No. 26-1503

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

MOTION TO EXPEDITE APPEAL AND FOR EXPEDITED BRIEFING SCHEDULE

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INTRODUCTION

A single district judge has frozen the architecture of the national immunization system. The Advisory Committee on Immunization Practices (ACIP) develops the Nation's vaccine recommendations. The interlocutory order under review stays thirteen of the committee's fifteen appointments, leaving the ACIP without a quorum. As a result, the committee cannot supply, change, or withdraw a vaccine recommendation—for any vaccine or population—until the stay is lifted.

Prompt review is warranted. Most of the questions presented are severable, purely legal, and potentially dispositive, while the harm is ongoing—a moving licensure pipeline and a recent Executive Order both demand ACIP action the quorumless committee cannot supply. Plaintiffs themselves have urged that the case be resolved "as soon as possible." ECF No. 309, at 4.[1]

Counsel for the government conferred with counsel for Plaintiffs, who oppose this motion.

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[1] ECF No. __ refers to entries on the district court's docket in No. 1:25-cv-11916 (D. Mass.). Pin cites are to the page numbers generated by the district court's CM/ECF system.

BACKGROUND

The ACIP, a FACA advisory committee operating since 1964, is the body through which the United States develops vaccine recommendations. Work groups review evidence and present findings to the parent ACIP committee for deliberation and discussion, the committee publicly votes, and the CDC Director adopts, modifies, or rejects the result. Those recommendations anchor the national immunization system: the Affordable Care Act requires insurers to cover ACIP-recommended vaccines, 42 U.S.C. § 300gg-13(a)(2); Medicaid must cover them, *id.* §§ 1396a(a)(10), 1396d(a)(13); the Vaccines for Children program purchases based on a list established by the ACIP, *id.* § 1396s(d)(1), (e); and veterans' benefits track the ACIP schedule, 38 U.S.C. § 1701(9)(G), (10).

Plaintiffs sued in July 2025 and, through successive amendments, added Count II, which challenges the Secretary's reconstitution of the ACIP, carried out through a series of appointments over many months. After the court denied the government's motion to dismiss, *Am. Acad. of Pediatrics v. Kennedy*, 814 F. Supp. 3d 150 (D. Mass. 2026) (ECF No. 168), it asked the parties whether *Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748 (2025), removed the ACIP from FACA. Plaintiffs said no, arguing that the ACIP

"remains a primarily advisory body" whose recommendations "are not self-effectuating and only trigger coverage determinations when subsequently adopted by the CDC Director." ECF No. 276, at 1, 4–5 (Ex. B).

On March 16, 2026, the court granted preliminary relief in part. *Am. Acad. of Pediatrics v. Kennedy*, No. 25-11916, 2026 WL 733828 (D. Mass. Mar. 16, 2026) (ECF No. 291) (Order, Ex. A). After a member-by-member review of each appointee's qualifications, it stayed thirteen of fifteen appointments, along with the January 5 Decision Memo and CDC-adopted votes from three ACIP meetings. Order at 29-30, 43-45. Plaintiffs had asked the court to enjoin the ACIP from meeting; the government argued that any stay should reach only as many appointments as necessary to cure an imbalance. ECF Nos. 183-1; 232 at 51. The court did neither. It instead stayed thirteen appointments on a theory that "the appointment process, in general, and thus the full committee, was tainted[,]" thereby leaving the committee without a quorum. Order at 43-44.

The government appeals only the stay of the appointments related to Count II. The stays of the Memo and the votes remain in place, and the pre–January 5 schedule continues regardless of this appeal. Reversing the appointment stay would restore the quorum, allow the agency to address

any imbalance issues on its own, and resume the recommendation process. The timing is critical. The 2026–2027 respiratory virus season (i.e., RSV, influenza, COVID) begins in the fall, and while the ACIP cannot act, no newly licensed or reformulated vaccine for those conditions can be added to the immunization schedule.

LEGAL STANDARD

This Court may suspend the ordinary schedule "to expedite its decision or for other good cause." Fed. R. App. P. 2. Good cause is presumed for "any action for temporary or preliminary injunctive relief[.]" 28 U.S.C. § 1657(a). The decision to expedite lies in the Court's discretion.

ARGUMENT

I. There is good cause for prompt appellate review.

Without expedited review, this appeal would be overtaken by events. For example, on June 18, 2026, FDA's Vaccines and Related Biological Products Advisory Committee meets to consider licensure of a new mRNA influenza vaccine.[2] If the vaccine is licensed, its placement on the immunization schedule, and the coverage that placement triggers, will

[2] *See* Vaccines and Related Biological Products Advisory Committee; Notice of Meeting, 91 Fed. Reg. 30,309 (May 22, 2026).

depend on a recommendation from the ACIP to enable implementation that a quorumless ACIP cannot supply.

The ACIP typically provides annual recommendations for the use of influenza vaccines for the prevention and control of seasonal influenza in the United States in the summer. For example, the ACIP voted to make annual influenza recommendations in its June 26, 2025 meeting. CDC adoption followed on August 28, 2025, in time for the fall flu season.[3]

Executive Order No. 14,407, 91 Fed. Reg. 33,575 (June 3, 2026), compounds the urgency. It directs the CDC and ACIP to update the childhood and adolescent schedule and every agency to align with it, a directive the frozen committee cannot carry out.

Expedition also conserves judicial resources. The questions of Count II are severable from the rest of the case, threshold, and purely legal; they need no factual development, and a single question, whether the appointments are final agency action, may dispose of the appeal, avoiding piecemeal review. The order's reach magnifies the need for resolution: by entertaining

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[3] *See Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025–26 Influenza Season* (https://perma.cc/Z5S9-FRDW).

a freestanding FACA challenge to individual appointments and reviewing each appointee's qualifications de novo, it supplies a template for judicial credentialing of advisory committee appointments government wide. *See* Fed. R. App. P. 2 advisory committee's note. Whether a court may displace the Executive's personnel choices in that fashion, rather than set aside a final agency action and remand for the agency to restore balance, is a substantial and important question. The resulting paralysis of a central advisory body, absent the question's resolution, persists each day the appeal is undecided.

The case for expedited review does not depend on the government's prevailing on the threshold issues. Even if the Court rejects them, resolving the narrower, antecedent question of the standard that governs the FACA fair-balance inquiry would still serve judicial economy: it would tell the district court what standard to apply and define the scope of its inquiry on remand. That standard remains unsettled—the district court applied Rule 12(b)(6) plausibility at the motion-to-dismiss stage and then de novo, member-by-member credentialing at the preliminary-injunction stage, without identifying any governing standard. Until this Court clarifies that standard, the merits proceedings on remand cannot sensibly go forward, and a judgment entered under an erroneous standard would only invite a

second appeal. Resolving the question now thus guides the litigation below and avoids duplicative review.

II. Substantial, purely legal, and important threshold questions warrant prompt review.

The appeal presents a single error with closely related components. The APA supplies the only cause of action, and it reaches only final agency action. The appointments are not final agency action. That same point defeats jurisdiction: Plaintiffs are not injured by the appointments precisely because the appointments are not final agency action and carry no legal consequences of their own. Standing and reviewability are thus two aspects of one defect, and the remedy error follows from the court's having adjudicated appointments the APA does not reach.

Standing. Plaintiffs must establish standing for each claim and for each form of relief they seek, and standing "is not dispensed in gross[.]" *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021). The relief at issue here is the stay of thirteen appointments, so the question is not whether Plaintiffs are injured by federal vaccine policy in general, but whether any concrete injury is fairly traceable to the composition of the committee and redressable by disturbing it. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). The

injuries the court identified—changed billing, unused doses, unreimbursed counseling—are not traceable to the committee's composition. They are severed from it by the Director's intervening, discretionary decision whether to adopt a recommendation, which plaintiffs concede is the operative act, and by the independent choices of insurers, providers, and patients. For the same reason, a stay of appointments does not redress them. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 380–83 (2024). The only interest tied to the appointments is an interest in who sits on an advisory body. That is not the concrete and particularized injury Article III requires, *id.* at 381, and a bare statutory entitlement to a balanced committee, without concrete harm, is "an injury in law," "not an injury in fact[,]" *TransUnion*, 594 U.S. at 427. The concrete injuries Plaintiffs and the district court identified, by contrast, are the downstream harms that trace to the adoption and implementation of a recommendation, not to the committee's composition.

Final agency action. The appointments are not "agency action" the APA makes reviewable. That term reaches a "rule, order, license, sanction, relief, or the equivalent," 5 U.S.C. § 551(13), each a discrete, circumscribed action, *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62–64 (2004). Appointments or reconstitution are none of them. And even if they were, they would not be

final. ACIP recommendations bind no one until the Director adopts them, and an appointment is a step further removed. *See Dalton v. Specter*, 511 U.S. 462, 469–71 (1994); *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997); *Cohen v. Rice*, 992 F.2d 376, 382 (1st Cir. 1993) (advisory recommendations are not final, and the techniques used to create them "even more preliminary"). Nor is a rolling series of appointments over seven months the discrete final action the APA requires. *Norton*, 542 U.S. at 62–64. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020), relied upon by the district court, is not to the contrary: there, a single written directive of general applicability barred a class of scientists from service the moment it issued, satisfying both *Bennett* prongs, and the remedy ran against the directive, not any appointment. Here, there is no directive, no published policy, and no governing instrument, only discrete, discretionary appointments whose legal consequences, if any, attach to the Director's later adoption of recommendations by the appointees.

Remedy. Plaintiffs sought to enjoin the ACIP's meetings; the government argued any stay should reach only as many appointments as necessary to cure the imbalance. ECF Nos. 183-1; 232 at 51. The court stayed thirteen appointments, including members it did not find unqualified,

disabling the committee. Injunctive relief must be no broader than necessary to redress the asserted injuries. *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). Here, as to the appointments, the proper interim remedy was none, because any interim relief connected to the harms Plaintiffs identified must run against the Director's adoption of recommendations, not the appointments themselves.

These defects share one root. Having reviewed a non-final action the APA does not reach, the court had no injury traceable to it, no final action to anchor review, and nothing to vacate and remand, so it credentialed the members itself and stayed the committee out of existence. Each error is legal and would require reversal, which makes the appeal both substantial and clean to resolve.

PROPOSED EXPEDITED BRIEFING SCHEDULE

To permit expedited resolution in advance of the public health events described above, the government respectfully proposes the following accelerated schedule, under which the Court could hear argument in August and decide the appeal as soon as practicable:

1. **Opening brief:** June 16, 2026;

2. **Response brief:** 30 days after service of opening brief (July 16, 2026);

3. **Reply brief:** 11 days after service of response brief (July 27, 2026);

4. **Oral argument:** in August 2026, at the Court's earliest convenience; and

5. A decision as soon as practicable.

By lodging its opening brief early, the government removes its own briefing time as a variable, leaving only a response and accelerated reply. The government remains prepared to brief on any schedule the Court sets.

CONCLUSION

For the foregoing reasons, the Court should grant the motion to expedite this appeal and enter the proposed briefing schedule.

Respectfully submitted,

/s/ Stanley E. Woodward, Jr.

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June 2026

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d) because it contains 2,068 words. This motion also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6) because it was prepared in Book Antiqua 14-point font.

/s/ Stanley E. Woodward, Jr.

CERTIFICATE OF SERVICE

I hereby certify that on June 11, 2026, I electronically filed the foregoing motion 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/ Stanley E. Woodward, Jr.

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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

MEMORANDUM AND ORDER ON
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 Humans 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

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[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/4FHW-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.

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[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).

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[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 prejudge 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 Stein[55]—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.

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

Dated: March 16, 2026

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

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' 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 PTSF'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]

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[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)

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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.

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[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

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I hereby certify that this document was filed and served through the ECF system upon the following parties on this 4th day of March 2026:

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