clinical data to support the repeat booster

1 strategy in children."

2 Dr. Makary says in that video, "There's no evidence
3 that healthy kids need it today," and Dr. Bhattacharya says,
4 "It's good science."

5 All three of those are false and misleading statements
6 that was disseminated through social media to the world to
7 see -- for the world to see.

8 The problem with those statements is that just a month
9 before at the April 15, 2025, ACIP meeting, Dr. Fiona Havers
10 gave a presentation, and we attached her presentation to her
11 declaration. It's a little bit mind-numbing if you try to read
12 it but -- and understand it because there's a lot of medical
13 jargon in there, and there's a lot of data.

14 And she concluded -- and if you got a chance to even
15 glance through Dr. Havers' declaration, I went to the YouTube
16 video of the ACIP meeting, and I put the link into her
17 declaration, and I pulled this exact quote from what she said
18 at the ACIP meeting. Okay.

19 And it is set forth in her declaration at
20 paragraph 11, and in that is also the time -- exact time at the
21 meeting where she said this if you wanted to verify it, and
22 believe me, I double-checked this.

23 So she said, quote, So in summary for pediatrics,
24 rates of COVID-19 hospitalizations are highest among the
25 youngest-aged groups. Although, among school-aged children,

1 hospitalization rates are -- I'm sorry -- are generally -- have
2 been higher for influenza than for COVID-19. More than half of
3 children and adolescents hospitalized with COVID-19 had more
4 than one underlying condition, and this increased with
5 increasing age, but a substantial proportion of children had no
6 underlying medical conditions. And the most common underlying
7 conditions also varied by age groups.

8 And, again, as we saw, the vast majority of children
9 who were hospitalized with COVID had not received the most
10 recently recommended COVID-19 vaccine during the 2023/'24
11 season.

12 And then -- Dr. Robert Schechter actually presented
13 before her, and then Dr. Ruth Link-Gelles presented after her.
14 And Link-Gelles is L-I-N-K, hyphen, G-E-L-L-E-S. And this next
15 name is a mouthful. I don't know if I'll pronounce it
16 correctly, but I'll give you the spelling, and then Dr. Lakshmi
17 Panagiotakopoulos -- Lakshmi is L-A-K-S-H-M-I, and
18 Panagiotakopoulos is P-A-N-A-G-I-O-T-A-K-O-P-O-U-L-O-S.

19 And they presented data with regard to vaccine
20 effectiveness and deaths among children ages zero to 17, and
21 they differentiated from zero to 17. I think there's a little
22 bit of a difference between children who are zero to six
23 months, and zero to two, and someone who's 17.

24 One thing when you look at the Memoli/Brenner memo,
25 they sweep everyone together. It's everyone 17 and under.

1 There's no differentiation between the different ages and the
2 different age cohorts between zero and 17.

3 And then inexplicably also just the week before the
4 May 19th directive, Dr. Makary and then Dr. Prasad, who is now
5 the director of what they call CBER, all caps, CBER, the Center
6 of Biologics and Evaluation of Research, stated in their
7 article that pregnancy and recent pregnancy are factors which
8 increase a person's risk of severe COVID-19.

9 How Dr. Makary could then go appear on a video that's
10 put out a couple weeks later to say that -- well, he was
11 referring to children, but the message that comes across is
12 there's no evidence to support these recommendations, and then,
13 again, the secretary said, there's a lack of any clinical data
14 when there was a wealth of data that was presented just a month
15 before.

16 Not getting into intent now, but it's, like, oh, maybe
17 they saw what's happening at the ACIP. He knew what he wanted
18 to do, and so, oh, I'm not going to get what I need so I'm
19 going to bypass them and get rid of this COVID-19
20 recommendation.

21 It's -- it's inexplicable. It's unexplained. It's
22 contrary to the data that was presented, and that -- this is a
23 quintessential example of arbitrariness and capriciousness.

24 But then to put it in case law jargon, quote, The
25 evidence tells a story that does not match the explanation the

1 secretary gave for his decision, end of quote. That's
2 *Department of Commerce versus New York*, 588 U.S. 752 at 784.

3 And the *State Farm* case, I think, and *Department of*
4 *Commerce versus New York* are two of the more applicable,
5 relevant cases to this particular case, Your Honor.

6 And the thing about *State Farm* is that, like here, it
7 involved a rescission and taking away of what you could call a
8 safety rule.

9 And in that decision, the Court found the decision to
10 remove the requirement of automatic seat belts, that they were
11 too quick to dismiss the safety benefits of it, and their
12 reported assessments were far too quick to dismiss the safety
13 efficacy and public health benefits, like here of the COVID
14 vaccine for children and pregnant women.

15 I think *State Farm* and *Department of Commerce* really
16 are controlling, and they provide this Court, I think, with a
17 means to justify a decision in the Plaintiff's favor that can
18 withstand scrutiny on appeal.

19 They fail to take into account serious reliance
20 interests, and that is one of the huge, huge parts of this
21 case. Because, as you know, the ACIP, unlike the United States
22 Preventive Services Task Force, has not been statutorily
23 legislated into existence.

24 The ACIP was formed in 1964 by the Surgeon General.
25 In 1972, it became a federal advisory committee when the

1 Federal Advisory Committee Act was passed. And then as we went
2 through on the 13th, Congress incorporated reliance on ACIP
3 recommendations as adopted or not by the CDC director into 13
4 different laws.

5 And we also went back and looked at how many different
6 sets of regulations are the ACIP incorporated into. There are
7 at least 17 sets of regulations. I think around 14 of them are
8 HHS regulations, but the DOD has a regulation, as does the
9 immigration nationalization service that incorporates reference
10 to and reliance on CDC recommendations, but that's just in
11 statute and regulation.

12 But when you look at the real world, you've got people
13 like Dr. Pring, the president of the Massachusetts Chapter of
14 American Academy of Pediatrics, who is often in scrubs when
15 we're on calls at the hospital, and she and other doctors, we
16 have learned, are -- when a patient comes in with a question,
17 sometimes the best thing to do and the quickest way to try to
18 get an answer is to go to the CDC website and see what it says
19 about an immunization. That's how it works out there. That's
20 how when a pharmacist gets a question from a customer at the
21 counter and they don't know necessarily how to answer it, they
22 go to the CDC website.

23 And that trust has been built into the entire system
24 in every corner of this country, and contrary to their -- the
25 mantra, oh, we're trying to restore trust; we're trying to

1 restore trust, well, maybe one way to look at that is, did you
2 actually take a look at whether or not on an action -- a
3 unilateral action by the secretary is going to increase or
4 decrease trust in the health care system before you -- before
5 you go there? They didn't do that.

6 So the directive itself is, like I said, we believe, a
7 just very clear -- I know Mr. Belfer is going to dispute me --
8 but almost indisputable example of a decision that is
9 unexplained, inconsistent, and didn't take into account
10 reliance interest.

11 Now, if I segue into the constitution of the ACIP,
12 that's when we could be getting into *Braidwood*-related
13 questions, and -- but also, as you've recognized, if you agree
14 that the ACIP was improperly constituted and that we have a
15 likelihood of success on the merits on that particular issue,
16 then one potential remedy is that the votes that they took, the
17 actions that they took by a tainted advisory committee should
18 be set aside, so then that's one fairly straightforward way to
19 set aside ill-advised votes that they took without delving into
20 the finer details.

21 We talked about membership balance plans last time
22 around.

23 THE COURT: We did. We spent a long time on that, but
24 I would like to hear more about how I'm supposed to distinguish
25 this under *Braidwood*.

1 MR. OH: So I'm going to start -- but if you don't
2 mind, we might do a little tag team and --

3 THE COURT: Sure.

4 MR. OH: -- I might have Mr. Hughes jump in here,
5 so --

6 THE COURT: Because I do think that -- I understand
7 why FACA is the easiest solution for you and why -- because I
8 think you're right, right. If there's a FACA violation, then
9 everything that the ACIP did falls away, but I'm struggling
10 with how to square that with what the Supreme Court said in
11 *Braidwood*.

12 MR. OH: So I think one pretty simple way to address
13 *Braidwood* is that it doesn't apply here. It's not relevant in
14 that one huge -- a couple huge distinguishing factors.

15 One is that when Congress legislatively put the task
16 force into existence through statute, okay, it actually
17 specifically exempted the USPSTF from FACA. There is a
18 specific statutory provision that says that this task force is
19 not a federal advisory committee.

20 A second way to distinguish it is -- and we can get
21 into this some more, the ACIP charter itself says that we are a
22 federal advisory committee subject to FACA.

23 And you're a former trial lawyer. You know that when
24 someone puts their signature on a document, that is like an
25 admission against interests under the Federal Rules of

1 Evidence, 801(d)(2), right.

2 And Secretary Kennedy renewed the charter on
3 December 3rd of 2025. His signature is there in blue for
4 everyone to see, and the only changes he made to this new
5 charter were to add the words "vice chair" in there a couple
6 times, and there was maybe one more. Everything else stayed
7 the same.

8 THE COURT: Okay.

9 MR. OH: So the secretary himself acknowledged on
10 December 3rd, 2025, that the ACIP is a federal advisory
11 committee subject to FACA.

12 If you want to go a little bit more into the weeds on
13 *Braidwood*, then I might need to turn it over to Mr. Hughes.

14 THE COURT: I'd love to hear what Mr. Hughes has to
15 say because I've spent a lot of time on this issue.

16 MR. HUGHES: Thank you, Your Honor.

17 THE COURT: And I recognize I'm at a disadvantage
18 since your briefing's not due yet, so I haven't had the
19 opportunity to review what you are doubtless preparing.

20 MR. HUGHES: Of course. And we will submit the
21 supplemental brief tonight or tomorrow.

22 I teach a very niche law seminar actually on these
23 committees, and so I can walk through it a little bit. They do
24 bear some similarities, so they're -- obviously, both of these
25 bodies are making evidence-based recommendations, and, of

1 course, the Affordable Care Act does reference both of those
2 bodies in the recommendations, but that's really where the
3 similarities end. So the ACIP is a purely advisory committee,
4 and *Braidwood* does not alter its status as an advisory
5 committee.

6 As Mr. Oh said, the task force was established by a
7 very specific statute. That statute does not reference the
8 task forces having advisory responsibilities.

9 The ACIP, on the other hand, was created under this
10 general authority under 217(a) (a) to create discretionary
11 advisory committees and councils. That same statute at
12 217(a) (c) says that the secretary can delegate functions to
13 those commitments which includes ACIP.

14 There are multiple statutes, and we've referenced many
15 of them, that recognize that ACIP recommendations are not
16 binding without further action by a politically accountable
17 official, specifically the CDC director.

18 THE COURT: Right.

19 MR. HUGHES: That includes the ACA. That includes the
20 Medicaid statute, the Vaccines for Children Program, the
21 Veterans Health Administration, and some others.

22 As Mr. Oh said, Congress did explicitly exempt the
23 task force from FACA. It did that in the ACA. It had the
24 wherewithal as it was adopting the preventive services coverage
25 requirement to exclude -- to exempt the task force from FACA.

1 It did not do that with respect to the task force, and, of
2 course, we can't read that silence to mean that it applies to
3 the ACIP. We'll provide further detail on that in our brief,
4 but we have to presume that they were purposeful in making that
5 choice.

6 Under FACA --

7 THE COURT: Can I just pause --

8 MR. HUGHES: Yes.

9 THE COURT: -- you for one second?

10 MR. HUGHES: Yes.

11 THE COURT: I'm going to give you a full chance, but
12 is your position that FACA applies? Just so I understand
13 whether -- because you didn't brief this either. This is --
14 just briefly and then I'll give you your time. Does FACA apply
15 to the ACIP?

16 MR. BELFER: Yes, it does.

17 THE COURT: Okay. Great. Thank you. That was the
18 one, sort of, wrinkle that I was like -- I recognize that might
19 be -- okay.

20 MR. OH: Does that mean he can sit down?

21 THE COURT: No. Well, unfortunately -- unfortunately,
22 I am required to make that conclusion on my own, but I
23 appreciate that, so, no, please continue.

24 MR. HUGHES: Thank you for that. I do want to make
25 sure that we're clear on what Justice Kavanaugh did in the

1 decision, and I think we will address that in detail in the
2 supplemental brief.

3 But, you know, just to be clear, under FACA, ACIP is
4 an advisory committee, and I think we've heard that, so the
5 committee is not the final decider. It's not operational, so
6 FACA applies.

7 And as Mr. Oh said, ACIP's always operated consistent
8 with FACA. It has a designated federal officer. It renews its
9 charter every year. It references FACA. The secretary just
10 signed the renewed charter. It publishes all of its meetings,
11 notices, and materials consistent with FACA.

12 *Braidwood* does not alter FACA's application to ACIP,
13 and this is really where the differences become apparent, so
14 the District Court in *Braidwood* actually disposed of the
15 appointments clause question with respect to ACIP, and he found
16 no appointments clause problem.

17 So he -- when he went through and distinguished each
18 of these bodies, he, you know, pointed out that the CDC
19 director must adopt the ACIP's recommendations, and he
20 observed -- he said, you know, there's no ACA language that
21 actually alters the background authority -- the advisory role
22 of the ACIP, and so --

23 THE COURT: What if there is -- well, the secretary
24 could or they could change the regulation to say that the
25 secretary doesn't have to approve it; right?

1 MR. HUGHES: They could, but they couldn't change the
2 statute that sits above that regulation. And Justice Kavanaugh
3 did not address that statute -- that specific part of the
4 statute, and this is 300gg-13.

5 THE COURT: Okay.

6 MR. HUGHES: And that is (a)(1) and 2 so under (a)(1)
7 and 2, 1 is the task force, 2 is the CDC. 1 says the United
8 States Preventive Services Task Force. 2 says the Advisory
9 Committee on Immunization Practices of the Centers for Disease
10 Control and Prevention. So it is very clear that the committee
11 is subordinate to the CDC, and so --

12 THE COURT: What if the CDC got rid of the regulation
13 that said the secretary has to approve?

14 MR. HUGHES: The statute actually has that language in
15 it, so --

16 THE COURT: You don't think -- so the secretary
17 couldn't.

18 MR. HUGHES: The secretary -- I think so. I mean, I
19 think the statute specifically references the CDC director, but
20 I don't think you can get around the fact that the statute
21 makes the ACIP a part of CDC.

22 THE COURT: I see. Okay.

23 MR. HUGHES: I think that --

24 THE COURT: That's great.

25 MR. HUGHES: -- solves it. Great.

1 THE COURT: Thank you very much, Mr. Hughes.

2 MR. HUGHES: Thank you.

3 MR. OH: So with regard to the way the ACIP was
4 constituted, our complaint and our brief focuses on it not
5 being in accordance with law.

6 And so what is the law that says that you need -- at
7 least back in 2025 before they amended the reg, what is the law
8 that they needed to require -- that they needed to follow in
9 terms of constituting the ACIP?

10 And there is a guidance that was issued by the GSA
11 which manages all of the federal advisory committees. You're
12 supposed to follow your charter and your membership balance
13 plan with them. There is a database that contains the
14 membership balance plans and the guidance which -- may I --

15 THE COURT: Sure.

16 MR. OH: -- approach? And I actually have a copy this
17 time for Mr. Belfer.

18 THE COURT: Is this something I've seen before, or are
19 you giving me something new?

20 MR. OH: I don't think so.

21 THE COURT: Okay.

22 MR. OH: So if you look at the second paragraph under
23 the introduction, this corresponding FACA final rule reiterates
24 this requirement at 41 CFR, Section 102-3.30(c) and for
25 discretionary -- I'm skipping the parenthetical -- and for

1 discretionary advisory committees being established, renewed,
2 reestablished, or merged requires agencies to provide a
3 description of their plan to attain fairly balanced membership
4 during the charter consultation process with the committee
5 management secretariat citing 41 CFR, Section 102-3.60 (b) (3) .

6 And this is the candidate identification process that
7 is in the last membership balance plan that is in the FACA
8 database, and that's from January of 2024.

9 THE COURT: This is also the one we know is not valid
10 anymore; right?

11 MR. OH: Pardon me?

12 THE COURT: We know that this is not valid anymore;
13 right?

14 MR. OH: It depends on what you mean by "valid," Your
15 Honor. In that, it was -- it's valid for application in 2025
16 but not for -- it doesn't have effect now in '26.

17 THE COURT: Right. I just want to make sure we're
18 talking about the same thing for your presentation.

19 MR. OH: This candidate identification process, which
20 I do not need to go through entirely, identifies the process
21 intended to be used to identify candidates for the federal
22 advisory committee, and the summary is supposed to describe the
23 process, et cetera, et cetera.

24 And then with regard to the ACIP secretariat,
25 procedures for application for ACIP membership are detailed on

1 the website; solicitation of potential candidates is conducted
2 by e-mail; solicitation of potential candidates is posted
3 annually in the Federal Register.

4 So this is another section of the ACIP membership
5 balance plan of 2024 which identifies criteria for selection,
6 expertise in the field of immunization practices,
7 multidisciplinary expertise in public health, expertise in the
8 use of vaccines and immunologic agents, knowledge of vaccine
9 development, evaluation, safety, and delivery, or in the case
10 of a consumer representative, knowledge about consumer
11 perspectives and/or social and community aspects of
12 immunization programs.

13 Now, we went back, and we identified all the MBPs that
14 are in the database. I think there's a gap during the pandemic
15 from '20 to '24, but consistently over the last 10 to 12 years,
16 the ACIP has been doing membership balance plans, filing them
17 in the FACA database, quite frankly, following the law.

18 And then Dr. Romero was able to find some documents
19 when he was chair of the ACIP. You had asked us: Does the
20 steering committee really exist?

21 THE COURT: Right.

22 MR. OH: And so this is a meeting of the steering
23 committee. It doesn't say that, but it is the steering
24 committee where on August 24th of 2017 -- and this is a
25 document that is attached to Dr. Romero's declaration, this

1 document shows that they're going to be meeting to review the
2 candidacies to replace these four individuals and these areas
3 of specialty or expertise.

4 And then -- this isn't the entire document, but that
5 last paragraph on your screen, "Following our usual practice,
6 we will aim to select candidates whose area of expertise,
7 specialty, board certification is similar to that of the
8 outgoing members." So this is adherence to a practice,
9 adherence to a process, a time-honored process for selecting
10 nominees.

11 And so the way it actually -- there's a fair amount of
12 legwork done before this meeting. They actually have a
13 spreadsheet, and I think I attached an example to Dr. Romero's
14 declaration as well.

15 And there's a principal reviewer, a secondary
16 reviewer, and their job is to come up with a nomination package
17 to send upstairs to the secretary for a primary and secondary
18 candidate for this position.

19 So the secretary decides for each open position
20 between two of the nominees. Now, he doesn't have to select
21 those two. Dr. Romero gave me an example of one time where the
22 secretary may have gone to the third choice, but -- and then --

23 THE COURT: The question was whether or not the
24 steering committee existed when -- has existed during the
25 period when the existing members were appointed.

1 MR. OH: Which existed? The current ones?

2 THE COURT: Yes.

3 MR. OH: I -- we have no knowledge that the steering
4 committee was ever convened to discuss candidates.

5 THE COURT: Right. Okay. I remember that came up
6 last time, and I didn't think we had an answer on it.

7 MR. OH: I'd be very surprised if there's any document
8 produced in the administrative record that demonstrates that
9 the ACIP chair sat down with the ACIP executive secretary and
10 the vice chair and put together a nomination package and then
11 others and then sent it up to the secretary.

12 THE COURT: Okay.

13 MR. OH: So these were ACIP steering committee
14 meetings where, as you can see, pretty regularly in August,
15 they had their meeting to select nominees.

16 And then as you saw in the membership balance plan,
17 you post a notice in the Federal Register to solicit
18 nominations.

19 And so we went back and over the last 20 years, these
20 are all the notices posted, and I can perhaps, for your clerks,
21 get you this -- copies of these two pages if you're interested.

22 THE COURT: Sure. Why don't you just submit the whole
23 PowerPoint.

24 MR. OH: I will. Okay. I'll take out the notes.

25 THE COURT: Yes. Please submit just the PowerPoint as

1 presented today.

2 MR. OH: Yes. Yes.

3 And so the last notice published in the Federal
4 Register soliciting nominations was from July 18th of 2024, so
5 failing to follow the process.

6 And I've been told I have a 10-minute warning. I will
7 not speak faster, though.

8 THE COURT: But let me interrupt with a question
9 that's maybe not directly on point. There was a similar case
10 that was filed in the -- I think in the Northern District of
11 California.

12 MR. OH: Yes.

13 THE COURT: Do you have any insight about what's
14 happening in that case and how it may or may not impact this
15 one?

16 MR. OH: I do.

17 THE COURT: Feel free to share.

18 MR. OH: I was answering the question I was asked,
19 Your Honor.

20 So 15 states led by -- really by Arizona and
21 California have filed. I think that they contemplated filing
22 here, but then Massachusetts decided not to join, and since
23 Arizona and California were in the lead, they figured that they
24 would stay closer to home and file there.

25 Their concerns, while similar, ultimately -- like,

1 remedy is -- that they seek is different because they are suing
2 on behalf really of the public health systems in their
3 states --

4 THE COURT: Right.

5 MR. OH: -- and the Medicaid funding.

6 And so their action, I think, it kind of mirrors ours
7 in terms of the legal theories under the APA, but their
8 interests and injunctive relief they're going to be seeking are
9 slightly different.

10 THE COURT: Okay. Thank you.

11 MR. OH: Okay. So the September -- I thought that we
12 had delineated how each particular agency action in and of
13 itself standing alone caused injury, and for purposes of
14 briefing, we did put them together under the ACIP process,
15 non-ACIP process, but there has been injury independently
16 flowing from each of these actions, and also, the September and
17 December '25 actions, because they are both ACIP votes, they
18 can be at least analyzed together for purposes of liability
19 here.

20 And there's a failure to engage in reasoned
21 decision-making with regard to both of these actions; didn't
22 follow GRADE, EtR; didn't consult the COVID work group.

23 And this is -- one of the big problems is that when
24 there has been a change to SCDM or when the advisory committee
25 initially says, we're going to recommend this as shared

1 clinical decision-making, they've published guidance on what
2 are the things you should talk about when you're engaged in
3 this type of a conversation, and that has not been provided,
4 which then leads to confusion and disruption, and so it is
5 causing irreparable harm now and it continues to multiply and
6 escalate.

7 We went through the HepB action last time around, and
8 it, quite frankly, in a way gets folded into the January 5
9 schedule change.

10 THE COURT: Right.

11 MR. OH: So this unexplained consistency --
12 inconsistency in how they went about making this -- those two
13 votes without going through what had been the process, without
14 publishing guidance, that's an APA violation.

15 And, again, there's just so many things that they just
16 swept aside, didn't consider, which I think if -- that a
17 functioning ACIP that is being consistent with its objective
18 and mission would be doing, and they did not do that, no new
19 data or studies.

20 And then there is just one point worth emphasizing.
21 This strategy that they adopted, risk-based for HepB, it failed
22 back in the '80s. Why they're reverting back to that is beyond
23 me.

24 And I'm a little bit at a loss on how the government
25 can argue that Plaintiffs have no reliance interest because,

1 yes, vaccine recommendations can change, sure, but the reliance
2 interest has been on a transparent, legitimate, structured
3 evidence-based process.

4 So I was a little bit concerned last time around when
5 you made the comment about how usually economic harm does not
6 warrant preliminary injunctive relief.

7 But in a case where there's sovereign immunity, in a
8 case where economic damages aren't recoverable, that's where
9 economic harm qualifies as irreparable harm in APA cases,
10 citing these cases, you'll have them now when I submit the
11 PowerPoint.

12 And I think one of the best cases --

13 THE COURT: Is that *California v. Kennedy* case -- I
14 don't remember you -- is that discussed in your brief?

15 Am I just not remembering it?

16 MR. OH: And if it isn't, our oversight.

17 THE COURT: No. No. I -- there's a lot of briefing
18 on this. I very well could have missed it. If you're going to
19 submit the PowerPoint --

20 MR. OH: Yes.

21 THE COURT: -- I'll look it up from there.

22 MR. OH: So when you are forcing pediatric practices
23 in Crossville, Tennessee, to either -- or in Mount Clemens,
24 Michigan, to either hire additional staff, set aside one person
25 just to engage in shared clinical decision-making, you take up

1 the time and you add up the time through the course of a week,
2 a month that goes uncompensated, the restructuring of their
3 whole workflow, did they consider the impact on specific
4 practices that a shared clinical decision-making recommendation
5 would lead to? There's no evidence of that.

6 And the ripple effects that come from an ACIP
7 recommendation approved by the CDC, it's immediate. And --
8 okay, yes, we did cite *California versus Kennedy* on page 46 of
9 our brief.

10 And then, also, in this particular case, especially
11 harm to the public is irreparable harm. And these cases here
12 stand and support that proposition.

13 So in terms of a correct legal standard to apply on
14 irreparable harm, can you make a finding that economic harm in
15 a case like this is sufficient to demonstrate irreparable harm?
16 Yes. Can you consider harm to the public as irreparable harm?
17 Yes.

18 And so two other -- so since you are going to be -- it
19 appears to be granting the motion for leave to file these
20 supplemental declarations, what we did since -- well, over the
21 weekend, again, was to go through all of the declarations and
22 we've created a summary chart of declarant, ECF number, and
23 then the particular quotes from their declarations specific to
24 each agency action, the May '25 action, the September '25 vote,
25 the December vote, and how each of those individually have

1 caused harm.

2 And I don't need to go -- I'm -- we submitted many
3 declarations in this case, but, you know, we're the plaintiffs.
4 We've got the burden, and so we need to -- and just because of
5 the urgency of this, we wanted to provide you with as
6 up-to-date possible evidence and facts for you to make a good
7 decision, so we have -- we put in these new declarations and --
8 but it's a lot to wade through. I know. And you've -- I think
9 this is not your only case.

10 THE COURT: It is not.

11 So the summary exhibits, do you want to walk me
12 through them now, or you want to say -- you want permission to
13 submit them?

14 MR. OH: I would like permission to submit them, Your
15 Honor.

16 THE COURT: Do you have any objection to him --

17 MR. OH: I'll show them to him.

18 MR. BELFER: We've never seen any of this.

19 THE COURT: Share them with Mr. Belfer. Mr. Belfer,
20 I'll give you a chance to look at them. I'm going to give you
21 a chance to respond to their declarations. Today's Wednesday.
22 What is the -- the day we scheduled the ACIP meeting is the
23 23rd; is that correct?

24 MR. OH: March 18th and 19th.

25 THE COURT: Okay. So I have sort of a -- I have a

1 hard deadline myself. Why don't I say you provide that to
2 Mr. -- you have it right now, you can provide it to him right
3 now.

4 MR. OH: Let the record reflect I'm handing a copy of
5 the exhibit.

6 THE COURT: And you'll e-mail him an electronic copy,
7 so he can --

8 MR. OH: Yes, that we would like to submit to the
9 Court.

10 THE COURT: Give it to the government. Give
11 Mr. Belfer an opportunity to object to it. Mr. Belfer, if you
12 don't object to it, let him know. He can file it on the docket
13 by the end of the day.

14 If you want to object to it, I'll give you until
15 Monday to object to both of this and anything you want to
16 submit in response to the declarations. That gives you -- that
17 doesn't give you an enormous amount of time, but we're under a
18 very tight timeline here.

19 So if you have no objection, tell Mr. Oh. He can
20 submit that summary chart today. If you do have an objection,
21 you can make it along with supplying anything you want to
22 supply in response to the declarations no later than Monday at
23 5 o'clock. Does that -- am I giving you enough time to pull
24 that off?

25 MR. BELFER: Sure. Thank you.

1 MR. OH: So speaking of the next meeting, this is the
2 last subject, then I'll be done.

3 THE COURT: Okay.

4 MR. OH: So I think it's a good thing to compare what
5 they plan on talking about as announced in the Federal Register
6 versus the last, what we would say, fulsome ACIP meeting that
7 occurred was on April 15th of 2025. We've already talked about
8 that meeting where Dr. Havers, Schechter, Link-Gelles, and
9 Panagiotakopoulos presented data on COVID.

10 And so a Federal Register notice was published very
11 recently, and it said, "The agenda will include updates on ACIP
12 work groups and discussions on COVID-19 vaccine injuries and
13 long COVID and ACIP recommendation methodology. Recommendation
14 votes may be scheduled for COVID-19 vaccine injuries and long
15 COVID and ACIP recommendation methodology."

16 One thing very striking about what they say is on the
17 agenda is what's missing. There's a big measles outbreak in
18 South Carolina right now. Why aren't they going to be talking
19 about that?

20 Isn't that the job of the -- one thing that the ACIP
21 can do, is they are supposed to be providing guidance to the
22 CDC director to control and prevent communicable diseases, and
23 they're not going to be talking about measles.

24 But then when you look at the agenda from a year ago,
25 it's a very, very specific and substantive agenda to talk about

1 presentation on immunogenicity of the Mpox vaccine to the
2 epidemiology and risk factors for COVID-19 hospitalizations
3 vaccine effectiveness, the CMV, cytomegalovirus, vaccines -- I
4 have no idea what that is -- CMV vaccine safety.

5 And here's the second day of that meeting, the agenda,
6 they're actually talking about vaccines. They're talking about
7 risks and benefits of vaccines.

8 At this next meeting, it looks like all they're going
9 to be talking about are risks and injury and how vaccines can
10 hurt you.

11 That is inconsistent with the mission and objective of
12 the ACIP. That is the recipe for spreading more distrust and,
13 dare I say, misinformation or disinformation about vaccines.

14 And it is entirely inconsistent with the charter,
15 which Secretary Kennedy himself signed on December 3rd, where
16 they are supposed to be advising on circumstances in which a
17 vaccine or related agent is recommended. They're supposed to
18 deliberate on the use of vaccines to control disease in the
19 U.S.

20 So this next meeting and the agenda that they have
21 posted is entirely inconsistent with what the ACIP charter says
22 they should be doing.

23 So for purposes of enjoining that next meeting, I
24 think there are sufficient grounds; there's a meaningful
25 standard for you to apply to justifiably enjoin that next

1 meeting from occurring.

2 So, like I said, their focus is all on harm. There's
3 no agenda item on benefits for this next meeting.

4 So thank you for letting me go over about six or seven
5 minutes.

6 THE COURT: Sure.

7 MR. OH: I know that you -- if you give me any
8 rebuttal, it will be just a little bit of time.

9 THE COURT: I'll give you five minutes of rebuttal.
10 We're going to take a 10-minute break. We'll come back at
11 10:25.

12 Mr. Belfer, I don't need you to spend a lot of your --
13 if you say Mr. Hughes got it all right, you needn't spend a lot
14 of time on that issue. Thank you.

15 THE CLERK: All rise.

16 (The Honorable Court exited.)

17 (Brief break from 10:17 a.m. to 10:33 a.m.)

18 THE CLERK: All rise.

19 (The Honorable Court entered.)

20 THE CLERK: Please be seated.

21 THE COURT: Thank you, all.

22 Mr. Belfer, you have the floor.

23 MR. BELFER: Thank you, Your Honor.

24 So with regard to the new declarations, we do oppose
25 those, and we'll file a response by Monday.

1 THE COURT: Okay. And if -- you're welcome to file a
2 response by Monday, but also if you, in the alternative, want
3 to file something in opposition to them, feel free to include
4 that too.

5 I don't know what your thinking on that is and maybe
6 you haven't read every page of 450 pages either, so go ahead
7 and file your opposition. I will look at your opposition.

8 If you also want to file something that says -- in
9 response, I would like to file X, Y, and Z, you should feel
10 free to do that too.

11 MR. BELFER: Understood.

12 When we were last before this Court, we explained that
13 Plaintiffs challenge to the January 2026 was ultimately about a
14 policy dispute. The same is true for Plaintiffs challenge to
15 the May 2025 secretarial directive and the September and
16 December ACIP recommendations. Plaintiffs disagree with how
17 the agency weighed the evidence regarding the COVID-19 and
18 hepatitis B vaccines.

19 THE COURT: I'm going to ask you to just slow down a
20 little bit.

21 MR. BELFER: Plaintiffs think the public health would
22 be better served by a recommendation that everyone receive the
23 vaccines, rather than the recommendation the agency chose, that
24 people discuss those vaccines with their health care provider.

25 But the Administrative Procedure Act does not permit

1 Courts to reweigh the evidence or substitute their policy
2 judgment for that of the agency.

3 Under our system of government, democratically
4 accountable agencies, such as HHS, are entitled to make complex
5 scientific determinations within their areas of expertise and
6 to make policy judgments.

7 The Court's role is very limited. It simply ensures
8 the agency has reasonably considered the relevant issues and
9 reasonably explained its decision.

10 Here, the agency has done that in spades. The agency
11 considered the vaccines' safety and efficacy as well as other
12 factors such as the risks of the underlying diseases, public
13 trust and confidence in vaccines, the impacts on insurance
14 coverage, and the pros and cons of different types of
15 recommendations.

16 In each case, the agency's decision was informed by
17 scientific evidence and insight of experts in the field. Now,
18 Plaintiffs disagree with the agency's immunization
19 recommendations, and that's fine. They're free to express
20 their disagreement and publish their own immunization schedules
21 as they've done.

22 But the APA does not allow them to overturn the
23 agency's reasonable policy judgments based on its reasonable
24 consideration of the evidence, nor may they use the APA as a
25 vehicle to effect broad programmatic changes to federal vaccine

1 policy.

2 And I think it's telling that in Plaintiffs'
3 presentation, they said, well, in March, the agency should
4 consider measles. What they want this Court to do is
5 essentially supervise federal vaccine policy indefinitely, but
6 that is not the role of a Court under the APA.

7 And, of course, we're here on a PI motion, and so it's
8 important to keep that standard in mind. A preliminary
9 injunction is an extraordinary remedy, and Plaintiffs have an
10 especially high burden.

11 They must make a clear showing that they're likely to
12 succeed on the merits, that they'll be irreparably harmed
13 absent an injunction, and that the public interest favors the
14 requested relief. Plaintiffs have not come close on any of
15 those factors.

16 So I'd like to start with likelihood of success on the
17 merits. And we'll begin with standing, and, you know, we
18 incorporate our arguments from our first preliminary injunction
19 opposition which apply equally here.

20 And there are a few additional deficiencies with
21 regard to the May 2025 secretarial directive and the ACIP
22 September and December votes.

23 In particular, none of those have any future effect.
24 So to seek standing, to seek -- to have standing to seek
25 prospective relief, such as an injunction, the plaintiff must

1 establish sufficient likelihood of future injury, and that is
2 from the Supreme Court's *Alliance for Hippocratic Medicine*
3 case.

4 And you assess standing as of the date the current
5 operative complaint was filed, which is February 17th, 2026.
6 As of that date, the directive in the September and December
7 votes had no future effect.

8 That is because in January, CDC issued a new
9 immunization schedule including recommendations for the
10 COVID-19 and hepatitis B vaccines.

11 Now, it's true the January decision memorandum
12 mentioned ACIP's recommendations for those vaccines for
13 September and December, but that was just one fact among many
14 that it mentioned.

15 The January recommendation was not at all contingent
16 on ACIP's votes for September or December or CDC's adoption of
17 those votes, and so the current operative schedule is from
18 January 2026.

19 And, you know, even if the Court were to vacate the
20 CDC's adoption of the ACIP votes in September and December,
21 that would have no effect because the current schedule is from
22 January. That would remain in place.

23 And so there's no future injury from the actions
24 challenged here. There's no redressability because even
25 vacating those actions would not change the current

1 recommendations.

2 THE COURT: But what if the January schedule is
3 vacated?

4 MR. BELFER: If the January schedule is vacated, then
5 it is true that the schedule would basically revert to before
6 that, but, again, the Court analyzes standing as of when the
7 current complaint was filed, so as of the filing of the fourth
8 amended complaint, there was no future effect -- no future
9 injury from the secretarial directive or the September or
10 December ACIP votes.

11 And then another way to look at this is mootness.
12 Because the January 2026 schedule has overtaken the actions
13 from 2025, Plaintiffs lack any legally cognizable interest in
14 the outcome of their challenges because an order of vacating
15 those 2025 actions would not change the currently operative
16 January 2026 schedule.

17 And so, you know, whether the Court looks at it from
18 standing purposes or mootness, the fact remains that the
19 actions challenged here, the directive and the September and
20 December ACIP votes, have no future effect, and there's no
21 future injury from them in light of the January 2026 schedule,
22 and so as of when the complaint was filed in February, there's
23 simply no standing.

24 Turning to the committed to agency discretion by law
25 issue, so the APA in 5 U.S.C. 701(a)(2) expressly does not

1 apply where agency actions are committed to agency discretion
2 by law, and that applies when the Court would have no
3 meaningful standard against which to judge the agency's
4 exercise of discretion, and that's from the First Circuit's
5 *Union of Concerned Scientists* case.

6 Here, the relevant statutes, as we discussed, is
7 42 U.S.C. 243(a) which authorized the secretary to assist
8 states and their political subdivisions in the prevention and
9 suppression of communicable diseases and advise the several
10 states on matters relating to the preservation and improvement
11 of the public health.

12 From that statute, there's just this general authority
13 to assist states in preventing communicable diseases and
14 promoting public health, but there is no guidance as to how the
15 agency should exercise its discretion, how it should help
16 promote the public health.

17 To use the language of the First Circuit in *Union of*
18 *Concerned Scientists*, there's no guidance in what the agency
19 should consider about when and how to exercise that authority.

20 Now, in Plaintiffs' presentation, they said, well,
21 agencies can constrain their own discretion, but here the
22 agency has not adopted any rule, any -- any legally binding
23 rule. There is no formal agency policy saying how the
24 secretary should exercise its authority under Section 243(a),
25 again, no binding rule, no formal agency policy, you know. All

1 Plaintiffs can point to is, well, there's this informal, kind
2 of, internal ACIP process.

3 And they -- they admitted -- in discussing *Braidwood*,
4 they admitted that ACIP is a -- is a purely advisory committee,
5 which we agree on. It is a purely advisory committee.

6 And so the internal operating procedure of a purely
7 advisory committee which has no legal authority on its own,
8 that is not anything that can bind the agency, and so that does
9 not supply any requirements that the Court could use to
10 evaluate the agency's exercise of its discretion.

11 And I would note the First Circuit's *Marasco &*
12 *Nesselbush* case where it said "The Court needs a set of
13 statutory or regulatory requirements to guide it in assessing
14 the propriety of the challenged actions."

15 So it's not just is there -- can we find some internal
16 process that may or may not have been followed. It's was there
17 a set of statutory or regulatory requirements to guide the
18 Court in evaluating how the agency exercised its discretion,
19 and here there are none.

20 So in short, the secretary has broad and unreviewable
21 discretion under Section 243(a) to decide how to go about
22 assisting and advising states in preventing communicable
23 diseases and preserving the public health. And so right off
24 the bat, because this is committed to agency discretion the APA
25 does not apply.

1 So let's turn to the arbitrary and capricious
2 analysis. And so to set the stage, you know, as the Court
3 knows, this comes from 5 U.S.C., Section 706, and as the First
4 Circuit held in the *District 4 Lodge* case, the Court has a very
5 narrow role to play.

6 As the Supreme Court said in *Prometheus Radio Project*,
7 the Court simply ensures the agency has acted in a zone of
8 reasonableness, it has reasonably considered the relevant
9 issues, and reasonably explained its decision. If the agency
10 action is supported by any rationale review of the record, it
11 must be upheld.

12 The First Circuit made clear that a difference of
13 opinion about how to evaluate the evidence has no place in
14 arbitrary and capricious review, and as the Supreme Court held
15 in *State Farm*, which Plaintiffs themselves cited, the Court
16 cannot substitute its judgment for that of the agency.

17 Plaintiffs also mentioned the *Department of Commerce*
18 case, and we agree that case is helpful, and Your Honor can
19 review it.

20 What the *Department of Commerce* case said is that the
21 secretary himself had authority to make policy. He didn't need
22 to defer to the census bureau. The secretary himself was
23 allowed to have policy preferences and to make policy himself.
24 That was the authority he had over the statute.

25 And so similarly here, the secretary has unreviewable

1 authority to -- to make vaccine recommendations and to assist
2 states in promoting the public health.

3 Before we get into --

4 THE COURT: Is it really -- is your position that it's
5 totally unreviewable? Meaning if the secretary said instead of
6 getting a vaccine -- instead of getting a vaccine to prevent
7 measles, I think you should get a shot that gives you measles;
8 is that unreviewable?

9 MR. BELFER: Yes. There -- there is no -- there is no
10 standard to apply to Section 243(a). I mean, the secretary
11 has --

12 THE COURT: Well, it's promoting the public health;
13 right?

14 MR. BELFER: So the goal -- the secretary's goal under
15 that statute is to help states promote the public health, but
16 how he goes about doing that, what evidence he considers, what
17 factors he considers, the process he goes through, all of those
18 are committed to agency discretion.

19 There is no statutory or regulatory requirement that
20 sets out how the secretary should go about promoting public
21 health, so all we have is this general policy goal, this
22 general goal of promoting public health.

23 But under the committed to agency discretion case law,
24 what the Court looks to is whether there is a statutory or
25 regulatory requirement that guides how the agency goes about

1 pursuing that general goal.

2 THE COURT: So if the secretary says, I think a better
3 way to get herd immunity on measles is for everyone to get
4 measles, and so I'm now going to recommend that everybody go to
5 their doctor and be exposed to measles, and then we're going to
6 get herd immunity because everyone's going to get measles, that
7 recommendation would be unreviewable.

8 MR. BELFER: Yes. I mean, if -- if the secretary were
9 to decide -- certainly, he hasn't done this, but if --

10 THE COURT: I know. I'm not saying he did decide
11 this. Don't get me wrong, but I'm just trying to understand.
12 Really you're saying that I -- the preamble about the goals of
13 the -- you know, preventing and public health being the
14 objective is so -- is so ambiguous that no decision made is
15 reviewable under any circumstance.

16 MR. BELFER: That's correct.

17 Now, I think something to keep in mind is there are
18 checks on government outside of Article 3 Courts.

19 THE COURT: Sure.

20 MR. BELFER: So if the secretary were to do something
21 that was not popular with Americans, you know, there's
22 electoral, there's political accountability.

23 Courts are not designed to remedy every potential
24 defect in agency decision-making, so the APA has a very
25 specific role and where there are, kind of, broad statutory

1 goals, but there's no statutory or regulatory requirement that
2 can guide Courts in evaluating how the agency goes about
3 pursuing that goal, the APA simply does not apply. There might
4 be other accountability mechanisms but not under the APA.

5 And so, you know, even if, for example, the Court --
6 if the secretary were to say, you know, under my judgment, I
7 think that herd immunity is the best way, then, you know, that
8 would be essentially unreviewable.

9 And, of course, here, what the secretary did is he
10 said -- well, the secretary as well as, you know, CDC, they
11 said, we think that the best way to promote public health is
12 for people to talk to a health care provider about the COVID-19
13 and hepatitis B vaccines, you know.

14 Everyone here is trying to promote the public health.
15 This isn't public health versus some other value. Everyone is
16 trying to promote public health. There's just a difference in
17 opinion as to how to go about promoting public health.

18 The secretary and the agency has decided to promote
19 public health by recommending shared clinical decision-making,
20 talk to a health care provider, and the secretary has decided
21 to consult certain experts over others.

22 But, kind of, going back to the core point, there is
23 no statutory or regulatory requirement that guides who the
24 secretary consults, what factors he considers, how he weighs
25 the evidence. All of those issues are committed to agency

1 discretion.

2 So let's turn to the first challenged action here,
3 which is the May 2025 secretarial directive. In Plaintiffs'
4 presentation, they focused on that short video posted online.
5 They said, well, that video doesn't provide an adequate
6 explanation.

7 But the explanation for the directive is not just from
8 that particular social media post. It's in the directive and
9 in the two detailed scientific memoranda that support the
10 directive as well as the rest of the record, which, of course,
11 we haven't yet produced the full record.

12 But just based on what we have so far, the directive
13 and those two memoranda from senior HHS officials, we see that
14 there was a reasonable explanation and a reasonable
15 consideration of the relevant factors.

16 And I will note that, you know, Plaintiffs said, well,
17 we had no idea these memos existed. The directive itself on
18 its face says that the secretary considered recommendations
19 from FDA and NIH, and so, you know, it's clear what it
20 considered.

21 Plaintiffs in their -- in their presentation, they
22 said, well, these memoranda were not from the ACIP or CDC, and
23 they weren't shared with them, but there was no requirement
24 that the secretary base the directive on the ACIP or from CDC,
25 you know.

1 Again, Plaintiffs admitted that the ACIP is a purely
2 advisory committee. It simply exists to advise the secretary
3 and the CDC director on vaccine recommendations.

4 There's no requirement that the secretary get his
5 advice from any particular one of his employees. The secretary
6 has discretion to consult whichever of his employees he thinks
7 is appropriate to advise him on his statutory authority, and so
8 it was fully appropriate and within his statutory authority for
9 the secretary to get advice from senior officials at FDA and
10 NIH.

11 And so let's talk a little bit about those memos.
12 With regard to children, the vaccination for children, the
13 relevant scientific assessment is from Matthew Memoli, who is
14 the principal deputy director of NIH, and Sarah Brenner, the
15 principal deputy commissioner of FDA, both of whom are -- have
16 medical degrees.

17 They -- those -- that memorandum evaluated Secretary
18 Becerra's recommendation from June 2022 that all children
19 receive the vaccine, and it found that after review of relevant
20 existing data including 39 scientific references and new
21 studies that were unavailable to Secretary Becerra in June
22 2022, that there was no clear evidence that the benefits of
23 vaccination for COVID-19 outweigh the risk of harm in children
24 under 18 years of age.

25 And in reaching that conclusion, they considered the

1 relative evidence. For example, they considered the risks to
2 children from COVID-19. They considered mortality evidence.
3 They considered hospitalization rates.

4 They also considered the risks of COVID-19
5 vaccination. For example, they mentioned that vaccination can
6 cause postvaccination myocarditis and pericarditis, seizures,
7 Bell's palsy, transverse myelitis, clotting disorders, strokes,
8 heart attacks, and acute kidney injury as well as non-COIVD-19
9 lower respiratory tract infection, so, again, those are all --
10 that's all evidence that the memorandum considered.

11 In addition to the risks of the vaccine, it considered
12 the efficacy of the vaccine, and it found that the past and
13 current true efficacy of the COVID-19 vaccines remains unclear.

14 It looked at the particular studies that had been
15 done, and it said that in light of those studies, we still
16 don't know enough about efficacy.

17 And so what the memorandum concluded is that the
18 currently available data in published studies do not provide
19 sufficient clinical and scientific evidence to broadly
20 recommend COVID-19 vaccination for those under 18 years of age;
21 rather given the low risk of infection to those under age of
22 18, the known risks of vaccination outweigh any small potential
23 benefit.

24 And so what you see in the memorandum is that there
25 was a detailed analysis of the evidence. They looked at the

1 studies that were out there. They weighed the risks and
2 benefits, and they reached a reasoned conclusion in light of
3 their evaluation of the evidence.

4 And then similarly, regarding the recommendation for
5 pregnant women, this was based on a scientific assessment from
6 Tracy Beth Hoeg, M.D., Ph.D., who is an advisor to the FDA
7 commissioner.

8 Like the other memorandum, this cited multiple
9 scientific references. It considered safety risks, finding
10 that there was a lack of high-quality data of the safety of
11 mRNA vaccines during pregnancy.

12 In particular, it noted that Pfizer and Moderna lack
13 high-quality randomized trial safety data. There was only one
14 insufficiently powered, i.e. very small, randomized study of
15 the Pfizer vaccine, and no randomized trial for pregnant women
16 for the Moderna vaccine.

17 In other words, this memorandum looked at the
18 particular studies that were available. It did a detailed
19 analysis of the available evidence, and it considered the
20 reliability and the quality of the existing scientific
21 evidence. Those are areas about which the Court needs to defer
22 to the expert judgment of the agency.

23 So in addition to looking at data about safety, it
24 also looked at efficacy. It found that the current benefit of
25 these vaccines against severe disease is uncertain given the

1 widespread immunity from prior infection and a lack of
2 randomized placebo-controlled trials looking at clinical
3 outcomes in this setting.

4 And the memo further found that vaccine efficacy in
5 our current circumstances has been deduced from observational
6 data and immunobridging data and the applicability of the
7 initial randomized controlled trials to today's epidemiological
8 circumstances in a population that has been exposed to the
9 SARS-CoV-2 virus is not well defined.

10 Again, the memo is doing an in-depth look at the
11 particular evidence that's out there, it's -- and analyzing the
12 quality and reliability of the scientific studies in making a
13 reasoned conclusion based on that.

14 So in light of the lack of high-quality data
15 demonstrating the safety of the vaccines as well as concern
16 about efficacy, the memo reached its conclusion, and the
17 secretary reasonably relied on those memoranda.

18 And, you know, the case law is clear. The secretary
19 is entitled to rely on the opinions of his own experts, so here
20 the secretary reasonably relied on the memoranda from senior
21 officials with sterling credentials from FDA to NIH to reach
22 the conclusions in the directive.

23 And, you know, I think it's especially helpful to look
24 at the case law holding -- you know, for example, the *Baltimore*
25 *Gas and Electric* case from the Supreme Court. The Court should

1 be at its most deferential when the agency makes scientific
2 determinations within the agency's area of special expertise.

3 And then, you know, in the recent *Novartis* case in the
4 D.C. Circuit, there the Court deferred to FDA because its
5 analysis turned on the FDA's expertise in evaluating the
6 clinical significance of drug studies which will not likely
7 second guess.

8 And, then, of course, the D.C. Circuit in the *Rempfer*
9 case afforded a high level of deference to FDA's scientific
10 judgment within its area of expertise.

11 So in light of the agency's detailed scientific
12 analysis in these two memoranda and the secretary's reasonable
13 reliance on that scientific analysis, the agency has plainly
14 met the reasonableness requirement under the arbitrary and
15 capricious standard.

16 You know, Plaintiffs make a variety of arguments.
17 They say that the agency did not consider new data, but that's
18 simply not true. They considered data from 2024 and 2025 in
19 both of those assessments. But, of course, they didn't need
20 to. There's no requirement to consider new data, but they did
21 so anyway.

22 And, you know, they say that these memoranda are
23 inconsistent with data showing the risks of COVID-19, but,
24 again, no one is questioning that COVID-19 has risks. Instead,
25 they're looking at the risk of COVID-19 as well as safety and

1 efficacy data for the vaccines and considering all of that to
2 reach the reasonable conclusions that they did.

3 Plaintiffs say that the directive did not rely on an
4 ACIP vote, and they say that was somehow improper, but, again,
5 under Section 243(a), the secretary had wide and indeed
6 unreviewable discretion about what to consider, what evidence
7 to consider, what factors to consider, who to consult in
8 exercising his authority under Section 243(a).

9 There was no requirement to base the directive on
10 ACIP. Again, ACIP is purely advisory, and it exists solely to
11 advise the secretary to the extent that he needs advice in
12 exercising his statutory functions.

13 And, you know, notably in the previous PI hearing,
14 Plaintiffs conceded there have been at least three examples in
15 the past where CDC has deviated from ACIP recommendations, so
16 not only is basing recommendations on ACIP not required,
17 there's not even a uniform practice. There are examples where
18 the agency has deviated based on the agency's own policy
19 judgment and review of the evidence.

20 THE COURT: On those three occasions, they had had a
21 recommendation. They just didn't follow it; right?

22 MR. BELFER: That's true. They decided not to follow
23 an ACIP recommendation, but there's no meaningful difference
24 between that and making a recommendation without ACIP going
25 first.

1 I mean, what's true in both examples is that the
2 agency is saying we are not going to follow ACIP. We're going
3 to make our own decision about vaccine recommendations based on
4 our own analysis of the evidence. In both cases, that's fully
5 within their authority. There's no requirement that the
6 vaccine recommendations be based on ACIP votes.

7 You know, Plaintiffs also talk about reliance
8 interests, and, you know, we explain in our brief why vaccine
9 recommendations change all the time. There's no reliance
10 interest in any one vaccine recommendation staying in place
11 forever.

12 What Plaintiffs said today is, well, our reliance
13 interests are actually in the process, you know. They say, we
14 have a reliance interest in ACIP's decision-making process.

15 But what the case law says is that under the arbitrary
16 and capricious standard, agencies -- agencies have to consider
17 reasonable reliance in the agency's positions, so if an agency
18 changes a rule or changes some official policy, like the
19 regular reliance interest in that rule or official policy that
20 you have to consider, but the case law does not support this
21 notion that you might have reliance interests in some, kind of,
22 internal operating procedure for an advisory committee. There
23 was no reliance interest in ACIP's, kind of, internal operating
24 procedures.

25 And, you know, there were no -- there were no policies

1 here, no rules, no binding policies that weren't followed. The
2 only change is that we made these recommendations without going
3 through the ACIP's process, but, again, there are no reliance
4 interests in ACIP's internal operating procedures.

5 Okay. And so I think we can turn to the September and
6 December votes. I think with regard to FACA, you know, we
7 addressed FACA in our prior briefing and at the last PI
8 hearing, so I don't think we need to get into it now.

9 With regard to *Braidwood*, we agree with Plaintiffs
10 that *Braidwood* does not apply here, that FACA does apply to the
11 ACIP, and we'll explain that more fully when we submit our
12 brief tomorrow.

13 THE COURT: Thank you.

14 MR. BELFER: And then, you know, we'll also -- you
15 know, we'll respond to the new declarations on Monday.

16 One other point, before I get into the September and
17 December votes, Plaintiffs criticized the announcement in the
18 Federal Register about the March ACIP meeting, and they
19 compared that Federal Register announcement to the agendas for
20 prior ACIP meetings, but that's comparing apples to oranges.

21 It is true that the March meeting has been announced,
22 but the full agenda for the March meeting has not been
23 released, so we don't yet have a full agenda, and so, you know,
24 we don't -- we just don't know everything that they're going to
25 talk about in March. It will be released, but it hasn't been

1 released yet.

2 So let's -- let's talk about the September and
3 December meetings. And so, you know, we go through in detail
4 what was discussed at these meetings in our briefs. We don't
5 need to go through all that now.

6 But just at a high level, in September that's where
7 they considered the COVID-19 recommendations. The September
8 meeting involved numerous scientific presentations about the
9 COVID-19 vaccine from experts in the field including CDC
10 subject matter experts and members of ACIP's COVID-19
11 immunization work group.

12 Plaintiffs said today that ACIP did not consider the
13 work group. That's simply untrue. There were presentations
14 from the COVID-19 work group at the September meeting.

15 So, you know, there were presentations on COVID-19
16 epidemiology from CDC, on COVID-19 vaccine implementation, on
17 vaccine effectiveness, so, you know, there were multiple
18 presentations on vaccine safety and effectiveness from relevant
19 experts. There was a presentation on safety from the work
20 group, actually, multiple presentations from the work group on
21 safety.

22 And so what you have from this meeting is you have
23 multiple presentations from the work group, from other
24 scientific experts on vaccine safety and efficacy, other
25 relevant considerations.

1 And in addition to the presentations, there was
2 discussion at the meeting about safety and efficacy and
3 considerations into trust and public confidence.

4 They also discussed the proposal to recommend shared
5 clinical decision-making, and there were discussions about the
6 benefits and disadvantages of a shared clinical decision-making
7 recommendation.

8 So they really considered all relevant factors. They
9 also considered insurance coverage, you know, noting that there
10 would be no loss to insurance coverage under this
11 recommendation.

12 And so in light of all of that discussion and
13 engagement with the evidence, engagement with the science and
14 the evidence and advice from experts, ACIP reached a reasonable
15 recommendation to recommend shared clinical decision-making.

16 And then in October, the CDC adopted that
17 recommendation. It explained that the prior recommendation
18 that everyone get the COVID-19 vaccines had deterred health
19 care providers from talking about the risks and benefits of
20 vaccination for the individual patient or parent, and it noted
21 vaccine uptake concerns, that only 23 percent of adults had
22 followed the most recent seasonal COVID-19 recommendation and
23 that there were widespread risk-benefit concerns about booster
24 shots.

25 So in light of those concerns as well as the ACIP's,

1 you know, reasonable recommendation, CDC adopted the
2 recommendation to recommend shared clinical decision-making.

3 What you can see from all of this is that, you know,
4 this is not some, you know, arbitrary process. This is a
5 careful, deliberative process where ACIP considered scientific
6 evidence. It heard from experts. It heard from the work
7 group.

8 And CDC considered the ACIP's deliberations. It
9 considered safety and efficacy concerns, vaccine uptake
10 concerns, and it reached a reasoned conclusion to recommend
11 shared clinical decision-making.

12 You know, Plaintiffs say that ACIP should have
13 followed the GRADE or EtR frameworks, but there was no
14 requirement to do that. There was simply, kind of, a best
15 practice that ACIP had adopted in the past, but, again, there
16 is no -- there's no requirement that ACIP, which is, again, is
17 a purely advisory committee, there was no requirement that they
18 follow any particular process in evaluating evidence, and so
19 there -- there was no requirement and there was no need to
20 explain why they adopted a different process, you know.

21 They had to -- ACIP, as an advisory committee, had
22 discretion about how they evaluated evidence, and the Court
23 should defer to ACIP's expert analysis of the evidence.

24 And we'd also note that, you know, even if there were
25 any failure to follow the EtR or GRADE frameworks, that would

1 be harmless because, you know, again, Plaintiffs are not
2 challenging the ACIP recommendations themselves. What
3 Plaintiffs are challenging is CDC's adoption of ACIP's
4 recommendation.

5 And, you know, the secretary, and by extension CDC,
6 have wide and unlimited discretion in adopting vaccine
7 recommendations, so they are not limited by which processes
8 ACIP did or didn't follow. They have full discretion about
9 which vaccine recommendations to adopt.

10 And so even if there were some kind of procedural
11 default, some failure to follow some process within ACIP,
12 any -- you know, which procedures ACIP followed internally
13 don't create any arbitrary and capricious problem for the
14 ultimate decision by CDC and the secretary to adopt vaccine
15 recommendations.

16 And, you know, again, Plaintiffs say there's a failure
17 to consider new data, but we did consider new data. If you
18 look at the record of the September meeting, they did consider
19 2024 and 2025 data.

20 So just as the September meeting was reasonable and
21 reasonably explained, so for the December meeting. This
22 meeting considered the hepatitis B vaccine recommendations, and
23 it recommended shared clinical decision-making for parents
24 deciding whether to give the hepatitis B vaccine, including the
25 birth dose, to infants born to women who tested negative for

1 the virus. On the other hand, for -- it had a different
2 recommendation if you tested positive, but if the mother tests
3 negative, it recommended shared clinical decision-making.

4 And it noted risks to consider. It said, "Parents and
5 health care providers should consider whether there are
6 infection with risks, such as a household member who has
7 hepatitis B or frequent contact with persons who have emigrated
8 from areas where hepatitis B is common."

9 And so, you know, the agency made the recommendation.
10 They said, here's some risk factors to consider, and that was
11 based on a reasoned scientific analysis.

12 If you look at the December ACIP meeting and you look
13 at the presentations at that meeting, you can see ACIP received
14 multiple scientific presentations from CDC, from the Centers
15 for Medicare and Medicaid Services or CMS and the child
16 adolescent scheduled work group.

17 Plaintiffs say that we didn't consider the work group.
18 That's false. The December ACIP meeting did involve
19 presentations from the work group.

20 So if you look at the presentations, they analyzed
21 safety. They analyzed efficacy. They analyzed insurance
22 coverage. They looked at the work group's process for making
23 this recommendation.

24 And in particular, the second presentation from
25 Dr. Pebsworth is worth looking at because that goes through the

1 work group's process. It noted that between October 17th and
2 November 24th of 2025, the childhood and adolescent schedule
3 work group received 12 presentations by CDC staff, work group
4 members, and invited ad hoc experts that covered clinical
5 ethics, non-specific vaccination effects, aluminum adjuvant
6 exposures, clinical practice challenges and solutions, and the
7 Alaska hepatitis B vaccine trials.

8 There was a thorough work group process that led to
9 the presentations at the December meeting. And Dr. Pebsworth
10 reported the work group's findings regarding safety and
11 efficacy and, you know, the need for the vaccine.

12 And they ultimately recommended shared clinical
13 decision-making because it provided a return to decision-making
14 to parents in collaboration with the health care provider and
15 the providers to recommend a flexible schedule and tailor care
16 to individual needs, risks, and preferences. It considered
17 safety and efficacy and all the relevant factors.

18 And then CDC ultimately adopted ACIP's recommendation.
19 It explained that the recommendations reflect ACIP's rigorous
20 review of available evidence and restored the balance of
21 informed consent to parents whose newborns face little risk of
22 contracting hepatitis B. And that's from CDC's announcement of
23 its decision to adopt ACIP's recommendation.

24 CDC also noted very low incidents of perinatal
25 hepatitis B transmission in the U.S. due to existing prevention

1 systems and the high reliability of prenatal hepatitis B
2 screening which identifies nearly all hepatitis B infections
3 during pregnancy, so, again, the CDC considered all of these
4 scientific factors and made a reasoned conclusion.

5 They also explained that they would develop materials
6 to support clinicians in discussing vaccination timing with
7 families, so, you know, Plaintiffs say, well, we don't have
8 enough guidance to consider, but, again, CDC said they would --

9 THE COURT: Slow down.

10 MR. BELFER: -- CDC said they would provide materials.
11 And I would note there is no requirement that CDC provide any
12 sort of public guidance regarding the recommendations. There
13 was no failure to follow any requirement.

14 Nonetheless, in December, CDC said they would be
15 providing guidance to clinicians about how to follow this
16 recommendation, so the December vote, just like the September
17 one, was reasonable and reasonably explained.

18 THE COURT: Why if the -- if the ACIP had had a policy
19 that they would follow the GRADE and the EtR framework and then
20 they choose not to and don't explain why not, how is that not
21 arbitrary?

22 MR. BELFER: So there is no --

23 THE COURT: They didn't explain why not; right?

24 MR. BELFER: I'm not aware of an explanation of why
25 they didn't follow that.

1 THE COURT: And that had been the practice for many
2 years before; right?

3 MR. BELFER: So they -- they had followed that
4 practice in the past. I'm not sure if they followed it every
5 single time. If I knew -- at least in some cases, yes, they
6 did follow GRADE and EtR, but there was no -- there was no
7 binding rule. There was no formal agency policy that required
8 them to follow the GRADE and EtR process.

9 Again, ACIP is a purely advisory committee, and so the
10 internal procedures they choose to follow in evaluating
11 evidence are not binding.

12 THE COURT: Okay. That's what I thought the argument
13 you were making was. I wanted to make sure I understood.

14 So assume, for the sake of argument, ACIP says, the
15 way we're going to consider about change in a vaccine schedule
16 is we're going to look at the effectiveness of the vaccine in
17 Step A. We're going to look at the negative effects in Step B.
18 We're going to send it to a subcommittee for study on Step 3.
19 We're going to compare it to the -- whatever. They've laid
20 out, we're going to do these 10 things; that's how we're going
21 to make our recommendation.

22 And then they come in to have a meeting, and they're,
23 like, actually, today we're not doing any of those things.
24 We're just doing thumbs-up, thumps-down. Who thinks we should
25 recommend this vaccine?

1 Does the fact that the previous, let's say, 10 years
2 they followed this protocol, and then they just -- this
3 particular meeting they're like, we're not following it, is
4 that reviewable under the APA here, or is your position that it
5 doesn't matter what ACIP did since the final decision-making
6 authority came out of the CDC?

7 MR. BELFER: So we -- we continue to believe that
8 these decisions are unreviewable, and that's so -- for several
9 reasons.

10 THE COURT: Well, right. So I understand your
11 position. That wasn't quite what I was getting at. I
12 understand you're saying it's committed to agency discretion.
13 I can't review it.

14 But assume that I can -- putting that aside, the final
15 recommendation, if the ACIP itself has behaved in a way that is
16 inconsistent with its past practice, is that reviewable at all,
17 such that the ACIP recommendation is suspect because it hasn't
18 been subject to the same rigorous protocol its prior
19 recommendations had been, or is basically everything that ACIP
20 does not subject to judicial review at all?

21 MR. BELFER: Right. So the mere fact that in the past
22 ACIP might have followed certain procedures to evaluate
23 evidence and did not -- did not follow -- excuse me --

24 THE COURT: Sure.

25 MR. BELFER: Get some water.

1 So the mere fact that ACIP followed certain procedures
2 to evaluate the evidence in the past and did not follow those
3 procedures going -- you know, in the current meeting, that is
4 not by itself an APA violation.

5 The, you know, cases that talk about an agency, kind
6 of, change in position, that's talking about if the agency has,
7 kind of, a binding rule that it changes; there's some official
8 formal policy that's being changed.

9 Here, there was no binding rule. There was no formal
10 agency policy that was being changed, all you have is ACIP, a
11 purely voluntary -- a purely advisory committee changing its
12 internal practices for how it looks at the evidence.

13 And so the mere fact that an advisory committee like
14 ACIP changes its internal processes for evaluating the
15 evidence, that change does not by itself create an APA
16 violation.

17 Now, the Court, you know, still will review --
18 assuming it can review, the Court can look at whether the
19 agency decision as a whole is arbitrary and capricious, so you
20 can say, well, did the agency consider the relevant factors?
21 Did it reasonably explain its decision? The Court can do that.

22 But the mere fact that the ACIP, this purely advisory
23 committee, changed its internal processes for evaluating
24 evidence, that change by itself is not an APA violation.

25 THE COURT: Okay. Thanks.

1 MR. BELFER: So what the record shows is that both in
2 September and in December, the ACIP considered the scientific
3 evidence. They heard from the work group. They heard from
4 other subject matter experts.

5 They considered the vaccine's safety and efficacy,
6 impacts on insurance coverage, the advantages and disadvantages
7 of a shared clinical decision-making recommendation. They
8 considered all of that, and they reasonably explained the
9 recommendations.

10 And, of course, the CDC was entitled to rely on the
11 expert advice of its own experts in making the CDC's ultimate
12 recommendation, and, of course, given all of this involves
13 complex scientific questions within the agency's area of
14 expertise, including how to evaluate scientific studies,
15 studies' reliability and equivalent, those are all highly
16 technical scientific questions about which the agency has
17 expertise and the Court should defer to the agency.

18 And I would also note that the agency did consider new
19 data. They considered data from 2024 and 2025, and the work
20 group in particular received 12 expert presentations on medical
21 and scientific issues at its meetings in October, November
22 2025. So for all of those reasons, the challenged actions were
23 reasonable and reasonably explained.

24 We'll finally turn to the irreparable harm and public
25 interest factors. Plaintiffs said that you can have

1 irreparable harm simply from harm to the public, but that's not
2 true.

3 Under binding precedent, the Court has to find
4 irreparable harm to the plaintiffs in particular, and here they
5 haven't shown that.

6 We incorporate our arguments from our first brief and
7 our first argument, but something to note for these acts in
8 particular is that Plaintiffs don't explain how each challenged
9 action caused harm to these Plaintiffs in particular. They
10 lump everything together. They use these general labels, like,
11 the ACIP actions, the non-ACIP actions, but that doesn't
12 suffice.

13 Each action has its own subject and effect, and
14 Plaintiffs have to show when each challenged action will
15 irreparably harm them in the time between now and final
16 judgment, and they have not met that standard.

17 And then with regard to the public interest,
18 Plaintiffs try to frame this case as, you know, the public
19 interest is on their side and the government is on a different
20 side.

21 But everyone here, Plaintiffs as well as the
22 government, everyone is pursuing the same goal, which is
23 promoting the public health. That's what we're all trying to
24 do. We disagree about how to get there, but we're all trying
25 to pursue the public health.

1 So the question here is who is entitled, under our
2 system of government, to make vaccine recommendations, to
3 evaluate the evidence, and to make these policy calls? And the
4 answer is HHS and CDC.

5 You know, Plaintiffs are trying to substitute their
6 preferred policies for those adopted by senior democratically
7 accountable federal officials in the Department of Health and
8 Human Services, but Congress directed the secretary of HHS, not
9 the plaintiffs, to assist states in preventing communicable
10 diseases and promoting the public health.

11 Congress also authorized the secretary to establish
12 the ACIP to advise the CDC director regarding vaccines and
13 related agents for effective control of vaccine-preventable
14 diseases.

15 So under the system established by Congress, the ACIP,
16 the CDC director, and the secretary are entitled to -- sorry --
17 they're entrusted with the responsibility to make vaccine
18 recommendations. They have authority to evaluate the evidence
19 and to determine which vaccine recommendations best promote the
20 public health.

21 So this is not, you know, public health versus some
22 other value. This is we're all trying to promote the public
23 health, and the question is who is entitled to evaluate the
24 evidence and make vaccine policy including vaccine
25 recommendations under our system of government?

1 And under the system Congress established, the
2 responsibility and the authority for evaluating scientific
3 evidence and making vaccine recommendations based on that
4 review of the evidence, that falls to the government, to the
5 secretary, and to the CDC.

6 And, you know, again, I would also note there are
7 First Amendment values here. Plaintiffs are trying to force
8 the government to make a recommendation that we don't believe
9 in.

10 But under -- you know, for example, the Supreme
11 Court's *NRA v. Vullo* case, the government must remain free to
12 select the views that they want to express about vaccine --
13 views they want to express, which also applies to vaccine
14 recommendations. They can share their views in the hopes of
15 persuading others to follow their lead.

16 And so we have the authority, and under the First
17 Amendment, we have the right to express our views about what
18 vaccine recommendations best promote the public health.

19 And then, finally, you know, Plaintiffs talk about
20 confusion, but really the injunction they asked for would just
21 create more confusion. They're basically asking the Court
22 to -- to go back to the vaccine recommendations from a year
23 ago, and then that might potentially change based on the final
24 decision in this case and on appeal. So this kind of
25 flip-flopping between vaccine recommendations is not conducive

1 to the consistency and the public trust that Plaintiffs claim
2 to want.

3 Ultimately, what this case boils down to is that
4 there's a dispute about the best way to promote public health,
5 which vaccine recommendations best promote public health.

6 And what we've shown is that the ACIP and the CDC have
7 reached a reasonable conclusion based on the evidence about
8 vaccine recommendations.

9 Plaintiffs might disagree with those recommendations,
10 but ultimately, the government has the authority to weigh the
11 evidence and to make the recommendations that the
12 democratically accountable officials believe best promote
13 public health. That's what we've done here. And so for all of
14 those reasons the requested relief is not warranted.

15 THE COURT: Thank you, Mr. Belfer.

16 Mr. Oh, a brief response.

17 MR. OH: I'd like to start this rebuttal with the
18 notion that the secretary's discretion is totally unfettered
19 and not subject to judicial review; that is not consistent with
20 the case law, and, quite frankly, I think, a decision adopting
21 the position that the government would want to take -- wants
22 the Court to take would make bad law.

23 And you asked the question, Your Honor, about the ACIP
24 following GRADE or EtR, is there -- you know, can they just
25 jettison that?

1 And I mentioned this case earlier today, and I want to
2 quote a passage from *INS versus Yang*, 519 U.S., and this is at
3 page 32, it's a unanimous opinion written by Justice Scalia,
4 though the agency's discretion is unfettered at the outset, if
5 it announces and follows by rule or by subtle course of
6 adjudication a general policy by which its exercise of
7 discretion will be governed an irrational departure from that
8 policy, paren, as opposed to an avowed altercation to it,
9 closed paren, could constitute action that must be overturned
10 as, quote, arbitrary and capricious or an abuse of discretion,
11 end of quote, within the meaning of the Administrative
12 Procedure Act.

13 So in terms of we've got law here. We've got
14 regulation. We have charter. We have membership balance plan.
15 We have a charter that Secretary Kennedy signed on December 3rd
16 of last year where he basically agreed to be fettered to a
17 certain extent.

18 And by engaging in a unilateral decision that bypasses
19 a general policy by which its exercise of discretion will be
20 governed, that is a violation of the APA, Your Honor.

21 And then, with regard to the -- I think *Union of*
22 *Concerned Scientists* is also directly on point and addresses
23 this issue. And in that case, at pages 18 and 19, 954 F.3rd,
24 this is about whether FACA furnishes any meaningful standards.

25 And we disagree with the EPA -- this is what the First

1 Circuit said, quote, We disagree with the EPA that Courts are
2 not well equipped to enforce at least the outer boundary
3 arranges of this type, nor does the fact that the statute
4 leaves a great deal of discretion to the agency make actions
5 taken pursuant to it unreviewable, citing *Weyerhaeuser* 139
6 Supreme Court at 370, and the parenthetical is, quote, A Court
7 could never determine that an agency abused its discretion if
8 all matters committed to agency discretion were unreviewable.

9 And it is rudimentary administrative law that
10 discretion as to substance of the ultimate decision does not
11 confer discretion to ignore the required procedures of
12 decision-making.

13 So with regard to the government's argument that we
14 relied on our own experts and we're simply disagreeing with the
15 policy decision that they made, we're not going into the
16 substance of the Memoli/Brenner May 12th memo now or the Hoeg
17 memo of May 12th now.

18 I, quite frankly, think it's going to be easy to pick
19 apart those memos at the right time, but the point here is that
20 the process that they followed in making that change to the CDC
21 schedule and bypassing the ACIP is what is the issue here at
22 this stage of the case.

23 And so it's simply a -- I think, a red herring, an
24 absolute red herring to rely on, let's say, 243(a). If you
25 look at where that particular statutory section falls in

1 42 U.S.C., it is a section on federal state cooperation, and
2 then 243(a) goes into how the feds and the states can cooperate
3 in terms of controlling vaccine-preventable diseases.
4 That's -- that statute is really not the source of what Your
5 Honor should really be looking at.

6 What has been, I think, established through an
7 abundance of evidence is that there has been agreed-to fetters
8 and constraints that the secretary recognizes, by his own
9 signature on the charter, that this is a process and procedure
10 by which vaccine recommendations should be made, but then a
11 month after he actually signs that charter, he totally
12 disregards it without explanation.

13 That is the action of a -- what's the right word to
14 describe it? It's the action of, I guess, someone who believes
15 that he can do whatever he wants whenever he wants and he can
16 regard process here and then disregard process there. That is
17 not what the APA allows or requires.

18 I'd also like to note that -- I do want to direct the
19 Court's attention to one other case --

20 THE COURT: Okay.

21 MR. OH: -- involving some pretty scientific and
22 complex questions of whether or not to ban a certain chemical
23 on food crops. It is *Red River Valley Sugarbeet Growers*
24 *Association versus Regan*, 85 F.4th 881, Eighth Circuit 2023.
25 And that case held that the EPA's decision to ban chlorpyrifos,

1 C-H-L-O-R-P-Y-R-I-F-O-S, on food crop without considering other
2 options was arbitrary and capricious because the decision was
3 not based on, for example, new findings, and, thus, the EPA
4 failed to consider important aspects of the problem.

5 At this stage of the case, we are not asking the Court
6 to delve into substantive scientific questions or the
7 credibility of the memos.

8 We are asking the Court to look at what is and has
9 been the procedure and processes that the secretary and his
10 predecessors have all agreed and admitted that they should
11 follow, and that hasn't been done here, Your Honor.

12 And the injury and the irreparable harm that flows
13 from that -- I didn't have the time this morning to go through
14 all of the declarations that show for each specific action what
15 irreparable injury is flowing from them, and it has been
16 happening since May of last year. There has been a moving
17 target that we've been trying to just get the target to stop
18 moving.

19 But there's -- the declarations and the exhibit that
20 we intend to submit to the Court demonstrates irreparable
21 injury flowing from each individual action, but then we can't
22 forget there is a cumulative effect that's been happening from
23 May to this point.

24 And so I'm going to take one second here because she
25 is handing me a cryptic note that I don't understand.

1 So the government brought up the previous examples
2 where the CDC didn't follow ACIP recommendations, but in those
3 previous examples, it either expanded recommendations or
4 addressed safety issues discovered through post-marketing
5 surveillance through the GRADE and EtR process, through careful
6 evaluation of the evidence and the data. They followed
7 transparent, structured, evidence-based decision-making process
8 and arrived at a recommendation.

9 And that is, quite frankly, all that the plaintiffs
10 are asking, is if you're not going to follow this process that
11 has been in place, that has been -- that Congress has saw fit
12 to incorporate into 13 different statutes where they
13 believed -- Congress believed that the ACIP could be trusted,
14 then the government's failure to follow that trusted process
15 upon which Congress has incorporated into many different
16 statutes and then state and local jurisdictions around the
17 country have also, 600 different statutes from around the
18 country, when you're going to upset the apple cart like that,
19 then give us a reasoned, rational explanation that is in
20 accordance with law, that is absolutely reviewable, and once
21 you get past that, Your Honor, then the evidence is very strong
22 that we are likely to succeed on the merits.

23 And Your Honor, I implore you to grant our motion for
24 preliminary injunction, vacate the January 5 schedule change,
25 enjoin the next ACIP meeting, and let's get the administrative

1 record. I'll be interested to see if there's anything more in
2 the administrative record on the secretarial directive from May
3 than those two memos, and let's preserve the status quo and get
4 to a decision on the merits as quickly as we can. So thank
5 you, Your Honor.

6 THE COURT: Thank you, Mr. Oh.

7 Mr. Belfer, I'll give you the last word.

8 MR. BELFER: Thank you, Your Honor.

9 Plaintiffs said that Section 243(a) is a red herring.
10 It is not a red herring. That is the relevant statute that
11 grants the agency authority here to make vaccine
12 recommendations, so far from a red herring, that is what the
13 Court should focus on.

14 The Court should look at the text of Section 243(a)
15 and ask whether there are any requirements in that statute to
16 guide the Court in evaluating the agency's exercise of
17 discretion, and there simply are no rules, no requirements to
18 guide the agency in exercising its discretion.

19 The agency is not required to base its recommendations
20 on ACIP votes. That is one way to make vaccine
21 recommendations, but there is no requirement that vaccine
22 recommendations must be based on an ACIP vote.

23 Similarly, ACIP's internal operating procedures, the
24 internal procedures of a purely advisory committee are not
25 binding on the agency.

1 And so for all of Plaintiffs talk of process, they
2 have not identified a single statute or regulation or any
3 binding policy that sets any process the agency did not follow
4 here.

5 Instead, what the record shows is the agency
6 reasonably considered the relevant issues and reasonably
7 explained its decision, which is all the APA requires.

8 THE COURT: Thank you, Mr. Belfer.

9 MR. OH: Your Honor, may I just say two things in less
10 than a minute?

11 THE COURT: Less than a minute.

12 MR. OH: The government's argument that 243(a) sets
13 forth no requirements is the wrong standard. Does 243 -- if
14 Your Honor thinks it's relevant, is there meaningful standards
15 to be applied? And there are two phrases in that statute where
16 you can meaningfully apply that to the ACIP process.

17 Okay. And in terms of requirements that the ACIP
18 process be followed, there's no statute that says, well, I
19 think there's the APA; the Administrative Procedure Act
20 provides constraints and some guardrails on agency actions that
21 are reviewable, and that statute provides the basis for
22 reliance interests to be developed and for my clients to put
23 their trust into a process.

24 And when that process is being jettisoned for no good
25 reason, then a reasonable explanation needs to be given that is

1 consistent with the evidence, and that just hasn't been done
2 here.

3 Thank you, Your Honor.

4 THE COURT: Thank you, Mr. Oh.

5 Mr. Oh, is this Mr. -- is it Mr. Jaffe in the back?

6 MR. JAFFE: Yes, sir.

7 THE COURT: Mr. Jaffe, I'm sure you're aware. I
8 denied your motion to intervene, but I invited you to file an
9 amicus brief. Is that something you intend to do?

10 MR. JAFFE: I do, and with the Court's permission, I
11 was planning on filing it on Monday along with all the other
12 filings, if that's appropriate.

13 THE COURT: You're one step ahead of me. That was
14 what I was going to ask, if you could get it in by Monday.
15 You're aware of the expedited time schedule we have to consider
16 this.

17 MR. JAFFE: I am aware, and I will comply. Thank you,
18 Your Honor.

19 THE COURT: Thank you, Mr. Jaffe.

20 Thank you, Mr. Oh. Thank you, Mr. Belfer. I
21 appreciate the argument, and I'll look at the briefing.
22 Everyone have a good day.

23 THE CLERK: All rise.

24 (The Honorable Court exited.)

25 (Adjourned at 11:41 a.m.)

C E R T I F I C A T E

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

I, Jennifer M. Vaillancourt, do hereby certify that the foregoing is a correct transcript from the record of proceedings taken on March 4, 2026, in the above-entitled matter to the best of my knowledge, skill, and ability.

/s/ Jennifer M. Vaillancourt 11th day of March, 2026

Jennifer M. Vaillancourt, RPR, CSR Date
Official Court Reporter

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,**

Plaintiffs,

v.

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

Defendants.

**Civil Action No.
25-11916-BEM**

**MEMORANDUM AND ORDER ON
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

MURPHY, J.

“Science,” like law, “is far from a perfect instrument of knowledge.” Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 29 (1997). History is littered with once-universal truths that have since come under scrutiny. Nevertheless, science is still “the best we have.” *Id.*¹

“Procedure is to law what scientific method is to science.” *In re Gault*, 387 U.S. 1, 21 (1967) (cleaned up). Although sometimes seemingly tedious, “the procedural rules which have been fashioned from the generality of due process are our best instruments for the distillation and evaluation of essential facts from the conflicting welter of data that life and our adversary methods present.” *Id.*

For our public health, Congress and the Executive have built—over decades—an apparatus that marries the rigors of science with the execution and force of the United States government.

¹ “In this respect, as in many others, it’s like democracy.” Sagan, *supra*, at 29–30.

One extraordinary product of that apparatus has been the eradication and reduction of certain communicable diseases through the development and use of vaccines. In the words of the Centers for Disease Control and Prevention (“CDC”), “[v]accines are one of the greatest achievements of biomedical science and public health.”² Since the rise of vaccine development and usage in the early- to mid-1900s, “[t]he United States of America [has been] one of the pioneering nations to conceptualize and implement a robust immunization system that helped the nation tackle major epidemics.”³

Since its founding in 1964, the Advisory Committee on Immunization Practices (“ACIP”) has aided this endeavor by providing expert guidance on the clinical use of vaccines.⁴ The Department of Health and Human Services (“HHS”), which indirectly oversees ACIP, formalized ACIP’s non-partisan, science-backed nature through ACIP’s governance documents.⁵ And Congress has, in turn, recognized the importance and value of having such independent experts involved in setting our national public health agenda by cementing ACIP’s role in the CDC’s issuance of immunization schedules, which—among other things—determines which vaccines are

² CDC, *Ten Great Public Health Achievements — United States, 1900–1999*, 48 *Morb. & Mortal. Wkly. Rep.* 241, 247 (1999), <https://www.cdc.gov/mmwr/PDF/wk/mm4812.pdf> [<https://perma.cc/T63J-8AU2>]; *see also* CDC, *Ten Great Public Health Achievements — United States, 2001–2010*, 60 *Morb. & Mortal. Wkly. Rep.* 605, 619 (2011), <https://www.cdc.gov/mmwr/pdf/wk/mm6019.pdf> [<https://perma.cc/4FW-SNRU>] (describing advances in vaccines and reductions in vaccine-preventable diseases as one of the country’s “[t]en [g]reat [p]ublic [h]ealth [a]chievements” from 2001 to 2010).

³ Sandeep Divate Sathyanarayana et al., *Vaccines in the United States: A Systematic Review on History of Evolution, Regulations, Licensing, and Future Challenges*, 9 *Clin. & Exp. Vaccine Rsch.* 69, 70 (2020), <https://pmc.ncbi.nlm.nih.gov/articles/PMC7445324/> [<https://perma.cc/KBN5-5A86>].

⁴ Jean Clare Smith, Alan R. Hinman & Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices — United States, 1964–2014*, 63 *Morb. & Mortal. Wkly. Rep.* 955, 955 (2014), <https://www.cdc.gov/mmwr/pdf/wk/mm6342.pdf> [<https://perma.cc/4VFQ-V8U8>].

⁵ *See generally*, e.g., Dkt. 185-21 (“ACIP Charter”) (signed by Secretary Kennedy); *see also* *Federal Advisory Committee (FAC) Membership Balance Plan*, ACIP (Jan. 29, 2024), <https://gsa-geo.my.salesforce.com/sfc/p/#t0000000Gyj0/a/3d000002n0y5/SCRGimkNFsTsAtm1GcT4Gu7TM88BO3PwKJZhrdHKkFg> [<https://perma.cc/89RA-KZJE>]; *Advisory Committee on Immunization Practices Policies and Procedures*, ACIP (June 2022), <https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf> [<https://perma.cc/G3D2-VZX4>].

available to patients through insurers and government healthcare programs.⁶ This is all to say that there is a method to how these decisions historically have been made—a method scientific in nature and codified into law through procedural requirements.

Unfortunately, the Government has disregarded those methods and thereby undermined the integrity of its actions. First, the Government bypassed ACIP to change the immunization schedules, which is both a technical, procedural failure itself and a strong indication of something more fundamentally problematic: an abandonment of the technical knowledge and expertise embodied by that committee. Second, the Government removed all duly appointed members of ACIP and summarily replaced them without undertaking any of the rigorous screening that had been the hallmark of ACIP member selection for decades. Again, this procedural failure highlights the very reasons why procedures exist and raises a substantial likelihood that the newly appointed ACIP fails to comport with governing law.

Today, faced with Plaintiffs’ motion for preliminary relief, the Court concludes that Plaintiffs are likely to succeed in showing that the reconstitution of ACIP and the January 2026 changes to the childhood immunization schedule violate the Administrative Procedure Act (“APA”). For the reasons stated below, the Court will grant Plaintiffs’ motion in part.

I. Background

A. Factual Background

This case concerns Defendants’ recent changes to the CDC vaccination schedules and the reconstitution of ACIP, the committee tasked with making recommendations regarding those schedules to the CDC. The Court has previously laid out much of the relevant factual and legal

⁶ See, e.g., 42 U.S.C. § 300gg-13(a)(2); 38 U.S.C. § 1701(1), (9)(G); 42 U.S.C. § 1396a(a)(10)(A), (a)(13)(B).

background.⁷ *See Am. Acad. of Pediatrics v. Kennedy* (“*AAP I*”), — F. Supp. 3d —, 2026 WL 33719, at *1–3 (D. Mass. Jan. 6, 2026).⁸

B. Procedural Background

Plaintiffs filed suit on July 7, 2025. Dkt. 1. The initial complaint challenged only Secretary Kennedy’s May 27, 2025 order that the CDC stop recommending pregnant women and “healthy” children receive the COVID vaccine, *see generally id.*, and was amended to add additional Plaintiffs, *see generally* Dkt. 63. Plaintiffs filed a second amended complaint on September 3, 2025, without objection from Defendants, to add an additional Plaintiff and additional factual allegations. *See generally* Dkt. 99. Plaintiffs filed a third amended complaint on November 5, 2025, again without objection from Defendants, which added challenges to ACIP’s September 2025 vote downgrading the recommendation for the COVID vaccine and the reconstitution of ACIP. *See generally* Dkt. 139. On January 6, 2026, the Court denied Defendants’ motion to dismiss the third amended complaint, holding that Plaintiffs had standing, that the case was not moot, and that Plaintiffs stated a plausible claim for violations of the Federal Advisory Committee Act (“FACA”), 5 U.S.C. § 1001, *et seq.*⁹ *See generally AAP I*, 2026 WL 33719.

On February 13, 2026, the Court granted Plaintiffs’ motion for leave to file a fourth amended complaint.¹⁰ Dkt. 241 (clerk’s notes). Plaintiffs now challenge: (1) Secretary Kennedy’s May 2025 order that the CDC remove its recommendation that pregnant women and “healthy” children receive the COVID vaccine; (2) the reconstitution of ACIP; (3) three votes ACIP took in

⁷ The underlying facts will be discussed in more depth below, when considering the merits of preliminary relief. *See infra* Section III.A.

⁸ Capitalized and collective terms not otherwise defined have the same definitions as used in *AAP I*.

⁹ The parties agree that FACA applies to ACIP.

¹⁰ The fourth amended complaint contains the same allegations as the third amended complaint, which was at issue in the Court’s January 6, 2026 order, and additional allegations, as described below.

2025; and (4) Director O’Neill’s January 2026 memorandum revising the CDC’s childhood immunization schedule (collectively, the “Challenged Actions”). Dkt. 245 (“Complaint” or “Compl.”) ¶¶ 2–5. On January 26, 2026, Plaintiffs moved for preliminary relief, seeking to set aside the Challenged Actions, enjoin further ACIP meetings, and enjoin Defendants from relying on the 2025 ACIP Votes.¹¹ Dkt. 183; *see also* Dkts. 184, 232, 237, 272. The Court held hearings on February 13, 2026, and March 4, 2026, and took the motion under advisement.

II. Standard of Review

Plaintiffs seek a stay of the Challenged Actions under the APA, 5 U.S.C. § 705, and a preliminary injunction barring ACIP from holding additional public meetings until the Court adjudicates the merits of ACIP’s reconstitution.¹² The same standard governs both forms of relief. *See Mass. Fair Hous. Ctr. v. U.S. Dep’t of Hous. & Urb. Dev.*, 496 F. Supp. 3d 600, 609 (D. Mass. 2020); *see also Colorado v. Env’t Prot. Agency*, 989 F.3d 874, 883 (10th Cir. 2021) (“These four [preliminary injunction] factors also determine when a court should grant a stay of agency action under section 705 of the APA.”).

“[T]he issuance of preliminary injunctive relief is ‘an extraordinary and drastic remedy that is never awarded as of right.’” *Howe v. U.S. Bank Nat’l Ass’n as Tr. for RMAC Tr. Series*

¹¹ Though Plaintiffs’ motion is styled as one for a preliminary injunction, Plaintiffs ask the Court to “set aside” various past actions, in addition to enjoining certain future actions. *See, e.g.*, Dkt. 184 at 8 (“[T]he final actions challenged herein violate the Administrative Procedure Act . . . and must be set aside.”). In a preliminary posture, a court stays, rather than sets aside, agency action. *See All. for Hippocratic Med. v. U.S. Food & Drug Admin.*, 78 F.4th 210, 254 (5th Cir. 2023) (“[A] stay is the temporary form of vacatur.”), *rev’d and remanded on other grounds sub nom., Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367 (2024). Thus, the Court construes Plaintiffs’ motion as seeking both a preliminary injunction and a stay.

¹² In relevant part, 5 U.S.C. § 705 provides:

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.

2016-CTT, 440 F. Supp. 3d 99, 102 (D. Mass. 2020) (quoting *Peoples Fed. Sav. Bank v. People's United Bank*, 672 F.3d 1, 8–9 (1st Cir. 2012)). “A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.” *Together Emps. v. Mass Gen. Brigham Inc.*, 32 F.4th 82, 85 (1st Cir. 2022) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). “The movant’s likelihood of success on the merits weighs most heavily in the preliminary injunction calculus.” *Ryan v. U.S. Immigr. & Customs Enf’t*, 974 F.3d 9, 18 (1st Cir. 2020). “If the movant ‘cannot demonstrate that he is likely to succeed in his quest, the remaining factors become matters of idle curiosity.’” *Id.* (quoting *New Comm Wireless Servs., Inc. v. SprintCom, Inc.*, 287 F.3d 1, 9 (1st Cir. 2002)).

The Court has “broad discretion in deciding what evidence to consider in connection with a motion for preliminary injunction” or other preliminary relief. *Rice v. Wells Fargo Bank, N.A.*, 2 F. Supp. 3d 25, 31 (D. Mass. 2014). The Court may, for example, “rely on otherwise inadmissible evidence, including hearsay.” *Bos. Taxi Owners Ass’n, Inc. v. City of Boston*, 84 F. Supp. 3d 72, 78 (D. Mass. 2015) (citing *Asseo v. Pan Am. Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986)). The Court may also take judicial notice of information on official government websites. *See Gent v. CUNA Mut. Ins. Soc’y*, 611 F.3d 79, 84 n.5 (1st Cir. 2010) (relying on the contents of the CDC’s website).

III. Preliminary Injunction and Stay

A. Findings

1. May 2025 Directive

On May 27, 2025, Secretary Kennedy ordered the CDC to stop recommending that pregnant women and “healthy” children receive the COVID vaccine (the “May 2025 Directive”

or “Directive”). Dkt. 185-1 at 2; Dkt. 185-2 at 2. The CDC partially implemented this order by removing the COVID vaccine recommendation for pregnant women from the immunization schedule and by redesignating the vaccine recommendation for children as subject to “Shared Clinical Decision Making” (“SCDM”), where the schedule had previously designated the vaccine “routine.”¹³ See generally Dkt. 185-3. Defendants do not dispute that ACIP was not consulted before this change was made.¹⁴ See, e.g., Dkt. 272 at 31.

2. ACIP Reconstitution

On June 9, 2025, Secretary Kennedy terminated all 17 members of ACIP.¹⁵ Secretary Kennedy then appointed new members to ACIP on June 11, 2025, September 11, 2025, and

¹³ According to the CDC, “[u]nlike routine . . . recommendations, shared clinical decision-making vaccinations . . . are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. . . . For routine . . . recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated.” *ACIP Shared Clinical Decision-Making Recommendations*, CDC (Jan. 7, 2025), <https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html> [<https://perma.cc/3QBY-RXFN>]; see also Dkt. 185-25 ¶ 20. The CDC had previously designated only four other vaccines as SCDM. In those instances, the designation was made after application of the Evidence to Recommendation (“EtR”) framework and was limited to specific age groups with certain risk characteristics. See, e.g., Dkt. 146-17 ¶ 10 (“For example, when ACIP considered expanding the HPV (human papillomavirus) vaccine use to adults between 27 and 45 years of age, the EtR framework indicated uncertainties related to the public health problem and acceptability in this age group, variable individual benefits, and high costs associated with use of resources if the recommendation was routine. Accordingly, the HPV vaccine was designated as SCDM for adults between 27 to 45 years of age.”); see also *infra* note 14 (for a discussion of the EtR framework). On those four prior occasions, Plaintiffs allege that the CDC issued an explanation of its underlying rationale and guidance on healthcare providers’ engagement in SCDM with patients, neither of which was issued for the COVID vaccine. Compl. ¶ 88(d).

¹⁴ Plaintiffs allege that this change circumvented the required procedure for changes to vaccine recommendations—including by failing to consult CDC leadership, ACIP, or any public health data, and by failing to use the EtR framework. Compl. ¶¶ 96–102. ACIP adopted the EtR framework to help panels making recommendations move from evidence to decisions, and to provide transparency around the impact of additional factors on deliberations when considering a recommendation.” CDC, *ACIP Evidence to Recommendation User’s Guide* 3 (2020), https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf [<https://perma.cc/C7ER-N2A6>].

¹⁵ Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, Wall St. J. (June 9, 2025, at 16:00 ET), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112> (cited at Dkt. 237 at 21 n.37); see also *HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP*, HHS (June 9, 2025), <https://www.hhs.gov/press-room/hhs-restore-public-trust-vaccines-acip.html> [<https://perma.cc/C5YC-Q7ZA>].

January 13, 2026.¹⁶ On February 27, 2026, after the filing of Plaintiffs’ motion, HHS announced the appointment of two new ACIP members.¹⁷ Secretary Kennedy also terminated the participation of members of liaison organizations, including some members of Organizational Plaintiffs, on ACIP workgroups, claiming that liaison organizations constitute “special interest groups.”¹⁸

3. Threatened Legal Liability

After Defendants’ changed the immunization schedules, Plaintiffs began counseling Organizational Plaintiffs’ member-doctors who were directly impacted, *see, e.g.*, Dkt. 185-27 ¶¶ 26–27, and publishing their own immunization schedules, *see, e.g., id.* ¶ 22. The same day that AAP published its own immunization schedules, Secretary Kennedy stated on social media: “AAP today released its own list of corporate-friendly vaccine recommendations. . . . AAP should also

¹⁶ Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, at 16:36 ET), <https://x.com/SecKennedy/status/1932899858920120692> [<https://perma.cc/RRE6-V8Y5>] (cited at Dkt. 237 at 21 n.39); *see also* ACIP Membership Roster, CDC (Mar. 2, 2026), <https://www.cdc.gov/acip/membership/roster.html> [<https://perma.cc/ST8M-39AA>]. One of these members, Dr. Kulldorff, is no longer a member of ACIP. Dkt. 272 at 14 n.3; *see also* ACIP Membership Roster, *supra*.

¹⁷ *Secretary Kennedy Appoints Two Physicians to CDC’s Advisory Committee on Immunization Practices*, HHS (Feb. 27, 2026), <https://www.hhs.gov/press-room/secretary-kennedy-appoints-two-physicians-cdc-advisory-committee.html> [<https://perma.cc/AR66-A574>]. According to Plaintiffs, this entire reconstitution was a pretextual effort to replace the prior ACIP members with individuals whose views aligned with Secretary Kennedy’s “anti-vaccine agenda” and circumvented established, rigorous application and vetting procedures. Compl. ¶¶ 75, 78–81.

¹⁸ Brenda Goodman, *HHS Further Constrains Certain Vaccine Advisors to the CDC, Limiting Their Input in Evidence Reviews*, CNN (Aug. 1, 2025), <https://www.cnn.com/2025/08/01/health/hhs-liaison-acip-vaccine-advisers-cdc> [<https://perma.cc/D2GQ-2ZNH>] (cited at Compl. ¶ 82 n.73). Liaison organization members, for example, have previously been responsible for reviewing clinical evidence that may ultimately inform individual members’ votes. *See id.* Workgroups refer to ACIP subcommittees that study scientific research on the safety and effectiveness of vaccines, consider issues of public health importance, and draft the language for recommendations to be voted on by the full committee. *See id.*

be candid with doctors and hospitals that recommendations that diverge from the CDC’s official list are not shielded from liability under the 1986 Vaccine Injury Act.”¹⁹

4. 2025 ACIP Votes

As relevant here, the newly constituted ACIP voted three times to change ACIP’s official vaccine recommendations (the “2025 ACIP Votes”).²⁰ At the June 2025 meeting, ACIP voted in favor of “three recommendations requiring that flu shot manufacturers discontinue the use of thimerosal in the production of influenza vaccine doses aimed at children, pregnant people, and adults” (the “June Vote”).²¹ See Dkt. 185-6 at 73–74; Dkt. 185-7 at 2–3. At the September 2025 meeting, ACIP voted to change the COVID vaccine recommendation for adults and children from routine to SCDM (the “September Vote”). See Dkt. 185-11 at 89–90. At the December 2025 meeting, ACIP voted “8 to 3 to recommend individual-based 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” (the “December Vote”).²² See Dkt. 185-16 at 2–4.²³ Each of these recommendations was implemented through changes to the CDC immunization schedules. See generally Dkt. 185-8; Dkt. 185-9; Dkt. 185-12; Dkt. 185-13; Dkt. 185-14; Dkt. 185-17.

¹⁹ Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, at 17:17 ET), <https://x.com/SecKennedy/status/1957914911415153107> [<https://perma.cc/RRE6-V8Y5>] (cited at Compl. ¶ 124 n.117).

²⁰ Plaintiffs do not challenge any other votes taken by the newly constituted ACIP.

²¹ Helen Branswell, *HHS Secretary RFK Jr. Accepts Recommendations to Drop Thimerosal From U.S. Flu Vaccines*, Stat (July 23, 2025), <https://www.statnews.com/2025/07/23/kennedy-approves-acip-recommendation-thimerosal-removed-from-flu-vaccines/> [<https://perma.cc/7SAA-8D5X>] (cited at Dkt. 237 at 24 n.49).

²² *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus*, CDC (Dec. 5, 2025), <https://www.cdc.gov/media/releases/2025/2025-acip-recommends-individual-based-decision-making-for-hepatitis-b-vaccine-for-infants-born-to-women.html> [<https://perma.cc/G2ZG-AD6W>].

²³ Plaintiffs allege that ACIP members and invited speakers made inaccurate or misleading claims at each meeting prior to the voting. Compl. ¶¶ 84–85, 87, 89, 91.

5. January 2026 Memo

On January 5, 2026, HHS issued a memorandum announcing that Director O’Neill had revised the childhood immunization schedule upon recommendations from the Director of the National Institutes of Health, the Administrator of the Centers for Medicare and Medicaid Services, and the Commissioner of the Food and Drug Administration (the “January 2026 Memo”).²⁴ Dkt. 185-18 at 2, 9–10. The January 2026 Memo was the result of a Presidential Memorandum that “direct[ed] . . . [HHS] to ‘FAST TRACK’ a comprehensive evaluation of Vaccine Schedules from other Countries around the World, and better align the U.S. Vaccine Schedule.”²⁵

The January 2026 Memo introduced a new immunization schedule that reduced the number of childhood vaccinations recommended as “routine” from seventeen to eleven, limited the recommendations for RSV, Hepatitis A, Hepatitis B, and Meningococcal ACWY, Meningococcal B, and dengue vaccinations to only high-risk groups, and downgraded the designations for Rotavirus, COVID, Influenza, Hepatitis A, Hepatitis B, and Meningococcal vaccinations to SCDM. Dkt. 185-18 at 2–3, 6–9. In the January 2026 Memo, Director O’Neill stated that he relied on discussions with health officials from Japan, Germany, and Denmark; discussions “with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy”; and a “review of peer nations’ best practices

²⁴ None of these three individuals were affiliated with the CDC or ACIP at the time of the January 2026 Memo. Since then, Jayanta Bhattacharya, who had been serving as the Director of the National Institutes of Health, was appointed acting Director of the CDC. *Acting Director*, CDC (Feb. 18, 2026), <https://www.cdc.gov/about/leadership/director.html> [<https://perma.cc/KK9Y-WJKV>].

²⁵ Presidential Mem., *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries* (Dec. 5, 2025), <https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/> [<https://perma.cc/P67Y-8UQL>].

and the scientific evidence underlying those practices.” Dkt. 185-18 at 2–3; *see also* Dkt. 185-19 (HHS assessment reviewing peer nations’ vaccination practices). ACIP was not involved in this change. *See generally* Dkt. 185-18; *see also* Dkt. 232 at 22–23 (arguing that the CDC had authority to modify the immunization schedules without consulting ACIP).

B. Likelihood of Success on the Merits

The APA provides that courts must “hold unlawful and set aside agency action” that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right”; “arbitrary” or “capricious”; or “otherwise not in accordance with law.” 5 U.S.C. § 706(2). Plaintiffs contend that they are likely to establish that Defendants violated the APA because the January 2026 Memo, May 2025 Directive, and 2025 ACIP Votes were arbitrary and capricious, and because the reconstituted ACIP does not comport with FACA. In opposition, Defendants argue that Plaintiffs lack standing to assert these claims, that the January 2026 Memo, May 2025 Directive, and 2025 ACIP Votes are not reviewable because they are not final agency action and are committed to agency discretion by law, and that none of the Challenged Actions violated the APA. The Court addresses each in turn.

1. January 2026 Memo

a. Standing

Defendants reassert standing arguments made in their motion to dismiss. Dkt. 232 at 38–42. The Court rejected those arguments in that posture, *see AAP I*, 2026 WL 33719, at *4–8, and does so here again.²⁶

²⁶ The Court notes that its standing determination did not previously, and does not now, turn on every harm Plaintiffs have alleged in their Complaint and various declarations. *See, e.g., All. for Hippocratic Med.*, 602 U.S. at 393–94 (recognizing that a perceived need to engage in issue advocacy does not constitute an injury for standing purposes).

b. Final Agency Action

Defendants argue that the January 2026 Memo is not “final agency action” and thus not reviewable. Dkt. 232 at 20–21 (quoting 5 U.S.C. § 704). In particular, Defendants highlight that the CDC’s immunization schedules are styled as sets of “recommendations” that Defendants assert are “non-binding for States and localities,” characterizing any other consequences as merely “collateral.” Dkt. 232 at 21. However, in so arguing, Defendants fail to acknowledge the legal consequences of the CDC’s immunization schedules and therefore of the January 2026 Memo.

Under the APA, agency action is considered “final” when it is “the ‘consummation’ of the agency’s decisionmaking process,” and an action “by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). Where a decision is so memorialized, an “agency statement . . . designed to implement, interpret, or prescribe law or policy” constitutes the relevant action. *Cf. Biden v. Texas*, 597 U.S. 785, 810 (2022) (quoting 5 U.S.C. § 551(4)). Generally, courts take a “‘pragmatic’ approach” to APA finality. *U.S. Army Corps of Eng’rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016) (quoting *Abbott Lab’ys v. Gardner*, 387 U.S. 136, 149 (1967)).

To begin, the CDC’s vaccine schedule sets the liability regime for healthcare providers. As Secretary Kennedy himself has pointed out, if healthcare providers’ recommendations “diverge from the CDC’s official list[,] [they] are not shielded from liability under the 1986 Vaccine Injury Act.”²⁷ Thus, in changing the content of the CDC’s vaccine ‘recommendations,’ the January 2026

²⁷ Robert F. Kennedy, Jr. (@SecKennedy), X (Aug. 19, 2025, at 17:17 ET), <https://x.com/SecKennedy/status/1957914911415153107> [<https://perma.cc/RRE6-V8Y5>] (cited at Compl. ¶ 124 n.117). “The Vaccine Act establishes a no-fault compensation program pursuant to which a person injured by a covered vaccine may file a petition for compensation in the U.S. Court of Federal Claims, naming the Secretary of Health and Human Services as the respondent.” *In re Gardasil Prods. Liab. Litig.*, 619 F. Supp. 3d 1356, 1357 n.4 (U.S. Jud. Pan. Mult. Lit. 2022).

Memo has the coercive effect of “expos[ing] [healthcare providers] to . . . civil liability.”²⁸ Cf. *Parsons*, 878 F.3d at 167; see also *Gen. Elec. Co. v. Env’t Prot. Agency*, 290 F.3d 377, 383 (D.C. Cir. 2002) (“[I]f the language of [a] document is such that private parties can rely on it as a norm or safe harbor by which to shape their actions, it can be binding as a practical matter.” (quoting Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidances, Manuals, and the Like—Should Federal Agencies Use Them to Bind the Public?*, 41 Duke L.J. 1311, 1329 (1992))). Clearly, changing legal liability for vaccine administration is agency action from which “legal consequences will flow.” See *Bennett*, 520 U.S. at 178 (quoting *Port of Bos. Marine Terminal Ass’n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)); *Parsons v. U.S. Dep’t of Just.*, 878 F.3d 162, 167 (6th Cir. 2017) (“[A]gency actions that expose an individual to criminal or civil liability cause legal consequences.”).²⁹

The CDC’s immunization schedules moreover determine patients’ entitlement to care. Under federal law, patients are entitled to have their insurers cover, at no cost, vaccines recommended by the CDC. 42 U.S.C. § 300gg-13(a)(2); 45 C.F.R. § 147.130(a)(ii). The immunization schedules likewise determine certain veterans’ benefits, 38 U.S.C. § 1701(9)(G), Medicaid benefits, 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(13)(B), and benefits under other programs, such as those benefiting low-income children, *id.* § 1396s(a)(2)(A), (d)(1).

²⁸ See, e.g., *Covered Vaccines*, Health Resources & Servs. Admin. (Jan. 2026), <https://www.hrsa.gov/vaccine-compensation/covered-vaccines> [<https://perma.cc/6N5S-3HGM>] (“For a vaccine to be covered, the Centers for Disease Control and Prevention (CDC) must recommend the category of vaccine for routine administration to children or pregnant women, and it must be subject to an excise tax by federal law.”); *Frequently Asked Questions*, Health Resources & Servs. Admin. (Jan. 2026), <https://www.hrsa.gov/vaccine-compensation/faq> [<https://perma.cc/58SZ-Q9YH>] (same).

²⁹ The Court need not resolve the extent to which changing the recommendations from routine to SCDM impacts doctors’ liability under this act. The fact is that CDC changes to its immunization schedules impact liability.

While Defendants downplay the cascading effect of the CDC’s immunization schedules as implemented through local law and policy, *see* Dkt. 232 at 21, that is an overtechnical analysis that ignores “pragmatic” reality, *see Hawkes*, 578 U.S. at 599 (quoting *Abbott*, 387 U.S. at 149). States risk catastrophic losses of funding if they fail to follow the CDC’s ‘recommendations.’ *See, e.g.*, 42 U.S.C. § 1396c. And even where funding is not at issue, states necessarily act against the backdrop of federal law, which establishes nationwide industry standards, *see, e.g.*, 42 U.S.C. § 300gg-13(a), and thus constrains states’ individual power as a matter of administrability, *cf. Appalachian Power Co. v. Env’t Prot. Agency*, 208 F.3d 1015, 1023 (D.C. Cir. 2000) (“The short of the matter is that the Guidance, insofar as relevant here, is final agency action, reflecting a settled agency position which has legal consequences both for State agencies administering their . . . programs and for [other regulating entities].”); *Texas v. United States*, 809 F.3d 134, 152–53 (5th Cir. 2015) (in standing analysis, recognizing practical consequences of federal action under state law), *aff’d by an equally divided court*, 579 U.S. 547 (2016).³⁰ It is thus unrealistic to talk about more localized consequences as merely the product of states’ choosing to adopt a set of helpful suggestions by the CDC.

c. Contrary to Law

Defendants next argue that, even if the January 2026 Memo is final agency action, it is not reviewable under the APA because it is an action “committed to agency discretion by law.”

³⁰ For further comparison, *see Parsons v. United States Department of Justice*, 878 F.3d 162 (6th Cir. 2017). In *Parsons*, the Sixth Circuit held that the Attorney General’s designation of a group of musical fans as a “loosely-organized hybrid gang” was not final agency action, *id.* at 165, even though it resulted, for example, in one member’s being “detained and questioned numerous times by . . . state and local law-enforcement officers,” *id.* at 166. The court held that these consequences were not attributable to the federal designation because the state officers had only “discretionarily relied on the gang designation.” *Id.* at 170 (concluding that “the government officials’ actions . . . [were] the product of their own independent decisionmaking”). By contrast, as relevant here, individual entities’ compliance with the CDC’s vaccine schedule, under the states’ laws, is not “discretionar[y].” *Cf. id.* And those state laws were themselves enacted against the backdrop of a complex statutory and regulatory regime that, in a number of instances provided in this section, effectively requires states to adopt the vaccine schedule.

Dkt. 232 at 19–20 (quoting 5 U.S.C. § 701(a)(2)). However, Defendants’ argument presupposes that Director O’Neill had authority to issue the order in the first place. “An agency, after all, ‘literally has no power to act’—including under its regulations—unless and until Congress authorizes it to do so by statute.” *Fed. Election Comm’n v. Cruz*, 596 U.S. 289, 301 (2022) (quoting *La. Pub. Serv. Comm’n v. Fed. Commc’ns Comm’n*, 476 U.S. 355, 374 (1986)).

Here, Congress has required ACIP’s involvement in the issuance of the immunization schedules. The CDC must, at least, consider ACIP’s recommendations before adopting an immunization schedule, and following or failing to follow that requirement is reviewable by this Court.³¹ For example, the Affordable Care Act requires insurers to provide, at no cost, “immunizations that have in effect *a recommendation from [ACIP]*.” 42 U.S.C. § 300gg-13(a)(2) (emphasis added). Veterans’ health benefits are likewise tied to the “recommended adult immunization schedule,” 38 U.S.C. § 1701(9)(G), defined as “*the schedule established . . . by [ACIP]*,” *id.* § 1701(10) (emphasis added). Medicaid plans likewise must provide “approved *vaccines recommended by [ACIP]*.” 42 U.S.C. § 1396d(a)(13)(B); *see id.* § 1396a(a)(10)(A). And, similarly, the Vaccines for Children program requires the HHS Secretary to purchase pediatric vaccines for states according to “*the list established . . . by [ACIP]*.” *Id.* § 1396s(d)(1), (e) (emphasis added). As to each instance, Congress’s mention of ACIP would be rendered pure surplusage if the CDC Director were empowered to act entirely apart from it. *But see Fischer v. United States*, 603 U.S. 480, 486 (2024) (“[Courts] must ‘give effect, if possible, to every clause and word of [a] statute.’” (quoting *Williams v. Taylor*, 529 U.S. 362, 404 (2000))).

³¹ Because Director O’Neill acted entirely apart from ACIP, the Court need not decide whether the Director’s role is precisely limited to “adopt[ing]” ACIP’s formal recommendations. *Cf.* Dkt. 237 at 16; *see also* 45 C.F.R. § 147.130(a)(1)(ii) (“[A] recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention.”).

Defendants argue that Director O’Neill could unilaterally change the immunization schedules without consulting ACIP pursuant to the HHS Secretary’s general authority to “assist” and “advise” states and localities on public health matters.³² Dkt. 232 at 19 (quoting 42 U.S.C. § 243(a)). But that argument ignores the multiple other statutes listed above that directly contemplate ACIP as, at least, a meaningful participant in any change to the CDC’s immunization schedules.³³ *See Mellouli v. Lynch*, 575 U.S. 798, 809–10 (2015) (“Statutes should be interpreted ‘as a symmetrical and coherent regulatory scheme.’” (quoting *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000))). “A well established canon of statutory interpretation succinctly captures the problem: ‘[I]t is a commonplace of statutory construction that the specific governs the general’”:

³² Indeed, Defendants argue that the Secretary’s authority under 42 U.S.C. § 243(a) is so broad that he could withdraw all immunization schedules, following no protocol at all. *See* Dkt. 260 at 154:17–19 (“[Defense counsel:] Indeed, the agency has discretion whether to issue immunization schedules at all and even more discretion about what to consider in issuing those schedules.”); *see also id.* at 132:12–15 (“THE COURT: So even if what the agency was saying is we like communicable diseases and we think you should get more of them, that’s not judicially reviewable. [Defense counsel]: No.”); Dkt. 283 at 52:5–9 (“THE COURT: . . . if the secretary said instead of getting a vaccine -- instead of getting a vaccine to prevent measles, I think you should get a shot that gives you measles; is that unreviewable? [Defense counsel]: Yes.”).

³³ The CDC’s immunization schedules and ACIP’s recommendations are necessarily linked. ACIP makes no recommendations apart from the immunization schedules, *see* ACIP Charter at 2–3, and the CDC does not issue any separate immunization schedule, *see, e.g., General Committee-Related Information*, CDC (Aug. 12, 2025), <https://www.cdc.gov/acip/about/index.html> [<https://perma.cc/36Y9-X69B>] (“CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP*.” (emphasis added)). It defies logic that the CDC could retain independent discretion as to the creation or revision of the immunization schedules where Congress has explicitly tied obligations to ACIP’s exercise of that same authority. That ACIP also takes an additional vote to direct which pediatric vaccines the HHS Secretary purchases for states under the Vaccines for Children program, *see* 42 U.S.C. § 1396s(d)(1), (e), does not change this conclusion.

The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission. . . . But the canon has full application as well to statutes such as the one here, in which a general authorization and a more limited, specific authorization exist side-by-side. There the canon avoids not contradiction but the superfluity of a specific provision that is swallowed by the general one.

RadLAX Gateway Hotel, LLC v. Amalgamated Bank, 566 U.S. 639, 645 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)). Thus, Defendants cannot rely on the Secretary’s “general authorization” to override “specific authorization[s]” that overwhelmingly implicate ACIP. *Cf. id.*

The CDC’s own guidance documents and historical practice provide “one more reason yet to question whether [Defendants’] current position represents the best view of the law.” *Bittner v. United States*, 598 U.S. 85, 97 (2023) (“[C]ourts may consider the consistency of an agency’s views when . . . weigh[ing] the persuasiveness of any interpretation it proffers in court.”). By the CDC’s own words, “CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP*.” *General Committee-Related Information*, *supra* note 33 (emphasis added). The CDC immunization schedules themselves cite ACIP’s recommendations. *See, e.g.*, Dkt. 185-3 at 2; Dkt. 185-4 at 2. Moreover, in establishing ACIP’s Policies and Procedures, the agency described a robust process by which the CDC Director was to adopt or reject ACIP recommendations, with required documentation at each step. *See Advisory Committee on Immunization Practices Policies and Procedures* 8, *supra* note 5. By all accounts, this was the consistent practice of the CDC for decades.

In sum, Congress has spoken directly to the CDC’s immunization schedules and has required ACIP’s specific involvement. This rule governs over any more general authorization to “assist” or “advise.” *See* 42 U.S.C. § 243(a); *cf. RadLAX*, 566 U.S. at 645. It is undisputed that Director O’Neill issued the January 2026 Memo without sufficiently consulting ACIP, *see*

generally Dkt. 185-18.³⁴ Therefore, he lacked authority to issue the January 2026 Memo and, in so doing, acted contrary to law.

d. Not Committed to Agency Discretion

Even if one reads the above-cited authorities more loosely, Congress has at least established standards that this Court can apply to evaluate the issuance of the January 2026 Memo such that it was not “committed to agency discretion,” as Defendants argue. Dkt. 232 at 18–20. The APA exempts from judicial review actions that are “committed to agency discretion by law.” 5 U.S.C. § 701. However, the Supreme Court has interpreted this exception “quite narrowly, restricting it to those rare circumstances where the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency’s exercise of discretion.” *Dep’t of Com. v. New York*, 588 U.S. 752, 772 (2019) (internal quotation marks omitted) (quoting *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 586 U.S. 9, 23 (2018)). The exception is “generally limited . . . to ‘certain categories of administrative decisions that courts traditionally have regarded as “committed to agency discretion.”’” *Id.* (quoting *Lincoln v. Vigil*, 508 U.S. 182, 191 (1993)).

Defendants point the Court to no cases, nor could the Court find any such case, suggesting that the kind of regulatory power at issue in this case has been “traditionally” recognized, *cf id.*, as committed to agency discretion. *See* Dkt. 232 at 18–20. Nevertheless, Defendants argue that the HHS Secretary’s statutory authority to “‘assist States and their political subdivisions in the prevention and suppression of communicable diseases’ and ‘advise the several States on matters

³⁴ The assessment underlying the January 2026 Memo cites in part to the September and December ACIP Votes. Dkt. 185-19 at 21, 25. That does not address the fact that ACIP had no role in any of the *other* changes to vaccine recommendations in the January 2026 Memo.

relating to the preservation and improvement of the public health” provides no judicially manageable standards for this Court to apply. *See* Dkt. 232 at 19 (quoting 42 U.S.C. § 243(a)).

This argument can only be countenanced if one completely abandons the idea of objective fact, a nihilist endeavor this Court does not find appropriately read into Congress’s public health statutes. An exchange during oral argument sums it up well:

THE COURT: . . . let’s say that instead of revising the vaccine schedule, the CDC said, actually, we think measles is good for you; you should go have lunch with someone with measles, and we are sponsoring measles lunches in every city, come have some measles lunch, that would seem to -- that would seem to go right up against the goal of preventing communicable diseases. Would such a policy by the CDC be judicially reviewable?

[DEFENSE COUNSEL:] I think that would still be committed to agency discretion by law.

THE COURT: So even if what the agency was saying is we like communicable diseases and we think you should get more of them, that’s not judicially reviewable.

[DEFENSE COUNSEL:] No.

Dkt. 260 at 132:3–15.³⁵ Suffice it to say that the Court disagrees and would be unlikely to find much difficulty, for example, in assessing whether the Secretary’s theoretical endorsement of getting a communicable disease like measles could reasonably be calculated to advance “the prevention and suppression of communicable diseases.” *See* 42 U.S.C. § 243(a). This common-sense reading is further reinforced by neighboring statutes that, for example, direct the Secretary to fund “a national, evidence-based campaign to *increase awareness and knowledge of the safety and effectiveness of vaccines* for the prevention and control of diseases, combat

³⁵ *See also* Dkt. 283 at 52:5–9 (“THE COURT: . . . if the secretary said instead of getting a vaccine -- instead of getting a vaccine to prevent measles, I think you should get a shot that gives you measles, is that unreviewable? [DEFENSE COUNSEL:] Yes.”). Even though this example is somewhat ridiculous, it is appropriate to note that the Court does not necessarily prejudice even this hypothetical, appreciating that counterintuitive solutions (particularly in the complex realms of health and science) can sometimes be correct (or at least reasonable). Notwithstanding this complexity, the underlying question is nonetheless fully addressable.

misinformation about vaccines, and disseminate scientific and evidence-based vaccine-related information, *with the goal of increasing rates of vaccination across all ages*, as applicable, particularly in communities with low rates of vaccination, to reduce and eliminate vaccine-preventable diseases.” *Id.* § 245(a) (emphases added). It would be quite strange for Congress, in one statute, to authorize the Secretary to “assist” states by encouraging the spread of communicable diseases, *see id.* § 243(a), while, in another statute, requiring the Secretary to work toward “eliminat[ing]” the spread of communicable diseases, *see id.* § 245(a).

Moreover, Defendants’ narrow focus on the Secretary’s “assist” and “advise” authority continues to ignore the broader statutory context within which the CDC issues its immunization schedules. As set forth above, Congress has interwoven and given special effect to the immunization schedules through other statutes, which overwhelmingly implicate ACIP, a recognized body of health experts. *See, e.g.*, 42 U.S.C. § 300gg-13(a)(2). These delegations demonstrate Congress’s intent that decisions be made in accordance with “specialized experience and judgment,” rather than by fiat, untethered to scientific basis or reasoning. *Cf. Tummino v. Hamburg*, 936 F. Supp. 2d 162, 185 (E.D.N.Y. 2013).

The CDC’s consistent past practice with respect to its immunization schedules provides yet another baseline against which this Court might assess the January 2026 Memo’s reasonability. The CDC has consistently treated its role in promulgating the immunization schedules as arising only after ACIP has issued a recommendation. *See supra* p. 17. Put simply, this is not the kind of agency action that is “committed to agency discretion” and not subject to APA review.

e. Arbitrary and Capricious

Having determined that the issuance of the January 2026 Memo is reviewable, the Court concludes that, in addition to being contrary to law, the issuance of the January 2026 Memo was arbitrary and capricious because it abandoned the agency’s longstanding practice of getting

recommendations from ACIP before changing the immunization schedules without sufficient explanation. As discussed above, the CDC cannot simply bypass ACIP in altering the immunization schedules. *See supra* Section III.B.1.c. Even were this not a legal requirement, however, the record contains no explanation for why Defendants circumvented this decades-old practice, other than to comply with a Presidential Memorandum.³⁶

“The APA’s arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained.” *Fed. Comm’n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). “A 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.” *Id.* The “reasoned explanation requirement . . . is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public.” *Dep’t of Com.*, 588 U.S. at 785.

Defendants cannot disregard the APA’s requirements simply because they are following the President’s orders. *See, e.g., New York v. Trump*, 2025 WL 3514301, at *9 (D. Mass. Dec. 8, 2025) (“Circuit precedent forecloses” the argument that “an agency is exempt from the requirements of § 706(2)(A) whenever it acts pursuant to a presidential command.”); *Nebraska v. Su*, 121 F.4th 1, 15 (9th Cir. 2024) (“[F]inal agency actions, even if implementing an executive order, are subject to judicial review under the APA.”). As the CDC itself explains, the “CDC sets the U.S. adult and childhood immunization schedules *based on recommendations from ACIP*.” *General Committee-Related Information*, *supra* note 33 (emphasis added). “If an agency,” like the CDC, “announces and follows—by rule or by settled course of adjudication—a general policy

³⁶ Presidential Mem., *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries*, *supra* note 25.

by which its exercise of discretion will be governed, an irrational departure from that policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as ‘arbitrary, capricious, [or] an abuse of discretion’ within the meaning of the [APA].” *Thompson v. Barr*, 959 F.3d 476, 484 (1st Cir. 2020) (alteration in original) (quoting *Immigr & Naturalization Serv. v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996)).

While there might be circumstances that could justify bypassing ACIP, the record lacks any explanation, let alone a reasoned one.³⁷ See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“The reviewing court should not attempt itself to make up for such deficiencies: we may not supply a reasoned basis for the agency’s action that the agency itself has not given.”). On the current record, the Court cannot conclude that Defendants “articulate[d] a satisfactory explanation for its action.” *Id.* at 43.

2. May 2025 Directive

Defendants argue that the challenge to the May 2025 Directive is moot because the Directive has been “overtaken” by the January 2026 Memo, Dkt. 272 at 20, and that the Directive is not “final agency action” subject to APA review because it is merely a “recommendation[] without concrete legal effects,” *id.* at 23.

Before turning to the merits of these arguments, it is worth spending a moment considering what the May 2025 Directive purports to do. The Directive “rescind[s]” the June 2022 “HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years” and “the CDC recommendation that pregnant women receive the

³⁷ Additionally, the individuals who advised Director O’Neill on the January 2026 Memo have no affiliation with the CDC and no statutory or regulatory role in the CDC’s vaccine policy development. See Dkt. 185-18 at 2 (noting that the recommendations to change the CDC’s immunization schedules came from the Director of the National Institutes of Health (Jayanta Bhattacharya), the Administrator for the Centers for Medicare and Medicaid Services (Mehmet Oz), and the Commissioner of Food and Drugs (Martin Makary)). Defendants have provided no explanation for relying on their recommendations rather than those of ACIP.

COVID-19 vaccine.” Dkt. 185-1 at 2. In addition, under the May 2025 Directive, “the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunizations Schedule by Age and recommended vaccines during pregnancy.” *Id.* Shortly after Secretary Kennedy issued the May 2025 Directive, the CDC made changes to the vaccine recommendations for pregnant women and “healthy” children. *See generally* Dkt. 185-3.

The relationship between these related agency actions complicates the inquiry as to mootness and finality: the May 2025 Directive is unreviewable if it was *not* a final agency action, but even if it *was* a final agency action, it may have been mooted by subsequent agency actions. To begin, Defendants may be correct that the May 2025 Directive is not final agency action because it does not “mark[] the ‘consummation’ of the agency’s decisionmaking process” and is therefore not an action “by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Bennett*, 520 U.S. at 178 (citations omitted). This characterization is supported by the fact that shortly after the May 2025 Directive was issued, the CDC implemented it by making changes to the COVID vaccine recommendations for pregnant women and “healthy” children. *See* Dkt. 185-3 at 3–6; *see also* Dkt. 185-4 at 5. Notably, the CDC downgraded the recommendation for “healthy” children to SCDM, but did not remove the COVID vaccine from the schedule as instructed by the May 2025 Directive. Dkt. 185-3 at 3, 6. This suggests that the May 2025 Directive was not the “consummation of the agency’s decisionmaking process,” but rather an underlying policy, while the CDC’s implementation thereof and the January 2026 Memo were final agency actions “from which legal consequences [] flow[ed].” *Bennett*, 520 U.S. at 178 (citations and internal quotation marks omitted); *see also supra* Section III.B.1.a. If this is the case, the May 2025 Directive is not final agency action subject to review under the APA. *See* 5 U.S.C. § 704.

If, as Plaintiffs contend, however, the May 2025 Directive *was* a final agency action—also a reasonable proposition, given that the Directive purports to “rescind” prior CDC recommendations and HHS ratifications thereof and to direct agency staff’s actions, Dkt. 185-1 at 2—that action was likely mooted by the CDC’s change to the childhood vaccine schedule made shortly thereafter, which was also, itself, final agency action, as discussed above.³⁸ *See Anderson v. U.S. Dep’t of Hous. & Urb. Dev.*, 731 F. Supp. 3d 19, 31 (D.D.C. 2024) (“[W]hen one agency action supersedes another, prospective challenges to the superseded agency action generally become moot. In those circumstances, vacating the old agency action will not deliver the plaintiff any relief. The new agency action, not the old one, is what injures the plaintiff going forward.” (citations omitted)). Under this reading, it is the CDC’s changed immunization schedules that are the source of Plaintiffs’ alleged harms. Thus, the challenge to the May 2025 Directive would “no longer [be] a ‘Case’ or ‘Controversy’ for purposes of Article III.” *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quoting *Murphy v. Hunt*, 455 U.S. 478, 481 (1982)); *see also id.* (“No matter how vehemently the parties continue to dispute the lawfulness of the conduct that precipitated the lawsuit, the case is moot if the dispute is no longer embedded in any actual controversy about the plaintiffs’ particular legal rights.” (internal quotation marks omitted)). Put simply, if the May 2025 Directive is *not* a final agency action, it is unreviewable, and if it *is* a final agency action, it may have been mooted by subsequent agency actions.

The Court need not determine at this preliminary stage which characterization of the May 2025 Directive is correct. The Court need only determine, as it does here, that Plaintiffs have not met their burden of establishing that their challenge to the May 2025 Directive presents a

³⁸ In light of this conclusion, the Court need not address whether the January 2026 Memo may also have mooted the May 2025 Directive, as argued by Defendants. *See* Dkt. 272 at 20.

justiciable claim that Plaintiffs are likely to win on the merits. Because it is not clear that Plaintiffs’ challenge is viable on threshold questions of mootness and finality, the Court need not evaluate whether Plaintiffs would have standing to bring such a challenge.³⁹

3. ACIP Reconstitution

a. Standing

As with the January 2026 Memo, the Court rejects Defendants’ standing arguments that are based on the same theories articulated in their motion to dismiss. *See supra* Section III.B.1.a. But the parties also raise a new argument: whether Plaintiffs have standing to pursue their FACA claim insofar as standing is based on the termination of Organizational Plaintiffs’ participation in ACIP working groups. Dkt. 232 at 42–43.

Both parties’ argument on this misses the point. FACA’s “‘fairly balanced’ requirement was designed to ensure that persons or groups directly affected by the work of a particular advisory committee would have some representation on the committee,” and, therefore, when that “requirement is ignored, persons having a direct interest in the committee’s purpose suffer injury-in-fact sufficient to confer standing to sue.” *Am. First Legal Found. v. Cardona*, 630 F. Supp. 3d 170, 180 (D.D.C. 2022) (quoting *Nat’l AntiHunger Coal. v. Exec. Comm. of President’s Private Sector Survey on Cost Control*, 711 F.2d 1071, 1074 n.2 (D.C. Cir. 1983)); *see also Nat’l Ass’n of Consumer Advocs. v. Uejio*, 521 F. Supp. 3d 130, 144–45 (D. Mass. 2021) (same); *NAACP Legal Def. Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 129 (D.D.C. 2020) (collecting cases). Plaintiffs, comprised of professional medical organizations and individual patients, clearly have “a direct interest in [ACIP’s] purpose,” *Am. First*, 630 F. Supp. 3d at 180, which is the

³⁹ *See, e.g., Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (considering mootness before standing). Similarly, the Court will not analyze the remaining factors for preliminary relief as to the May 2025 Directive, because likelihood of success is the “sine qua non” for preliminary relief. *New Comm*, 287 F.3d at 9.

“effective control of vaccine-preventable diseases in the civilian population of the United States.”⁴⁰ Organizational Plaintiffs’ past participation in ACIP working groups merely demonstrates the obvious—ACIP’s actions “directly affect[]” them in their line of work. *See Am. First*, 630 F. Supp. 3d at 180. In other words, Organizational Plaintiffs’ past participation in ACIP working groups evidences the fact that an unfairly balanced ACIP causes them current injury and Plaintiffs thus have standing to assert that ACIP is not “fairly balanced” under FACA.

b. Contrary to Law

Plaintiffs contend that the reconstitution of ACIP violated FACA, Dkt. 237 at 43–49, which governs the functions and operations of advisory committees that provide expert recommendations to the executive branch, *see* 5 U.S.C. § 1001(2)(A). “FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest.” *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020); *see also* 5 U.S.C. § 1004(b)(2) (requiring “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”). As the First Circuit has noted, “[t]here are certainly many different points of view that [an agency] might take into account in forming its committees and different balances that can be struck in a committee’s membership.” *Union of Concerned Scientists*, 954 F.3d at 19. The Court must assess whether, in light of “the functions assigned to [the] committee[,] . . . its balance is fair.” *Id.* at 20. More specifically:

⁴⁰ ACIP Charter at 2. This version of the ACIP charter was revised on December 3, 2025, and has as a filing date of April 1, 2026. *Id.* at 6. However, prior versions of the charter contained the same or substantially similar language. *See, e.g.*, Kalwant Smagh, *Amendment to the Charter of the Advisory Committee on Immunization Practices*, CDC (April 1, 2024), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/6CNV-L5XR>]. Any differences between the two versions are not material to this motion.

[A]gencies should ensure that they fully consider and understand the potential implications or anticipated impacts of the advisory committee’s potential recommendations. This includes consideration of the groups and entities potentially affected or interested in such recommendations, as appropriate based on the nature and functions of the advisory committee, so that the agency can make informed decisions on the areas of expertise or perspectives that would advance the work of the advisory committee. *Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.*

41 CFR § 102-3.60(b)(1).⁴¹ Furthermore, “[h]aving identified the points of view that would promote a fairly balanced advisory committee membership, agencies should conduct broad outreach.”⁴² *Id.* § 102-3.60(b)(2).

The Court begins with ACIP’s function. ACIP is responsible for “develop[ing] recommendations on the use of vaccines in the civilian population of the United States.”⁴³ These recommendations trigger various obligations in the U.S. health care system. *See supra* Section III.B.1.b; *see also, e.g.*, 42 U.S.C. § 300gg-13(a)(2) (requiring insurers to provide, at no cost, “immunizations that have in effect a recommendation from [ACIP]”). To accomplish this purpose, ACIP considers “disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and

⁴¹ FACA requires that all agency heads “establish uniform administrative guidelines and management controls for [their] advisory committees” and “maintain systematic information on the . . . operations of each advisory committee within its jurisdiction.” 5 U.S.C. § 1007(a). Any advisory committee guidelines and management controls must be “consistent with directives of the [General Services Administration] Administrator,” *id.*, pursuant to their authority to “prescribe administrative guidelines and management controls applicable to advisory committees,” *id.* § 1006(c). Defendants have done so through the ACIP Charter, Membership Balance Plan, and Policies and Procedures. *See generally* ACIP Charter; *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5; *Advisory Committee on Immunization Practices Policies and Procedures*, *supra* note 5.

⁴² The prior version of the regulations, in effect at the time of the majority of Secretary Kennedy’s new ACIP appointments, gave further instruction as to what “broad outreach” should entail, noting that the outreach should “us[e] a variety of means and methods[] to ensure that the call for nominees reaches the interested parties and stakeholder groups likely to possess those points of view.” 89 Fed. Reg. 27673, 27683 (Apr. 18, 2024).

⁴³ *General Committee-Related Information*, *supra* note 33; *see also* ACIP Charter at 2 (“ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States.”).

implementation issues.” Dkt. 185-21 (“ACIP Charter”) at 3. Plaintiffs contend that the current ACIP members lack the qualifications and expertise necessary to achieve ACIP’s function and that the majority shares Secretary Kennedy’s anti-vaccine views. Dkt. 237 at 22, 44–49. Defendants contend that the current ACIP is fairly balanced, made up of members that all have advanced degrees and expertise “from a wide range of clinical and research backgrounds.” Dkt. 232 at 33. While the Court generally defers to an agency’s scientific assessments and recognizes that “[t]here are certainly many different points of view that [an agency] might take into account in forming its committees and different balances that can be struck in a committee’s membership,” *Union of Concerned Scientists*, 954 F.3d at 19, the Court concludes that Plaintiffs are likely to succeed in showing that the reconstitution of ACIP violated FACA and was therefore not in accordance with law under the APA.

The Court acknowledges that many of the ACIP members have extensive expertise in their chosen fields. But “[a]dvisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience *relevant to the functions and tasks to be performed by the committee.*” 41 C.F.R. § 102-3.60(b)(1) (emphasis added). And ACIP’s own charter directs that the members of the committee:

shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety.

ACIP Charter at 5.⁴⁴ On this point, there are glaring gaps.⁴⁵

First, of the fifteen members currently on ACIP, even under the most generous reading, only six appear to have any meaningful experience in vaccines—the *very focus of ACIP*.⁴⁶ The Court does not suggest that the other members are not experts in their respective fields, only that the committee as reconstituted is not “fairly balanced in terms of . . . the functions to be performed.” 5 U.S.C. § 1004(b)(2); *see also* ACIP Charter at 5 (directing that members “*shall be*” “knowledgeable in the fields of immunization practices,” “have expertise in the use of vaccines and other immunobiologic agents,” “have expertise with clinical or laboratory vaccine research,” or “have expertise in assessment of vaccine efficacy and safety” (emphasis added)). At least six ACIP members—Dr. Hillary Blackburn,⁴⁷ Dr. Evelyn Griffin,⁴⁸ Dr. Joseph Hibbeln,⁴⁹ Dr. Kirk

⁴⁴ The Court finds the requirements provided in the ACIP Charter instructive for assessing the relevant points of view to be balanced, especially because FACA itself mandates the submission of a charter. *See* 5 U.S.C. § 1008. Pursuant to 5 U.S.C. § 1008(c)(1), advisory committees must maintain a charter that specifies the “expertise or experience required” of its members. 41 C.F.R. § 102-3.75(l).

⁴⁵ The Court respects the technical expertise and specialized judgement of federal agencies and recognizes that agencies are thus entitled to some deference in this determination. Nevertheless, “Congress enacted FACA to constrain executive discretion, suggesting it did not intend to preclude judicial review” of the fair balance requirement. *NAACP Legal Def. Fund*, 496 F. Supp. 3d at 135.

⁴⁶ When Plaintiffs filed their motion, they challenged the appointments of 14 members. One of those members, Dr. Kulldorff, is no longer a member of ACIP, Dkt. 272 at 14 n.3, and so the Court need not consider his appointment. Additionally, on February 27, 2026, Secretary Kennedy announced the appointments of two additional ACIP members. *Secretary Kennedy Appoints Two Physicians to CDC’s Advisory Committee on Immunization Practices*, *supra* note 17. As these most recent appointments post-date the filing of this motion, the Court need not evaluate the two newest members’ qualifications and expertise and will instead assume for purposes of this motion that they are both sufficiently qualified for membership on ACIP.

⁴⁷ Dr. Blackburn is a Doctor of Pharmacy and the Director of Medication Access and Affordability at AscensionRx. *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that she has any relevant vaccine-related experience or expertise.

⁴⁸ Dr. Griffin, the Surgeon General for the State of Louisiana, is “board-certified in obstetrics and gynecology, lifestyle medicine, and functional medicine.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that she has any relevant vaccine-related experience or expertise.

⁴⁹ Defendants describe Dr. Hibbeln, a psychiatrist and neuroscientist, as having “experience in clinical research, public health policy, and federal service” and whose “work has informed U.S. public health guidelines, particularly in maternal and child health.” *ACIP Membership Roster*, *supra* note 16. There is no evidence in the record that he has any relevant vaccine-related experience or expertise.

Milhoan,⁵⁰ Dr. James Pagano,⁵¹ Dr. Raymond Pollak,⁵²—appear to lack *any* expertise or professional qualifications *related to vaccines or immunization* as required by ACIP’s Charter.

See ACIP Membership Roster, supra note 16. An additional three of the current ACIP members—Dr. Retsef Levi,⁵³ Dr. Robert Malone,⁵⁴ and Dr. Catherine Stein⁵⁵—though they have

⁵⁰ Dr. Milhoan “is a pediatric cardiologist and former U.S. Air Force flight surgeon,” who “holds a Ph.D. in the mechanisms of myocardial inflammation.” *ACIP Membership Roster, supra* note 16. There is no evidence in the record that Dr. Milhoan has any relevant vaccine-related experience or expertise.

⁵¹ Dr. Pagano “is a board-certified emergency medicine physician with more than 40 years of clinical experience.” *ACIP Membership Roster, supra* note 16. There is no evidence in the record that Dr. Pagano has any relevant vaccine-related experience or expertise.

⁵² Dr. Pollak “is a surgeon, transplant immunobiologist, and transplant specialist who has published more than 120 peer-reviewed works and served as principal investigator on NIH transplant biology grants and numerous drug trials.” *ACIP Membership Roster, supra* note 16. There is no evidence in the record that Dr. Pollak has any relevant vaccine-related experience or expertise.

⁵³ Defendants describe Dr. Levi, Professor of Operations Management at the MIT Sloan School of Management, as “a leading expert in healthcare analytics, supply chain and manufacturing analytics, risk management, and biologics and vaccine safety” and note that he has “collaborated with industry stakeholders and public health agencies to develop decision-support models to evaluate biologics and vaccine safety” and co-authored studies examining the association between mRNA COVID-19 vaccines and risks of cardiovascular disease, mortality, and adverse pregnancy outcomes.” *ACIP Membership Roster, supra* note 16. However, based on the current record, he has published only two papers discussing vaccines, and both of those were published mere months before his appointment. Retsef Levi, et al., *Twelve-Month All-Cause Mortality after Initial COVID-19 Vaccination with Pfizer-BioNTech or mRNA-1273 among Adults Living in Florida*, MedRxiv (Apr. 29, 2025), <https://www.medrxiv.org/content/10.1101/2025.04.25.25326460v1> [<https://perma.cc/NGN8-SARX>] (cited at Compl. ¶ 77(g) n.53); Josh Guetzkow, et al., *Observed-to-Expected Fetal Losses Following mRNA COVID-19 Vaccination in Early Pregnancy*, MedRxiv (June 20, 2025), <https://www.medrxiv.org/content/10.1101/2025.06.18.25329352v1.full-text> [<https://perma.cc/EKL3-ELMS>] (cited at Compl. ¶ 77(g) n.53). Publishing two papers on a topic, while no doubt relevant to ACIP, likely does not rise to the level of “expertise” called for under ACIP governing documents. *See Expertise*, Black’s Law Dictionary (12th ed. 2024) (defining “expertise” as “[s]kill or knowledge in a particular subject; specialized experience that gives rise to a facility that comparatively few people possess”).

⁵⁴ Defendants describe Dr. Malone, an adjunct professor at Pennington Biomedical Research Center, Louisiana State University, as “a vaccinologist, scientist, and biochemist known for his early contributions to mRNA vaccine technology” whose “expertise spans molecular biology, immunology, and vaccine development.” *ACIP Membership Roster, supra* note 16. The only evidence in the record of his experience related to vaccines is that he was involved in early research on mRNA technology in the 1980s and 1990s. *See id.* Even crediting that experience, the Court cannot conclude that this experience, thirty plus years ago, constitutes the requisite expertise necessary for ACIP today. Further, the scope of his role in that research is disputed, *see* Davey Alba, *The Latest Covid Misinformation Star Says He Invented the Vaccines*, N.Y. Times (Apr. 3, 2022), <https://www.nytimes.com/2022/04/03/technology/robert-malone-covid.html> (cited at Compl. ¶ 77(h) n.59), which the Court need not resolve at this juncture.

⁵⁵ Dr. Stein is a professor at Case Western Reserve University and “an epidemiologist with more than two decades of research experience on tuberculosis and infectious diseases and 115 peer reviewed publications.” *ACIP Membership Roster, supra* note 16. However, there is no evidence in the record that her experience and expertise relate to vaccines, vaccination, vaccine safety, or vaccine policy as to be relevant to ACIP’s function.

some experience arguably relevant to ACIP’s function, appear to lack the qualifications and experience to constitute *expertise in vaccines and immunization*. Compare *id.*, with ACIP Charter at 5.⁵⁶ In short, ACIP is not just a committee of doctors, or even a committee of public health experts; it is a committee specifically dedicated to the “use of vaccines and related agents for effective control of vaccine-preventable diseases.” ACIP Charter at 2. As to that specific function, the newly appointed members appear distinctly unqualified. A committee of non-experts cannot be said to embody “fairly balanced . . . points of view” within the relevant scientific community. See 5 U.S.C. § 1004(b)(2). It is more accurate to say that they do not represent points of view within the relevant expert community.

The deficiencies in ACIP’s membership become more pronounced when considered against ACIP’s own statements on what would constitute a fairly balanced committee. ACIP has a membership balance plan (“MBP”), which identifies specific considerations and requirements that the agency determined would ensure ACIP’s compliance with FACA.⁵⁷ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5. As relevant here, the MBP mandates that individual members have certain expertise: “expertise in the field of immunization practices”; “multi-disciplinary expertise in public health”; “expertise in the use of vaccines and immunologic agents”; or “knowledge of vaccine development, evaluation, safety and delivery.” *Id.* at 2. Further, the MBP directs the Steering Committee that recommends nominees for ACIP to consider

⁵⁶ The Court recognizes that there may be evidence to demonstrate that each of these individuals have more relevant experience or expertise than what is before the Court at this juncture. However, Defendants have provided no basis for the Court to assess how these individual’s experiences and qualifications relate to ACIP’s functions or evidence to contradict that of Plaintiffs, relying only on the ACIP website’s summary of credentials. See Dkt. 232 at 33–34. Thus, on the current record, there is no evidence to demonstrate that these individuals have the *relevant* expertise necessary for membership on ACIP.

⁵⁷ When Secretary Kennedy began reconstituting ACIP, advisory committees were required to have a MBP when establishing or renewing an advisory committee. 41 C.F.R. § 102-3.60(b)(3) (May 20, 2024). This requirement was removed from the regulation, effective on December 16, 2025. 90 Fed. Reg. 58408, 58408 (Dec. 16, 2025). Regardless, ACIP still has a governing MBP.

whether there is a “[b]alance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer issues, state and local health department perspective, academic perspective, public health perspective, etc.).” *Id.* at 3. Through the MBP, Defendants have set forth the requirements and procedures *they* think necessary to achieve a balanced committee that complies with FACA, *see generally id.*, and the MBP has guided appointments for decades, *see, e.g.*, 73 Fed. Reg. 72055 (Nov. 26, 2008) (soliciting nominations for ACIP membership and describing requirements using the MBP phrasing). The Court thus finds the MBP to be instructive as to how a fairly balanced ACIP might be achieved and what it would look like.

The lack of formality and process attending the new ACIP members’ appointment further validates the Court’s finding as to the end product. For example, the FACA regulations direct that, “[h]aving identified the points of view that would promote a fairly balanced advisory committee membership, agencies should conduct broad outreach.” 41 CFR § 102-3.60(b)(2).⁵⁸ Historically, this process took approximately two years, and as directed by ACIP’s MBP, involved a broad e-mail solicitation for potential candidates,⁵⁹ required applicants to submit a current curriculum vitae, letters of recommendation, a cover letter, and various forms related to conflicts and ethics, and included an in-depth review of applicants by the ACIP Steering Committee.⁶⁰ *See, e.g.*,

⁵⁸ *See supra* note 42.

⁵⁹ Including “to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations such as the National Medical Association and the National Hispanic Medical Association, academic centers, and other contacts in the field of vaccinology.” *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5.

⁶⁰ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5. The Court finds the requirements laid out in the ACIP MBP instructive, as they represent the agency’s determination of “the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance.” *Id.*

Dkt. 185-47 ¶¶ 6–8, 18–20; Dkt. 185-48 ¶¶ 8–10; Dkt. 289 ¶¶ 7–19.⁶¹ However, on the current record, the most generous description of the appointment process is that it took a few months and involved some limited outreach to candidates.⁶² Dkt. 240-1 ¶¶ 6–11; Dkt. 185-47 ¶ 24. Defendants also failed to issue a Federal Register notice and ignored the year-round online application process as set forth in ACIP’s MBP and Policies and Procedures.⁶³ This ad hoc outreach fails to comply with the spirit or letter of the FACA regulations governing outreach, all of which seek to promote FACA’s overarching goal of public accountability and transparency.⁶⁴

Even if these regulations are not binding, as Defendants contend, FACA itself directs that “*standards and uniform procedures* should govern the establishment . . . of advisory committees.” 5 U.S.C. § 1002(b)(4) (emphasis added). The Government’s failure to follow both longstanding practice and regulations aimed at ensuring that “the points of view that would promote a fairly balanced advisory committee membership” are represented on the committee is strong evidence

⁶¹ The Court allowed Plaintiffs’ motion for leave to file supplemental declarations. Dkt. 285. The Court did so in light of the nature of the case and motion, and recognizing that because Defendants were given an opportunity to respond, they were not substantially prejudiced. That said, the Court emphasizes that future requests to file last-minute, supplemental materials will not be regarded favorably.

⁶² There were only two days between the termination of the prior ACIP members and the announcement of the first batch of new members. *See, e.g.*, Dkt. 185-47 ¶ 24. However, it is possible that the review process for new applicants began earlier than the date of the terminations. That said, considering Secretary Kennedy was not confirmed to his position until February 13, 2025, Press Release, *Robert F. Kennedy, Jr. Sworn in as 26th Secretary at HHS, President Trump Signs Executive Order to Make America Healthy Again*, HHS (Feb. 13, 2025), <https://www.hhs.gov/press-room/eo-maha.html> [<https://perma.cc/2T54-RMJS>], the evidence suggests that the outreach and appointment process took less than four months, even under the most generous view.

⁶³ *Federal Advisory Committee (FAC) Membership Balance Plan*, *supra* note 5; *Advisory Committee on Immunization Practices Policies and Procedures*, *supra* note 5. Again, even treating these documents as non-binding, the lack of adherence to these prescribed procedures, designed to ensure compliance with FACA, provides strong evidence that the newly constituted ACIP likely violates FACA.

⁶⁴ FACA was passed out of growing “concerns that the number and membership of advisory committees had proliferated and that the committee operations were not consistent or transparent.” Meghan M. Stuessy & Kathleen E. Marchsteiner, Cong. Rsch. Serv., R47984, *The Federal Advisory Committee Act (FACA): Overview and Considerations for Congress* (2024). Accordingly, “FACA’s principal purpose was to enhance the public accountability of advisory committees established by the Executive Branch and to reduce wasteful expenditures on them.” *Pub. Citizen v. U.S. Dep’t of Just.*, 491 U.S. 440, 459 (1989)

that there is a FACA problem here. The Court reiterates that agencies generally have much discretion in assembling advisory committees. But the constellation of evidence before the Court strongly suggests that little, if any, attention was paid by Secretary Kennedy to the requirements of FACA when appointing the new ACIP members. In light of the evidence before the Court that many of the new members lack relevant experience, the Court concludes that Plaintiffs have demonstrated a strong likelihood of prevailing on the merits of their fairly balanced claim. Having so concluded, the Court need not address Plaintiffs' arguments about undue influence.⁶⁵

Moreover, for all of the reasons described above, the Court concludes that Plaintiffs are likely to succeed in demonstrating that the reconstitution of ACIP was arbitrary and capricious. Defendants have provided no explanation for their disregard of the requirements laid out in ACIP's Charter, MBP, and Policies and Procedures. This failure to articulate *any* reason, let alone a "satisfactory explanation for [the] action," renders the ACIP reconstitution unlawful. *Penobscot*, 164 F.3d at 719; *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016) ("Whatever potential reasons the Department *might have* given, the agency *in fact* gave almost no reasons at all." (emphases added)); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy sub silentio.").

C. Irreparable Harm

Plaintiffs have demonstrated that they are likely to face irreparable harm should the requested preliminary relief not issue. "'Irreparable injury' in the preliminary injunction context means an injury that cannot adequately be compensated for either by a later-issued permanent injunction, after a full adjudication on the merits, or by a later-issued damages remedy." *Rio*

⁶⁵ Nor will the Court address Plaintiffs' challenges to the 2025 ACIP Votes. *See infra* Section III.E.2 (discussing the scope of remedy).

Grande Cmty. Health Ctr., Inc. v. Rullan, 397 F.3d 56, 76 (1st Cir. 2005). “A finding of 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.” *Baptiste v. Kennealy*, 490 F. Supp. 3d 353, 381 (D. Mass. 2020) (quoting *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004)). “District courts have broad discretion to evaluate the irreparability of alleged harm and to make determinations regarding the propriety of injunctive relief.” *K-Mart Corp. v. Oriental Plaza, Inc.*, 875 F.2d 907, 915 (1st Cir. 1989) (quoting *Wagner v. Taylor*, 836 F.2d 566, 575–76 (D.C. Cir. 1987)).

1. January 2026 Memo

Plaintiffs and declarants describe a wide range of harms they contend are likely should the Court decline to issue preliminary relief. The Court focuses on two: the financial harm to Organizational Plaintiffs’ member doctors arising from uncompensated work now required because of the new immunization schedules and the financial harm to Organizational Plaintiffs arising from their work to support their members in complying with the Challenged Actions.⁶⁶

Defendants focus much of their opposition on whether these constitute harm, rather than whether such harms are irreparable. *See* Dkt. 232 at 45–50. Defendants do not dispute that by changing recommendations from routine to SCDM, they require Organizational Plaintiffs’ member doctors to engage in additional work, and instead argue that “creating space for a basic dialogue between physician and patient about whether to receive a vaccine hardly amounts to irreparable harm.” *Id.* at 49. But the issue here is not just lost time, but the lack of compensation.⁶⁷

⁶⁶ The Court is skeptical on the current record that some of the other harms alleged, such as Individual Plaintiffs’ anxiety, constitute irreparable harm. *See Charlesbank*, 370 F.3d at 162.

⁶⁷ Nor is magnitude of harm an issue. *See California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (explaining that the irreparable harm “analysis focuses on irreparability, ‘irrespective of the magnitude of the injury’” (quoting *Simula, Inc. v. Autoliv, Inc.*, 175 F.3d 716, 725 (9th Cir. 1999))).

See, e.g., Dkt. 185-25 ¶¶ 27, 31; Dkt. 185-26 ¶ 16; Dkt. 185-27 ¶ 16; Dkt. 185-28 ¶¶ 9, 11, 18–20; Dkt. 185-29 ¶¶ 21–23, 28–29; Dkt. 185-30 ¶¶ 10–11, 13, 16; Dkt. 185-31 ¶¶ 13; Dkt. 185-32 ¶¶ 18, 22–24; Dkt. 185-33 ¶¶ 8, 10–11, 13; Dkt. 185-36 ¶¶ 29, 31–33, 41; Dkt. 185-37 ¶¶ 13–15, 17, 31–33; Dkt. 185-38 ¶¶ 12–13, 19; Dkt. 185-40 ¶ 15; Dkt. 185-41 ¶¶ 22–27; Dkt. 185-42 ¶ 40; Dkt. 185-43 ¶¶ 13–18, 22, 26, 43; Dkt. 185-46 ¶¶ 13, 22–23; Dkt. 185-51 ¶¶ 37, 41–43; Dkt. 185-52 ¶¶ 10–12, 18; Dkt. 240-2 ¶ 11; Dkt. 287 ¶¶ 3–6, 11–12, 15. Plaintiffs’ declarations are clear that the harms they describe from the May 2025 Directive have also arisen from the January 2026 Memo.⁶⁸ *See, e.g.*, Dkt. 185-32 ¶¶ 22, 24. That such work is “part and parcel of a physician’s ordinary clinical responsibility,” Dkt. 232 at 49, merely demonstrates that this is the cost of compliance with the January 2026 Memo.

With regards to Organizational Plaintiffs, the expense of counseling members constitutes harm. Organizational Plaintiffs have detailed how they have been forced to divert resources away from their usual tasks and initiatives in response to the January 2026 Memo, and how that resource diversion has frustrated both specific initiatives and their broader organizational missions, which the Court finds compelling.⁶⁹ *See, e.g.*, Dkt. 185-25 ¶¶ 30–31; Dkt. 185-27 ¶¶ 26–28; Dkt. 185-34 ¶¶ 18–19, 39; Dkt. 185-36 ¶¶ 27, 40–41, 43; Dkt. 185-40 ¶¶ 9–10, 17; Dkt. 185-44 ¶¶ 23, 36, 39; Dkt. 185-46 ¶¶ 17–18; Dkt. 286 ¶¶ 2, 6(c), 6(e), 13; Dkt. 288 ¶¶ 14–15; *see also Mass. Fair Hous. Ctr.*, 496 F. Supp. 3d at 611 (finding irreparable harm where agency action “pose[d] a real and substantial threat of imminent harm to [plaintiff’s] mission by raising the burdens, costs, and effectiveness of disparate impact liability”); *City & County of San Francisco v. U.S. Citizenship & Immigr. Servs.*, 408 F. Supp. 3d 1057, 1126 (N.D. Cal. 2019) (finding irreparable injury where

⁶⁸ Nor is there any reason to believe that this would not be true.

⁶⁹ The Court notes it has previously rejected a similar argument from Defendants in the context of standing. *See AAP I*, 2026 WL 33719 at *7–8; *see also supra* Section III.B.1.a.

the goals of providing healthcare and legal services were frustrated and that plaintiffs' changes to their programs and other diversions of resources constituted irreparable harm), *aff'd sub nom.*, *City & County of San Francisco v. U.S. Citizenship & Immigr. Servs.*, 981 F.3d 742 (9th Cir. 2020).

Although harm is likely to be reparable when it is "almost purely economic," *Longo En-Tech P.R., Inc. v. Env't Prot. Agency*, 2017 WL 878442, at *8 (D.P.R. Mar. 6, 2017), economic harm can be irreparable when it is not compensable by legal remedies, *K-Mart*, 875 F.2d at 914; *see also California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018) (explaining that economic harm can be irreparable where there is no adequate remedy to recover those damages); *Wages & White Lion LLC v. U.S. Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021) (holding that "complying with [an agency order] later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs . . . because federal agencies generally enjoy sovereign immunity for any monetary damages" (first alteration and emphasis in original) (citations omitted)). Indeed, "[i]rreparable harm most often exists where a party has no adequate remedy at law." *Charlesbank*, 370 F.3d at 162. Thus, "[w]here a plaintiff stands to suffer a substantial injury that cannot be adequately compensated by an end-of-case award of money damages, irreparable harm exists." *Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003).

Plaintiffs could not recover monetary damages in this APA action or in any post-factum recovery action against the Government. As described above, the Court finds compelling Plaintiffs' evidence regarding the financial harm they and their members face because of the January 2026 Memo, independent of their ongoing advocacy work. The cost of complying with the January 2026 Memo is substantial, and there is no real dispute that Plaintiffs will have no avenue to recover those costs even if it is deemed unlawful.

That some of these injuries may be a result of third-party actions (such as insurers making coverage decisions) does not sever the causal connection between the challenged action and harm. “There must be a ‘sufficient causal connection’ between the alleged irreparable harm and the activity to be enjoined, and showing that ‘the requested injunction would forestall’ the irreparable harm qualifies as such a connection.” *Nat’l Wildlife Fed’n v. Nat’l Marine Fisheries Serv.*, 886 F.3d 803, 819 (9th Cir. 2018) (quoting *Perfect 10, Inc. v. Google, Inc.*, 653 F.3d 976, 981–82 (9th Cir. 2011)). “However, a plaintiff ‘need not further show that the action sought to be enjoined is the exclusive cause of the injury.’” *Id.* (quoting *M.R. v. Dreyfus*, 697 F.3d 706, 728 (9th Cir. 2012)). Here, Plaintiffs have demonstrated that but for the January 2026 Memo, they would not suffer these harms. For the reasons described above, *see infra* Section III.B.1.b. it is illogical to claim that the medical community’s response to Defendants’ changes to the immunization schedules is so unrelated to those changes that it breaks the causal connection. That suffices at this stage. For these reasons, the Court concludes Plaintiffs have met their burden of demonstrating irreparable harm as to the January 2026 Memo.

2. ACIP Reconstitution

Plaintiffs have also established that they are likely to suffer irreparable harm should ACIP continue to operate with an unbalanced committee. The current constitution of ACIP thwarts Congress’s intent to “to enhance the public accountability of advisory committees,” *Pub. Citizen v. Dep’t of Just.*, 491 U.S. 440, 459 (1989), by violating Congress’s “command that [advisory] committees be fairly balanced,” *Union of Concerned Scientists*, 954 F.3d at 20–21. Even a procedural violation can give rise to irreparable harm justifying injunctive relief because “the damage done by [the agency’s] violation of the APA cannot be fully cured by later remedial action.” *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 18 (D.D.C. 2009). A final

judgment vacating ACIP appointments would not remedy the harm caused in the immediate future by the committee's action. It would merely guard against further violations post-judgment.

Moreover, Plaintiffs have demonstrated that the harms described above will continue to arise out of further ACIP actions. While Defendants argue that it is merely “speculative” that ACIP will take any votes at a future meeting, Dkt. 254 at 3–4, the Court finds the evidence both credible and compelling that a vote is likely at ACIP's upcoming meeting. When the Court held its first hearing on this motion, ACIP had a meeting scheduled for the end of February, for which the ACIP Vice Chair explicitly stated an intention for ACIP to vote on changes to the Vaccines for Children Program. *See* Dkt. 240-2 ¶ 3.⁷⁰ While this statement does not *guarantee* that ACIP will take a vote or make any recommendation changes, Plaintiffs need not demonstrate that the anticipated harm is certain, merely that it is likely.⁷¹ *See League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (“Damocles’s sword does not have to actually fall . . . before the court will issue [relief].”). Moreover, since rescheduling the ACIP meeting to March 18–19, ACIP's published statement of “Matters to be Considered” now includes the possibility of

⁷⁰ *See also* Dr. Robert W. Malone, *CDC to Make Announcement on Children's Health Tomorrow*, Malone News (Dec. 18, 2025), <https://www.malone.news/p/hhs-cdc-to-make-announcement-on-childrens> [https://perma.cc/ACK8-KVKX] (“ACIP will need to vote during their next meeting to approve language aligning the Congressionally mandated Vaccines for Children program with the new schedule.”) (cited at Dkt. 240-2 ¶ 3 n.1).

⁷¹ It is not unreasonable for the Court to take the ACIP Vice Chair at his word. Indeed, it is merely Defendants' own speculation that ACIP will *not* act in accordance with the ACIP Vice Chair's statements.

additional recommendation votes.⁷² 91 Fed. Reg. 9617 (Feb. 26, 2026). On this record, the Court finds it likely that ACIP will take further action and therefore irreparably harm Plaintiffs.⁷³

D. Balance of the Equities and Public Interest

Finally, the Court must weigh the balance of the equities and determine whether preliminary relief would be in the public interest. “These two inquiries merge in a case like this one, where the Government is the party opposing the preliminary injunction.” *Devitri v. Cronen*, 289 F. Supp. 3d 287, 297 (D. Mass. 2018) (citing *Nken v. Holder*, 556 U.S. 418, 435 (2009)). For the reasons discussed below, these factors favor Plaintiffs.

“To begin with, the Plaintiffs’ likelihood of success on the merits lightens [Defendants’] stated interests.” *Huisha-Huisha v. Mayorkas*, 27 F.4th 718, 734 (D.C. Cir. 2022). The Supreme Court has confirmed that “our system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors v. Dep’t Health & Hum. Servs.*, 594 U.S. 758, 766 (2021); *see also Nat’l Fed’n Indep. Bus. v. Dep’t of Lab.*, 595 U.S. 109, 120–21 (2022) (staying an unlawful vaccine mandate even though the Government said the mandate would save more than 6,500 lives); *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 582 (1952) (affirming district

⁷² Defendants argued during the March 4, 2026 hearing that this statement was not a final agenda, and thus may change. *See* Dkt. 283 at 63:21–64:1. Regardless of the finality of ACIP’s agenda, it provides compelling evidence that ACIP does plan to take votes at the upcoming meeting. At this time, the Court has no reason to believe that ACIP will not act in accordance with its published plans.

⁷³ The Court takes a moment to acknowledge that this case presents a close call on the issue of irreparable harm. *See Dominion Video Satellite, Inc. v. Echostar Satellite Corp.*, 356 F.3d 1256, 1262 (10th Cir. 2004) (“Determining whether irreparable harm exists can be a difficult and close question.”); *id.* (“The concept of irreparable harm does not readily lend itself to definition.”). It cannot be that all agency action creates irreparable harm—though nearly every agency action is likely to create some type of compliance cost—as Courts regularly determine that plaintiffs challenging agency action have not met their burden on showing irreparable harm. And Defendants’ arguments about the timing of this case are well taken—the Court itself has consistently offered to expedite this case as much as possible and will continue to do so as the parties brief the merits. But after reviewing the numerous declarations from Plaintiffs’ and their members, the Court is satisfied that Plaintiffs have met their burden in this case. *See Coal. to Protest Democratic Nat’l Convention v. City of Boston*, 327 F. Supp. 2d 61, 69 (D. Mass. 2004) (“The greater the likelihood of success on the merits, the less risk of irreparable harm to the plaintiff must be shown.”), *aff’d sub nom.*, *Bl(a)ck Tea Soc’y v. City of Boston*, 378 F.3d 8 (1st Cir. 2004).

court’s preliminary injunction of an illegal executive order even though a wartime president said his order was “necessary to avert a national catastrophe”).

Plaintiffs and amici have demonstrated that there is a substantial risk to public health absent preliminary relief. *See, e.g.*, Dkt. 218 at 26–35; Dkt. 228 at 24–30; Dkt. 237 at 55–58, 60–61. The Court finds it telling that Defendants make little effort to directly oppose this point, arguing only that Plaintiffs’ requested relief goes against the public interest by restraining Defendants’ speech.⁷⁴ Dkt. 232 at 43–44.⁷⁵ But as discussed above, the Court is not dictating what vaccine-related content Defendants may or may not espouse.⁷⁶ Instead, the Court is regulating the procedure by which Defendants do so. “There is generally no public interest in the perpetuation of unlawful agency action.” *Newby*, 838 F.3d at 12. Thus, the Government “cannot suffer harm from an injunction that merely ends an unlawful practice.” *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013).

Nonetheless, even if Defendants ultimately prevail, a stay, at most, causes Defendants to suffer the minimal harm of continuing their previous approach to promulgating immunization schedules.⁷⁷ Defendants state that their efforts seek to increase vaccination rates in the interest of public health. *See, e.g.* Dkt. 260 at 104:19–22 (“[Defense counsel]: . . . the government’s goal is

⁷⁴ The closest Defendants come on this point is to argue that the purpose of the January 2026 Memo is to promote public trust in vaccines as a general proposition, thereby increasing vaccination rates and improving public health. *See, e.g.*, Dkt. 260 at 108:17–19, 112:18–21; 113:4–13. But that fails to respond to Plaintiffs’ and amici’s evidence on the current risk to public health arising from the reduction in vaccination rates for the *specific* diseases for which the CDC has downgraded the vaccine recommendations.

⁷⁵ Amici Children’s Health Defense raises concerns about the safety of many of the vaccinations at issue. *See generally* Dkt. 281. While the vaccinations may pose some health risk to some individuals, Children’s Health Defense’s proffered evidence does not demonstrate that the risks outweigh the broader benefits of the vaccines. On the record currently before the Court, the Court finds Plaintiffs’ and the other amici’s evidence more compelling on the public health risks.

⁷⁶ As discussed below, the relief the Court will issue is not as broad as that which Plaintiffs request. *See infra* Section III.E.

⁷⁷ *See infra* Section III.E.

to increase vaccine uptake of consensus vaccines such as the measles vaccine. So, again, this is not pro- versus anti-vaccine. Both sides here believe in vaccines.”). Even if Defendants do show after the production of the administrative record that Plaintiffs’ challenges amount only to a difference in opinion as to how best to best achieve these goals, merely returning to Defendants’ prior approach for a short period while the Court adjudicates the merits of Plaintiffs’ claims can hardly be said to impose such a burden that relief would go against the public interest, especially where Plaintiffs have demonstrated a likelihood of success on the merits and irreparable harm.⁷⁸ Thus, the balance of equities and public interest factors weigh in favor of preliminary relief.

E. Remedy

“[I]n drafting equitable relief, courts must consider ‘what is necessary, what is fair, and what is workable.’” *Massachusetts v. Nat’l Insts. of Health*, 770 F. Supp. 3d 277, 328 (D. Mass. 2025) (quoting *North Carolina v. Covington*, 581 U.S. 486, 488 (2017)), *aff’d*, 164 F.4th 1 (1st Cir. 2026). Plaintiffs ask the Court both to stay the Challenged Actions and enjoin Defendants from conducting further public meetings until there has been an adjudication on the merits. *See generally* Dkt. 183-1. Defendants do not dispute that a stay of the January 2026 Memo would be the appropriate remedy should the Court rule for the Plaintiffs but argue that any remedy preventing Defendants from conducting further public meetings is too broad. Dkt. 232 at 50–52.

1. January 2026 Memo

The parties largely agree that, should the Court issue relief as to the January 2026 Memo, a stay is appropriate. Dkt. 232 at 50 (“If the Court finds a defect in the January 2026 action, it should at most enter a stay of that action under the APA.”). In the face of the parties’ agreement,

⁷⁸ Defendants also argue that staying the current immunization schedules would result in “whiplash” that would be exacerbated should Defendants ultimately prevail on the merits. But given the Court’s conclusion that Plaintiffs have demonstrated a likelihood of success on the merits, this “whiplash” is likely a result of Defendants’ own unlawful creation, which does not outweigh the public interests raised by Plaintiffs and amici.

the Court finds that a stay of the January 2026 Memo is an appropriate remedy. *See, e.g., Haitian Evangelical Clergy Ass’n v. Trump*, 789 F. Supp. 3d 255, 274 (E.D.N.Y. 2025) (“[C]ourts ‘routinely stay already-effective agency action under Section 705.’” (quoting *Texas v. Biden*, 646 F. Supp. 3d 753, 770 (N.D. Tex. 2022) (collecting cases))); *see also West Virginia v. Env’t Prot. Agency*, 577 U.S. 1126 (2016) (staying an Environmental Protection Agency rule pending the outcome of the case). To the extent Plaintiffs seek further relief, *see* Dkt. 183-1 ¶ 2, the Court declines to grant it at this time.

2. ACIP

The parties disagree as to the appropriate remedy for Plaintiffs’ FACA challenge. Plaintiffs ask the Court to enjoin Defendants “from convening, holding, or conducting the ACIP meeting currently scheduled . . . as well as any subsequent ACIP meetings of the current ACIP membership.” Dkt. 183-1 ¶ 3.⁷⁹ Defendants contend that, “[i]f 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.” Dkt. 232 at 51.

The Court lands somewhere in the middle. Plaintiffs are likely to succeed in showing that the reconstituted ACIP does not comport with FACA’s “fairly balanced” requirement. The Court made this determination not on a mathematical formula but based on the unexplained departure from the MBP and the overall composition of the new committee. *See supra* Section III.B.3.b. These findings go beyond “specific appointments,” *cf.* Dkt. 232 at 51, and instead suggest that the

⁷⁹ Since the filing of Plaintiffs’ motion, the ACIP meeting that had been scheduled for February 25–26, 2026, was rescheduled to March 18–19, 2026. 91 Fed. Reg. 9617 (Feb. 26, 2026); *see also* Dkt. 257.

appointment process, in general, and thus the full committee, was tainted. Thus, the remedy should cover the entire challenged committee.⁸⁰

However, it would be inappropriate for the Court either to enjoin ACIP from meeting, as Plaintiffs suggest, or to effectively select-by-veto a different ACIP, as Defendants suggest. There are many “different balances that can be struck in a committee’s membership.” *Union of Concerned Scientists*, 954 F.3d at 19. In the first instance, it is an agency’s job and prerogative to strike that balance, just as it is this Court’s to say when the agency has failed to do so. Identifying specific members of ACIP who should not have been appointed, based on an incomplete record, or assuming that HHS is wholly incapable of assembling a lawful ACIP at this stage and enjoining it from doing so, would impose a far greater intrusion into Defendants’ operation than merely staying the current appointments. A stay will prevent the irreparable injury Plaintiffs have shown is likely: while the appointments of the challenged members of ACIP are stayed, ACIP as currently constituted cannot meet, for how can a committee meet without nearly the entirety of its membership? Moreover, a stay is “less drastic” than, and thus preferable to, an injunction. *See Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 165 (2010). Thus, the Court concludes that the appropriate remedy at this juncture is to stay the appointments of the thirteen members of ACIP at issue in this motion.⁸¹

However, the Court will also stay all votes taken by the challenged ACIP, as they were taken by a committee that this Court has determined likely violates FACA.⁸² Though courts have recognized that injunctive relief may be appropriate to remedy a FACA violation, *see, e.g., W. Org.*

⁸⁰ *See supra* note 46.

⁸¹ *See supra* note 46.

⁸² Plaintiffs asked the Court to “set aside” the June Vote and the December Vote, either as part of the remedy for violating FACA or as a remedy for their separate challenges to the votes themselves. *See* Dkt. 237 at 22, 48.

of Res. Councils v. Bernhardt, 412 F. Supp. 3d 1227, 1243 (D. Mont. 2019) (concluding that “[a] use injunction” [preventing the agency from relying on an advisory committee’s recommendations or work product] is the only way to achieve FACA’s purpose[] of enhancing public accountability”), in this instance, ACIP’s votes have actual legal weight that can be mitigated directly by a stay.⁸³ Therefore, the Court need not resort to an injunction.

IV. Conclusion

For the foregoing reasons, Plaintiffs’ motion for preliminary relief is GRANTED in part.

(i) The Court STAYS the January 2026 Memo revising the CDC’s childhood immunization schedule pursuant to 5 U.S.C. § 705.

(ii) The Court STAYS the appointments of the thirteen ACIP members appointed on June 11, 2025, September 11, 2025, and January 13, 2026.

(iii) The Court further STAYS all votes taken by the now-stayed ACIP.

So Ordered.

Dated: March 16, 2026

/s/ Brian E. Murphy

Brian E. Murphy
Judge, United States District Court

⁸³ Defendants do not address the propriety of this remedy. *See generally* Dkts. 232, 272.