UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al.*, Defendants.	Case No. 1:25-cv-11916-BEM **ORAL ARGUMENT REQUESTED**

DEFENDANTS' RENEWED MOTION TO STAY PROCEEDINGS PENDING APPEAL AND TO POSTPONE RECORD DISPUTES

REQUEST FOR ORAL ARGUMENT

Defendants respectfully request the opportunity to present oral argument on this Motion.

INTRODUCTION

When the Court previously denied a stay on May 1, it did so based on the government's submissions at that time. Two things have changed since. First, the First Circuit has granted expedited review of Defendants' appeal (which is limited to Count II), so the Circuit's decision is no longer a distant prospect but a near-term proposition. Second, the issues have crystallized: the government's opening brief, now filed, frames questions about whether the Advisory Committee on Immunization Practices ("ACIP") appointments are reviewable, under what standard, and what remedy is appropriate—issues on which further proceedings in this Court depend.

These developments make a stay the efficient course, however the appeal is resolved: any outcome—on standing, finality, the standard of review, or remedy—either ends Count II or fixes the terms on which it proceeds. Moreover, given the overlap between Plaintiffs' Federal Advisory Committee Act of 1972 ("FACA") claim and their other claims, the First Circuit's resolution of Defendants' appeal could broadly impact proceedings before this Court. Forging ahead with the district court litigation would require the parties to brief and the Court to resolve record disputes and summary judgment motions on issues that the First Circuit's decision may moot or provide guidance on, potentially requiring the parties to redo briefing after the Circuit's decision.

A stay also costs Plaintiffs nothing. The government appealed only the FACA-based Count II relief, so the January 5, 2026, Memorandum and the challenged ACIP votes will continue to be stayed, and the pre-January 5 vaccination schedules remain in place. As Plaintiffs themselves have acknowledged, it is the preliminary relief, not the continuation of district-court litigation, that protects them from any asserted harm. And Defendants have already produced administrative

records for all the challenged actions, including the underlying decision memoranda. What a stay defers is not production of the administrative records but litigation over Plaintiffs' demands to expand those records.

Defendants do not seek delay. They moved to expedite the appeal (over Plaintiffs' objection), shortening only their own deadlines, and the First Circuit granted that request. The public interest lies in resolving controlling legal questions quickly and once, through the expedited appeal, rather than litigating related questions on two fronts in parallel. A stay of proceedings pending the expedited appeal is the most direct route to the orderly and prompt resolution of this case. In the alternative, the Court should stay proceedings at least as to Count II. And at a minimum, the Court should postpone any record disputes until this Motion is resolved.

BACKGROUND

A. The Preliminary-Relief Order

On March 16, 2026, the Court granted in part Plaintiffs' motion for preliminary relief. As relevant here, it stayed the appointments of thirteen of the ACIP's fifteen members, the reconstituted committee's votes, and the January 5 Decision Memo, and held that the CDC Director may not alter the immunization schedule without the ACIP's involvement. ECF No. 291, at 15 & n.31, 45. The stay of the January 5 Memo rested on independent arbitrary-and-capricious grounds, while the stay of the appointments rested on the Court's FACA ruling on Count II. *Id.* at 14–22, 44–45.

B. Defendants' Motion to Stay Proceedings, and the Court's Order

Defendants moved on April 23 to stay further proceedings pending appeal. ECF No. 304. The motion argued that the appeal "could narrow the issues in dispute and provide guidance on how to resolve any remaining issues," so that proceeding to compile administrative records and brief summary judgment before the appeal was resolved risked "wasted time and resources." *Id.*

at 1. Defendants explained there was no prejudice to Plaintiffs: "A stay of proceedings would not harm Plaintiffs because Defendants do not seek to stay the Court's preliminary relief order, and that order remains in full effect and continues to protect Plaintiffs against any irreparable harm." ECF No. 309, at 6 (quoting Defendants' correspondence).

Plaintiffs opposed. ECF No. 309. They urged that "this case must reach an adjudication of the merits as soon as possible." *Id.* at 1. They did not identify any harm a stay of proceedings would cause but instead acknowledged that the preliminary relief "remains in full effect and continues to protect Plaintiffs against any irreparable harm." *Id.* at 6. The appeal was beside the point. The notion that it "could narrow the issues in dispute," they wrote, rested on "dubious propositions," because "[t]he First Circuit cannot narrow—i.e., dismiss—any of the claims." *Id.* at 8. "Judicial economy," they argued, "will be better served by continuing with the proceedings before this Court while an appeal is pending." *Id.*

On May 1, the Court declined to stay proceedings, explaining that Defendants bore the burden of showing good cause and that their submissions at the time had not carried it. *See* ECF No. 311 (citing *Marquis v. FDIC*, 965 F.2d 1148, 1155 (1st Cir. 1992); *Contour Design, Inc. v. Chance Mold Steel Co.*, 649 F.3d 31, 34 (1st Cir. 2011)). The Court did not hold that a stay could never be warranted, only that Defendants had not then shown good cause.

C. The Appeal and the Motion to Expedite

Defendants noticed their appeal on April 29. ECF No. 306. On June 12, Defendants moved to expedite the appeal, proposing a schedule that shortened only Defendants' own briefing deadlines. Ex. A. The motion explained that the order "stays thirteen of the committee's fifteen appointments, leaving the ACIP without a quorum," so that "the committee cannot supply, change, or withdraw a vaccine recommendation—for any vaccine or population—until the stay is lifted," and that the appeal presented the question of "whether the appointments are final agency action,"

which "may dispose of the appeal." *Id.* at 1, 5.

Plaintiffs opposed expedition on June 15, abandoning the urgency they had pressed weeks before in this Court. While Plaintiffs argued in this Court that this case "must reach an adjudication of the merits as soon as possible," ECF No. 309, at 1, they changed their tune in the First Circuit, arguing that "ordinary appellate review [was] fully adequate," Ex. B at 11. They noted there would be no harm in the meantime because "existing schedules remain in place." *Id.* at 9. Similarly, whereas Plaintiffs argued to this Court that Defendants' appeal "cannot narrow—i.e., dismiss—any of the claims," ECF No. 309, at 8, they conceded to the First Circuit that the appeal presented issues of "standing, final agency action, the scope of FACA review, and remedy," Ex. B at 5, threshold matters that might dispose of Count II or at least guide future proceedings on the claim.

The First Circuit expedited the appeal the next day. Ex. C. It directed that briefing be completed by July and that "[o]ral argument, to the extent deemed necessary, will be scheduled as soon as practicable after the completion of briefing," with the matter to "be resolved without undue delay." *Id.*

D. Defendants' Opening Brief

Defendants filed their opening brief the day after, on June 17. The brief presents three principal issues. First, justiciability: "whether plaintiffs have Article III standing to challenge advisory committee appointments" and "whether such appointments constitute 'final agency action'" reviewable under the APA. Ex. D, Statement of the Issues. Second, standard of review: "[w]hether the district court applied the correct standard of review to the FACA fair-balance claim." *Id.* Third, remedy: whether "staying thirteen appointments, leaving the committee unable to convene, and conditioning any schedule change on ACIP involvement" was appropriate. *Id.*

The brief is explicit about the appeal's limited scope and its consequences. The government "challenges the FACA-based structural relief only" and "does not seek to disturb the stay of the

January 5 Memo, which rests on independent grounds," nor "the interim stay of the three adopted votes," and "the pre–January 5 immunization schedule remains in effect." *Id.* at 1, 5. The brief also describes what reversal would yield: "the stay of the thirteen appointments lifts, the Secretary can rebalance the ACIP, and the ACIP can reconvene," while the other relief stands and "[n]othing changes for patients or providers in the interim." *Id.* at 53–54.

LEGAL STANDARD

An order denying a stay is interlocutory and "may be revised at any time before the entry of a judgment." Fed. R. Civ. P. 54(b). The Court therefore may revisit its May 1 order due to changed circumstances. The breadth of the Court's discretion runs both ways: the same authority that supported declining a stay on the May record supports granting one now, on a materially different record.

A district court has inherent authority to stay proceedings "incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936); *accord Clinton v. Jones*, 520 U.S. 681, 706 (1997). A stay decision is reviewed for abuse of discretion. *Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 77 (1st Cir. 2004). That discretion is broad, but not unbounded. A stay must rest on "good cause," be "reasonable in duration," and reflect a balance of "competing equities," which the Court "must ensure . . . are weighed and balanced." *Marquis*, 965 F.2d at 1155.

ARGUMENT

I. Changed circumstances warrant reconsideration.

On June 16, 2026, after this Court denied Defendants' original stay motion, the First Circuit expedited Defendants' appeal and directed that argument be heard as soon as practicable after briefing closes in July, with a decision to follow without undue delay. Ex. C. Whereas in May, this

Court declined to enter an open-ended stay pending an appeal to be resolved in the ordinary course, the First Circuit's June expedition order ensures that a stay pending appeal would be "reasonable in duration," *Marquis*, 965 F.2d at 1155, likely measured in months (at most).

The remaining considerations have also shifted. When this Court ruled on Defendants' original stay motion, the scope of Defendants' just-noticed appeal was not yet known. Defendants have since filed their opening brief, which squarely frames the questions on appeal: whether the appointments are reviewable, under what standard, and what remedy is appropriate. The prospect that animated Defendants' original motion—that an appellate decision "could narrow the issues in dispute and provide guidance on how to resolve any remaining issues," ECF No. 304, at 1—is now concrete and imminent, not speculative. In similar circumstances, district courts have stayed proceedings pending an expedited appeal of preliminary relief where the appeal's resolution could guide further district court proceedings. *See, e.g.*, *San Luis Obispo Coastkeeper v. Cnty. of San Luis Obispo*, No. 2:24-CV-06854-SPG-AS, 2025 WL 2092809 (C.D. Cal. June 18, 2025); *Oregon v. Azar*, No. 6:19-CV-00317-MC, 2019 WL 9045195 (D. Or. Sept. 17, 2019).

Rule 54(b) permits the Court to account for these changes. This is not a request to revisit a settled question on the past record, but to weigh the equities on the current one. Even if there were not good cause for a stay of proceedings in May, the intervening developments in Defendants' appeal establish good cause for a brief stay of proceedings.

II. However the appeal is resolved, a stay would be efficient.

Defendants' appeal presents questions that govern proceedings on Count II in this Court: reviewability, standard of review, and remedy. The First Circuit's decision could require Count II to be dismissed, but even if not, the decision will fix the standard of review for a fair-balance claim under FACA, the scope of the record disputes the parties must litigate, and the framework for any summary-judgment briefing.

The stakes for the record on Count II are clear. Defendants have produced the administrative record, including the underlying decision memoranda. Fair-balance review in some circuits has been confined to the face of the committee's membership. That inquiry requires little more than the charter, the roster, and members' affiliations. *See, e.g.*, *Public Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419 (D.C. Cir. 1989) (fractured panel). Under the more searching review Plaintiffs now seek, Plaintiffs could attempt to obtain extra-record discovery. That expansive review heightens separation-of-powers concerns.[1] Under one standard, the produced record is sufficient. Under another, each of Plaintiffs' attempts to expand the record must be litigated. The First Circuit is about to say which.

Plaintiffs' prior refrain that "[t]he First Circuit cannot narrow—i.e., dismiss—any of the claims," ECF No. 309, at 8, is a technicality, not an answer. However the appeal comes out, the Circuit's decision will inform what happens next in this Court:

- If the First Circuit holds that Plaintiffs lack Article III standing to challenge the appointments, that defect is jurisdictional and requires dismissal of Count II.
- If it holds that the appointments are not final agency action, Count II fails as a matter of law, and a dismissal naturally follows on remand.
- If it holds that this Court applied the wrong standard, that holding will govern the standard under which Count II is adjudicated, and in turn, could affect resolution of record disputes.

[1] *See Cheney v. U.S. District Court*, 542 U.S. 367 (2004). The plaintiffs there alleged that the National Energy Policy Development Group, formed by the President and chaired by the Vice President, had not complied with FACA's open-meeting and disclosure requirements, and the district court approved sweeping discovery to determine whether FACA applied at all. The Supreme Court held that the court of appeals erred in refusing to intervene, explaining that "special considerations" govern civil discovery directed at senior Executive Branch officials, that the Executive's constitutional responsibilities and status are factors counseling judicial deference and restraint in litigation against it, and that FACA's statutory objectives—however important—could not justify discovery whose only purpose was to make it easier for private complainants to vindicate them, 542 U.S. at 384–90. The concern increasingly maps onto Plaintiffs' growing disclosure demands, which would train civil discovery on the Secretary's committee-selection deliberations themselves when no such disclosure may be needed to adjudicate their claims.

- Even a narrow ruling confined to the remedy could fix the boundaries of permissible relief and reshape what is left to litigate.

The First Circuit thus need not enter a "dismiss[al]" for its decision to be dispositive of Count II—or, at the least, controlling of future proceedings on Count II. Plaintiffs' suggestion that the appeal changes nothing cannot be reconciled with their own representation to the First Circuit that the appeal presents "standing, final agency action, the scope of FACA review, and remedy" issues. Ex. B at 5. Those are not minor issues but core questions on which Count II rises or falls.

Nor can the appeal's effects be tightly confined to Count II. Count I, for example, turns on whether the CDC Director may act on the immunization schedule apart from the ACIP. This is a question about the ACIP's role in the statutory scheme and where legal consequences attach within it. The preliminary-relief order answered that question by reasoning from statutes that reference the ACIP's recommendations. ECF No. 291, at 14–16 & n.31. The appeal examines the same statutory architecture through the lens of finality and the standard of review. Summary-judgment briefing on Count I would therefore require this Court to construe the ACIP's role at the very moment the First Circuit is construing it. Additionally, Plaintiffs' challenges to the reconstituted ACIP's votes overlap with their FACA claim. *See, e.g.*, ECF No. 291 at 43–45 (staying ACIP votes on the grounds that the ACIP was improperly constituted).

The expedited briefing will also clarify what this Court must decide. Plaintiffs' responsive appellate brief, due within ten days, will commit them to positions on whether the appointments are final agency action and what standard governs fair-balance review. Any record disputes are best resolved after Plaintiffs have committed to legal theories in their appellate brief, rather than while those theories remain a moving target. And depending on the First Circuit's ruling, the government may evaluate whether to seek voluntary remand for further agency proceedings.

III. In the alternative, the Court should stay proceedings on Count II, or at least postpone briefing on Count II record disputes until this Motion is resolved.

If the Court is not inclined to stay all proceedings, it should at least stay proceedings on Count II. The overlap with the appeal is direct and apparent: Count II is the claim on appeal, and its reviewability, governing standard, any related record disputes, and remedy all relate to questions now before the First Circuit.

At a minimum, the Court should defer briefing on record disputes until it resolves this Motion. Although the Court undoubtedly has authority to take up those issues now, a brief deferral is warranted because the parties' positions on record issues involve questions on appeal, including the standard of review. Plaintiffs themselves described these issues as "not as clean or severable" as the government suggests. Ex. B at 10–11. Taking Plaintiffs at their word, the record disputes should be decided once, not piecemeal. A brief deferral costs nothing and may spare the Court from issuing rulings that the First Circuit's forthcoming decision could unsettle.

IV. Plaintiffs' professed equities have shifted with the forum.

Plaintiffs' prior opposition to a stay rested on the urgency of reaching the merits. To defeat a stay in this Court, Plaintiffs claimed this case "must reach an adjudication of the merits as soon as possible" and that Defendants' appeal was a "delay tactic[]." ECF No. 309, at 1. Yet to defeat expedition of that same appeal in the First Circuit, Plaintiffs maintained that "ordinary appellate review is fully adequate," that "existing schedules remain in place" so nothing would be lost by waiting, and that Defendants' request for prompt review reflected "a contrived, manufactured sense of urgency." Ex. B at 1, 9, 11. Plaintiffs minimized the appeal here, telling this Court it "cannot narrow . . . any of the claims," and then told the First Circuit the appeal presents the dispositive questions of "standing, final agency action, the scope of FACA review, and remedy." *Id.* at 5; ECF No. 309, at 8.

As Part II explains, Plaintiffs correctly told the First Circuit the appeal is consequential. Any competing characterizations in this Court to resist a stay should be weighed against what they told the First Circuit. And on the question of speed, it is Plaintiffs—who opposed expediting the appeal—who have resisted the fastest path to resolving these questions, not Defendants.

V. A stay imposes no cognizable harm on Plaintiffs or anyone else.

The government's narrow appeal challenges only the FACA-based Count II relief. The government has not appealed the stay of the January 5 Memo, which rests on independent grounds, or the stay of the three challenged votes. Those stays remain in effect, and the pre-January 5 immunization schedule remains in place. Pausing the merits and record proceedings puts nothing Plaintiffs obtained from the preliminary-relief order at risk.

Plaintiffs have not disputed the point. In opposing the first stay motion, they noted that the preliminary relief "remains in full effect and continues to protect Plaintiffs against any irreparable harm." ECF No. 309, at 6. The requested stay leaves that protection untouched. A stay also would not disserve the public interest: it leaves the existing schedules and this Court's preliminary relief in place and spares everyone the waste of litigating a claim that may be dismissed or whose standard of review may be set by the First Circuit's forthcoming decision.[2]

[2] While "[a]n appeal from the grant or denial of a preliminary injunction does not divest the trial court of jurisdiction or prevent it from taking other steps in the litigation while the appeal is pending," *Contour Design*, 649 F.3d at 34, the appeal places the propriety and scope of the Count II relief and the standard of review for Count II before the First Circuit. Going forward on overlapping questions concurrently might require this Court to decide, issue by issue, what it may address without trenching on that appeal. A modest stay pending the expedited appeal avoids that line-drawing altogether.

CONCLUSION

The Court should stay all further proceedings pending the First Circuit's decision, or alternatively, stay proceedings on Count II. At a minimum, the Court should postpone record disputes until this Motion is resolved.

July 7, 2026

Respectfully submitted,

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LOCAL RULE 7.1 CERTIFICATE

As noted in the June 24, 2026, status report, ECF No. 322, at 4, Defendants conferred with Plaintiffs, who oppose this Motion.

/s/ Matthew C. Zorn
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CERTIFICATE OF SERVICE

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

July 7, 2026

/s/ Matthew C. Zorn
Matthew C. Zorn

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.
STANLEY E. WOODWARD, JR.
Associate Attorney General

MATTHEW C. ZORN
Senior Counsel to the Associate Attorney General
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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 B

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

PLAINTIFFS- APPELLEES' OPPOSITION TO APPELLANTS' MOTION TO EXPEDITE APPEAL AND FOR EXPEDITED BRIEFING SCHEDULE

PLAINTIFFS-APPELLEES' RULE 26.1 CORPORATE DISCLOSURE STATEMENT

Plaintiffs-Appellees submit this Disclosure Statement Pursuant to Federal Rules of Appellate Procedure 26.1:

1. Plaintiff–Appellee American Academy of Pediatrics is a non-profit corporation, has no parent corporation, and no publicly-held corporation owns any interest in the American Academy of Pediatrics.

2. Plaintiff–Appellee American College of Physicians has no parent corporation, and no publicly-held corporation owns any interest in American College of Physicians.

3. Plaintiff–Appellee American Public Health Association is a 501(c)(3) nonprofit membership organization, has no parent corporation, and no publicly-held corporation owns any interest in American Public Health Association.

4. Plaintiff–Appellee Infectious Diseases Society of America is a non-profit corporation, has no parent corporation, and no publicly-held corporation owns any interest in Infectious Diseases Society of America.

5. Plaintiff–Appellee Massachusetts Public Health Association is a nonprofit corporation, has no parent corporation, and no publicly-held corporation owns any interest in Massachusetts Public Health Association.

6. Plaintiff–Appellee Society for Maternal-Fetal Medicine is a non-profit corporation, has no parent corporation, and no publicly-held corporation owns any interest in Society for Maternal-Fetal Medicine.

7. Plaintiff–Appellee Massachusetts Chapter of the American Academy of Pediatrics is a non-profit corporation, is a member chapter of the American Academy of Pediatrics, and no publicly-held corporation owns any interest in Massachusetts Chapter of the American Academy of Pediatrics.

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INTRODUCTION

On March 16, 2026, Judge Murphy entered an order staying three discrete actions by Defendants-Appellants: (1) he stayed a final agency action by the Centers for Disease Control and Prevention ("CDC") on January 5, 2026, that bypassed the Advisory Committee on Immunization Practices ("ACIP") that unilaterally changed the CDC's childhood immunization schedule; (2) he stayed the appointments of thirteen members of the Advisory Committee on Immunization Practices ("ACIP"); and (3) he stayed all votes taken by the ACIP as comprised of members appointed on June 11, 2025, September 11, 2025, and January 13, 2026. District Ct. Dkt. No. 291 at 45. Appellants motion to expedite an appeal of the stay of the ACIP appointments should be denied because they have not shown good cause for extraordinary appellate treatment.

The Appellants waited six and a half weeks (44 days) before filing a Notice of Appeal on April 29, 2026 from Judge Murphy's March 16 Order. They then waited another six and half weeks (44 days) before filing the instant motion to expedite the briefing schedule. Appellants thus ***waited three months*** to seek expedition of this appeal and offer no explanation for why they waited so long. Their motion rests on a contrived manufactured sense of urgency, not on any showing that its appellate rights will be lost, that the appeal will become moot, or that ordinary appellate review will deprive this Court of the ability to grant effective relief.

The regular appellate review process will not moot this appeal. It will not extinguish any government right. It will not prevent Appellants from pursuing their standing, final agency action, Federal Advisory Committee Act, ("FACA"), or remedial arguments. It will merely prevent Appellants from using a self-created crisis to rush reinstatement of unlawful appointments.

Furthermore, Appellants purported concern that the upcoming respiratory virus season warrants expedition of this appeal is a red herring. Vaccine manufacturers have already prepared updated versions of the annual flu shot, as they normally do, for the Fall 2026/Winter 2027 respiratory virus season.[1] Sanofi, a vaccine manufacturer, reported to CIDRAP News that production for the annual flu shot already has started.[2]

Insurers have promised that they "will continue covering all ACIP-recommended immunizations with no cost-sharing through the end of 2027."[3] Americans will thus have access to flu shots this Fall even if this appeal is still pending.

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[1] "Flu vaccine production starts 6-9 months before distribution, which occurs in phases, ending by early December." *see* https://www.cdc.gov/flu/hcp/vaccine-supply/vaxadmin.html; FDA informed manufacturers of the FDA-approved seasonal influenza vaccines on March 12, 2026 *see* https://www.fda.gov/vaccines-blood-biologics/vaccines/influenza-vaccine-composition-2026-2027-us-influenza-season; https://www.theatlantic.com/health/2026/06/flu-vaccine-acip/687466/

[2] https://www.cidrap.umn.edu/influenza-vaccines/fda-vaccine-advisers-meet-recommend-strains-fall-flu-shots

[3] https://www.ahip.org/news/press-releases/ahip-statement-on-vaccine-coverage

Finally, if the Secretary truly is concerned about reconstituting the ACIP before the upcoming respiratory virus season, there are two simple solutions to the problems he has created: (1) he could appoint legitimate, qualified, credible members to the ACIP; (2) he could follow the ACIP Charter, which provides that "[i]f fewer than a quorum of ACIP members are eligible to vote … the DFO [designated federal officer], or designee, shall have the authority to temporarily designate the ex-officio members as voting members."[4]

Appellants' motion should be denied.

ARGUMENT

I. Appellants Have Not Shown Good Cause to Expedite the Briefing Schedule

The Appellants bear the burden of showing good cause for an extraordinary schedule. They have not done so.

The central assertion of their motion is that the appeal will be "overtaken by events" unless expedited. That assertion is wrong. Appellants seek review of the district court's stay of thirteen ACIP appointments. The validity of that stay will remain live whether the appeal proceeds on Appellants' preferred schedule or in the ordinary course. A later appellate decision can still determine whether the district court acted properly. A later appellate decision can still grant appropriate relief if

[4] *See* https://www.federalregister.gov/documents/2026/05/19/2026-10012/advisory-committee-on-immunization-practices-acip-notice-of-charter-re-establishment

Appellants prevail. Nothing about the ordinary schedule moots the government's appellate arguments or deprives this Court of jurisdiction.

The Appellants do not identify any legal right that will expire absent expedition. They do not identify any statutory deadline by which their challenged appointees must be restored. They do not identify any ACIP vote that federal law requires by a date certain. They do not identify any claim or defense that will become unavailable if this appeal proceeds normally. Instead, Defendants purport to invoke a generalized public health urgency and then insist that the only solution is expedited consideration of the Secretary's unlawful appointments to the ACIP. That is not a showing of good cause. It is an attempt to shift blame for the Secretary's own choices and to benefit from those choices.

The Secretary has lawful options available to him now. He may appoint credible, qualified, balanced ACIP members who comply with FACA and with the published ACIP Membership Balance Plan.[5] He may use lawful interim mechanisms contained in ACIP's charter while a quorum is unavailable. He may restore a functioning vaccine recommendation process without asking this Court to revive unlawful appointments. What he may not do is refuse those lawful paths and then claim that the resulting dysfunction requires emergency appellate relief.

---

[5] The Membership Balance Plan is available at: https://gsa-geo.my.salesforce.com/sfc/p/#t0000000Gyj0/a/3d000002n0y5/SCRGimkNFsTsAtm1GcT4Gu7TM88BO3PwKJZhrdHKkFg

Judge Murphy's order did not prohibit a lawfully constituted ACIP from meeting. The Secretary has lawful ways to restore ACIP. He wants only the unlawful one.

II. Ordinary Appellate Review Will Not Moot the Government's Rights or This Litigation

The government's mootness argument is not really about mootness. It is about speed. Nothing material to this appeal will disappear if the Court follows its established schedule. The challenged order will remain reviewable. The government's arguments will remain available. The legal questions Defendants seek to present—standing, final agency action, the scope of FACA review, and remedy—will remain justiciable. This Court will retain full authority to affirm, reverse, modify, or remand. *See, e.g., Providence Journal v. Federal Bureau of Investigation*, 595 F.2d 889, 890 (1st Cir. 1979).

Appellants' assertion that the appeal may be "overtaken by events" conflates policy preference with legal mootness. Public health events will continue to occur, as they always do. FDA may consider or license products. Professional societies may issue guidance on the administration of vaccines, and many have done so. Insurers and public programs may make operational decisions. Physicians may counsel patients. And the vaccine recommendations published by the CDC prior to 2025 have not been enjoined or stayed. None of that moots the question whether the district court properly stayed the Secretary's ACIP appointments.

Nor would the passage of time deprive Appellants of effective relief. If Appellants ultimately prevail, the Court may reverse the appointment stay. If they do not, then expedition would only have accelerated an effort to restore an unlawfully constituted committee and further destabilize vaccine policy. Either way, ordinary appellate review preserves the parties' rights and this Court's ability to decide the appeal.

This point is particularly important because Appellants' own motion confirms the limited scope of this appeal. They are appealing only the stay of the appointments. Appellants do not seek review here of the district court's stays of the January 5 Decision Memo or the stayed ACIP votes. And the pre–January 5, 2026 immunization schedule remains in place regardless of this appeal. Thus, even expedited reversal would not deliver the sweeping restoration Defendants imply. It would merely revive the Secretary's challenged appointees while the rest of the district court's preliminary relief remains intact.

That is not a basis for emergency treatment.

III. The Appellants' Claimed Urgency Is Self-Inflicted

Appellants' motion repeatedly suggests that the district court has paralyzed ACIP. That framing is misleading. The district court did not forbid the Secretary from establishing or maintaining a lawful ACIP. It stayed thirteen appointments that were likely unlawful.

The Secretary can solve the asserted quorum problem without this appeal. He can appoint legitimate members. He can select trusted experts. He can comply with FACA and with a Membership Balance Plan. He can restore public confidence by reconstituting ACIP lawfully rather than insisting on the return of appointees whose selection process the district court found tainted.

The Secretary's motion ignores those options because they do not give the Secretary what he wants: the return of his prior cadre of appointees and the ability to continue reshaping vaccine policy through an illegitimate committee. However, a self-inflicted urgency is not good cause. Courts do not expedite appeals merely because a party prefers a faster path to undoing preliminary relief. That is especially true where the party urging acceleration waited three months before seeking expedition of this appeal and has available lawful means to address the asserted harm.

Here, the Secretary's choices created the problem. He dismantled trust in the vaccine recommendation process. He reconstituted ACIP in violation of law. He refused to cure the problem by appointing a lawful committee. He then delayed three months before seeking expedited review from this Court and gave no reason for that delay. He now alleges that a crisis has emerged and asks this Court to treat the consequences of those choices as an emergency.

The Court should decline that invitation.

IV. Appellants Have Not Shown That ACIP is Legally Required to Vote on Appellants' Preferred Timeline

Appellants seek to revive their arguments by pointing to the approaching respiratory virus season, possible FDA action, and the annual cadence of influenza recommendations. However, they fail to identify any legal requirement that ACIP vote on a particular vaccine by a particular date.

ACIP has no freestanding legal obligation to vote merely because FDA considers or licenses a vaccine. Even where statutory provisions may require ACIP to consider a matter in certain circumstances, consideration is not the same as a mandatory recommendation. And it is certainly not a command to convene or rely upon an unlawfully constituted committee.

Appellants' argument is an exercise in trying to prove too much. If the Secretary's own failure to constitute a lawful ACIP creates operational difficulty, that failure belongs to the Secretary. It does not entitle him to reap the benefit of an expedited reinstatement of unlawful appointees.

Plaintiffs do not dispute that vaccine policy matters. They do not dispute that respiratory virus immunization recommendations matter. They do not dispute that the public health infrastructure in the United States depends on clarity. But Appellants cannot establish good cause by pointing to important policy questions and then insisting that those questions be answered by an illegitimate committee.

In the interim, the public has ample, evidence-based guidance. Existing schedules remain in place. Physicians, public health programs, insurers, and patients may rely on established immunization infrastructure, guidance from professional medical and public health organizations, and trusted experts. That interim approach is far preferable to allowing the Secretary to resume destruction of vaccine policy and vaccine confidence through an unlawful ACIP.

V. Expediting the Briefing Here Would Prejudice Plaintiffs and Disserve the Public Interest

The Appellants seek a compressed appellate schedule in a case involving the integrity of the national vaccine recommendation process, the lawful composition of a federal advisory committee, and the public's confidence in science-based immunization policy. These are not issues that should be rushed merely because the Secretary wants his appointees reinstated quickly.

The Secretary portrays expedition as neutral case management. It is not. Expedition would materially benefit Appellants by accelerating their effort to restore the challenged appointees before the full implications of their conduct can be presented through ordinary briefing. It would burden Plaintiffs, who represent pediatricians, public health professionals, patients, and families affected by the Secretary's actions. And it would disserve the public, which has a profound interest in vaccine recommendations developed through lawful, balanced, expert processes.

The public interest is not served by speed for speed's sake. It is served by legality, stability, expertise, full consideration, and trust.

Appellants invoke public health concerns while seeking to revive a committee whose composition has already undermined public confidence. Plaintiffs respectfully submit that the safer and more lawful interim path is to rely on existing schedules, established vaccine infrastructure, and guidance from trusted professional societies and experts while the Secretary either appoints a lawful ACIP or this appeal proceeds in the ordinary course.

VI. Appellants' Legal Arguments Do Not Justify Expediting the Briefing Schedule

Appellants argue that the appeal presents substantial, purely legal questions warranting immediate review. But every appeal from preliminary relief presents legal questions. That does not automatically justify expedition.

Appellants' questions are not as clean or severable as they suggest. The district court's order was based on a voluminous record concerning the Secretary's reconstitution of ACIP, the qualifications and balance of the challenged appointees, the process by which they were selected, and the consequences for vaccine policy. Appellants seek to recast the case as an abstract threshold dispute about reviewability and standing, but that reframing does not create good cause for a rushed schedule.

Appellants state generically that any review of a FACA violation is not reviewable under the Administrative Procedure Act. This is not the case at all. *Union*

of Concerned Scientists v. Wheeler, 954 F.3d 11, 20 (1st Cir. 2020)(failure to maintain a fair balance on an advisory committee subject to FACA ("plausibly state claims for judicial review under the APA."); *see also Alabama-Tombigbee Rivers Coal. v. Dep't of Interior,* 26 F.3d 1103, 1107 (11th Cir. 1994); *Western Organization of Resource Councils v. Bernhardt*, 362 F. Supp. 3d 900 (D. Mont. 2019).

Nor is the existence of an Executive Order a basis for expediting review. Executive Order No. 14,407, 91 Fed. Reg. 33,575 (June 3, 2026) is not a final agency action: if anything, it only instructs the Secretary to take an action that has not yet occurred. That second part of the two-step procedure in the order would likely be a final agency action subject to APA review.

In any event, ordinary appellate review is fully adequate to address those issues. If Appellants believe the district court erred on standing, final agency action, or remedy, they may make those arguments in the usual course. They do not explain why those arguments become unavailable, less reviewable, or moot absent expedition.

The answer is that they do not.

CONCLUSION

The Appellants have failed to show good cause to expedite the briefing schedule in this appeal. The motion to expedite should be denied.

Dated: June 15, 2026

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMIT

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/s/ Robert E. Wanerman
Robert E. Wanerman

CERTIFICATE OF SERVICE

I hereby certify that on June 15, 2026, this motion was filed electronically through the Court's CM/ECF system. I understand that the Court's CM/ECF system will send notice of this filing to all registered counsel of record.

/s/ Robert E. Wanerman
Robert E. Wanerman

EXHIBIT C

United States Court of Appeals
For the First Circuit

No. 26-1503

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN COLLEGE OF PHYSICIANS, INC.; AMERICAN PUBLIC HEALTH ASSOCIATION; INFECTIOUS DISEASES SOCIETY OF AMERICA; MASSACHUSETTS PUBLIC HEALTH ASSOCIATION, d/b/a Massachusetts Public Health Alliance; SOCIETY FOR MATERNAL-FETAL MEDICINE; MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS; JANE DOE; JANE DOE 2; JANE DOE 3,

Plaintiffs - Appellees,

v.

ROBERT F. KENNEDY, JR., in the official capacity as Secretary of the Department of Health and Human Services; UNITED STATES FOOD & DRUG ADMINISTRATION; JAY BHATTACHARYA, in the official capacities as Director of the National Institutes of Health and as Acting Director of Centers for Disease Control and Prevention; NATIONAL INSTITUTES OF HEALTH; CENTERS FOR DISEASE CONTROL AND PREVENTION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; KYLE DIAMANTAS, in the official capacity as Acting Commissioner of the Food and Drug Administration, DOES 1-50, Inclusive,

Defendants - Appellants.

ORDER OF COURT

Entered: June 16, 2026

This matter is before the court on defendants-appellants' "motion to expedite appeal and for expedited briefing schedule" and on plaintiffs-appellees' opposition to that motion. Those filings are resolved as follows. Briefing in this matter will proceed on the following schedule:

-- the opening brief shall be filed by June 17, 2026;

-- the response brief shall be filed by July 16, 2026;

-- any reply brief shall be filed within 11 days following service of the response brief, but also may be filed in advance of that date.

Briefing extensions should not be expected. Oral argument, to the extent deemed necessary, will be scheduled as soon as practicable after the completion of briefing, and this matter will be resolved without undue delay.

By the Court:

Anastasia Dubrovsky, Clerk

cc:
Donald Campbell Lockhart, Abraham R. George, Thomas Pulham, Michael L. Fitzgerald, Ashley Cheung Honold, Matthew Charles Zorn, Isaac Belfer, Douglas C. Dreier, James W. Harlow, Stanley Edmund Woodward, Jr., Robert E. Wanerman, Stuart M. Gerson, Elizabeth J. McEvoy, Kathleen Barrett, James J. Oh, Jeremy A. Avila, Richard H. Hughes, IV, William Walters, Maurice Wells, Daniella R. Lee, Gianna Monet Costello, Robert N. Meltzer, Richard Jaffe, Jose A. Perez, Francisco Maria Negrón, Jr., Molly A. Meegan, Thanithia R. Billings, Meaghan Hannan Davant, Kimberly A. Parker, Mark L. Hanin, Andrew Matthew London, Caroline Lindsay Farrell, Ashley H. Wisneski, Holly E. Peterson, Kevin M. Serafino, David Steven Schumacher, Wendy Ellen Parmet, Heather M. Romero, Julia Caldwell, Andrew J. Pincus, Natasha Harnwell-Davis, Allison Aviki, Graham White, Crystal Paulino, Megan Barbero, Kyle H. Keraga, Sarah Allen, Marilyn J. Icsman

EXHIBIT D

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

BRIEF FOR FEDERAL DEFENDANTS-APPELLANTS

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GLOSSARY

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

INTRODUCTION

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

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

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

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

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

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

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

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

The order as to Count II should be reversed.

JURISDICTIONAL STATEMENT

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

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

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

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

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

STATEMENT OF THE ISSUES

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

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

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

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

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

PERTINENT STATUTES AND REGULATIONS

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

STATEMENT OF THE CASE

A. The ACIP and the Vaccine Recommendation Process

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

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

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

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

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

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

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

B. The ACIP Reconstitution

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

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

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

C. The Three ACIP Votes

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

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

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

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

D. The Motion to Dismiss

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

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

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

E. The January 5, 2026 Decision Memo

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

F. The District Court's Preliminary Relief Order

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

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

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

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

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

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

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

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

SUMMARY OF ARGUMENT

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

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

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

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

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

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

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

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

STANDARD OF REVIEW

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

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

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

ARGUMENT

I. Count II Fails at the Threshold.

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

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

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

A. No Article III Standing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. No Reviewable Agency Action.

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

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

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

2. "FACA contains no private right of action." *Wheeler*, 954 F.3d at 17. Any cause of action, if one exists, must come from the APA.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Plaintiffs argued below that the government waived any objection to finality. Dkt. 237 at 30–31; App. 320. The final-agency-action requirement, however, is an element of the APA claim on which Plaintiffs bear the burden, and whether the appointments satisfy it is a pure question of law that this Court may resolve on the existing record. *See Wulff*, 428 U.S. at 121.[3]

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

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

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

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

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

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

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

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

Even where a downstream final action makes fair balance reviewable, that review is deferential. The fair-balance inquiry "falls short of mathematical precision in application," and "the difficulty of determining what precisely constitutes a 'fair balance' may incline courts to be deferential in reviewing the composition of advisory committees," a difficulty that "may defeat a plaintiff's claims in a given case[.]" *Pub. Citizen v. Nat'l Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 434 (D.C. Cir. 1989) (Edwards, J., concurring in part and dissenting in part). Judge Friedman's opinion in the same case makes the point on the merits: where a

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

The district court went far beyond *Wheeler*. The district court has never articulated a standard of review that would authorize its member-by-member credentialing. At the motion-to-dismiss stage, the court applied Rule 12(b)(6) plausibility and held that Plaintiffs "plausibly alleged" a violation. MTD Op. at 22; App. 140. At the preliminary-injunction stage, the court conducted a member-by-member credentialing review without stating what standard governed. PI Op. at 28–34; App. 843.[4]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

III. The Relief Below Is Improper

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

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

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

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

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

A. The Remedy Exceeds Statutory Authority

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

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

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

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

as necessary to cure the imbalance the court identified. Dkt. 232, at 51; App. 288. The court stayed all thirteen, including members it did not find unqualified, leaving the committee without a quorum. Injunctive relief "should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). A stay of every challenged appointment, when the court faulted only some members and a narrower stay would have cured any imbalance, exceeds that limit.

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

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

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

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

B. The Remedy Conflicts With *Braidwood*

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

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

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

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

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

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

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

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

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

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

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

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

D. The Practical Consequences and Correct Remedy

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

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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

/s/ Matthew C. Zorn

CERTIFICATE OF SERVICE

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

/s/ Matthew C. Zorn

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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,	)	
Plaintiffs,	)	
v.	)	**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))).

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[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

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[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. <u>Remedy</u>

"[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. <u>January 2026 Memo</u>

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,

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[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.

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

SUBCHAPTER II—ADMINISTRATIVE PROCEDURE

Short Title

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

§ 551. Definitions

For the purpose of this subchapter—

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

(A) the Congress;

(B) the courts of the United States;

(C) the governments of the territories or possessions of the United States;

(D) the government of the District of Columbia;

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

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

(F) courts martial and military commissions;

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

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

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

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

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

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

(6) ''order'' means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

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

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

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

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

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

(B) withholding of relief;

(C) imposition of penalty or fine;

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

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

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

(G) taking other compulsory or restrictive action;

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

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

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

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

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

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

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

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

Historical and Revision Notes

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

HISTORICAL AND REVISION NOTES—CONTINUED

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

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

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

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

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

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

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

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

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

CODIFICATION

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

AMENDMENTS

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

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

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

EFFECTIVE DATE OF 1976 AMENDMENT

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

STUDY AND REPORTS ON ADMINISTRATIVE SUBPOENAS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Editorial Notes

REFERENCES IN TEXT

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

AMENDMENTS

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

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

§ 702. Right of review

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

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

HISTORICAL AND REVISION NOTES

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

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

Editorial Notes

AMENDMENTS

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

§ 703. Form and venue of proceeding

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

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

HISTORICAL AND REVISION NOTES

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

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

Editorial Notes

AMENDMENTS

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

§ 704. Actions reviewable

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

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 705. Relief pending review

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 706. Scope of review

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

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

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

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

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

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

(D) without observance of procedure required by law;

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

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

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

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

HISTORICAL AND REVISION NOTES

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

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

Statutory Notes and Related Subsidiaries

ABBREVIATION OF RECORD

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

CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING

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

§ 801. Congressional review

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

(i) a copy of the rule;

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

(iii) the proposed effective date of the rule.

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

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

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

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

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

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

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

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 705. Relief pending review

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 706. Scope of review

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

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

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

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

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

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

(D) without observance of procedure required by law;

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

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

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

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

HISTORICAL AND REVISION NOTES

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

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

Statutory Notes and Related Subsidiaries

ABBREVIATION OF RECORD

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(i) a copy of the rule;

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

(iii) the proposed effective date of the rule.

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

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

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

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

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

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

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

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

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

JIMMY CARTER.

LOBBYISTS ON AGENCY BOARDS AND COMMISSIONS

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

Memorandum for the Heads of Executive Departments and Agencies

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

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

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

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

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

BARACK OBAMA.

§ 1003. Applicability

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

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

(1) the Central Intelligence Agency;

(2) the Federal Reserve System; or

(3) the Office of the Director of National Intelligence, if the Director of National Intelligence determines that for reasons of national security the advisory committee cannot comply with the requirements of this chapter.

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

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

HISTORICAL AND REVISION NOTES

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

§ 1004. Responsibilities of congressional committees

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

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

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

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

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

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

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

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

HISTORICAL AND REVISION NOTES

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

§ 1005. Responsibilities of the President

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

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

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

HISTORICAL AND REVISION NOTES

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

§ 1006. Responsibilities of the Administrator

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

(b) ANNUAL REVIEWS.—

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

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

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

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

(D) whether the committee should be abolished.

(2) OBTAINING INFORMATION.—The Administrator may from time to time request such information as the Administrator deems necessary to carry out functions under this subsection. Agency heads shall cooperate with the Administrator in making the reviews required by this subsection.

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

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

(d) GUIDELINES FOR UNIFORM FAIR PAY RATES.—

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

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

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

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

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

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

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

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

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

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

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

HISTORICAL AND REVISION NOTES

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

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

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

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

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

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

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

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

§ 1007. Responsibilities of agency heads

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

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

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by the agency;

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

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 1008. Establishment and purpose of advisory committees

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

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

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

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

(c) ADVISORY COMMITTEE CHARTERS.—

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

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

(B) with—

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

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

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

(A) the committee's official designation;

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

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

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

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

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

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

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

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

(J) the date the charter is filed.

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 1009. Advisory committee procedures

(a) COMMITTEE MEETINGS.—

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

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

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

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

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

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

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

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

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

HISTORICAL AND REVISION NOTES

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

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

§ 1010. Availability of transcripts

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

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

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

HISTORICAL AND REVISION NOTES

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

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

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

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

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

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

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

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

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

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

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

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

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

''(2) DISCONTINUANCE OF ALL COVERAGE.—

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

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

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

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

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

''(1) in the large group market; or

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

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

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

EFFECTIVE DATE

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

§ 300gg–13. Coverage of preventive health services

(a) In general

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

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

(2) immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved; and [1]

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

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

[1] So in original. The word ''and'' probably should not appear.

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

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

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

(b) Interval

(1) In general

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

(2) Minimum

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

(c) Value-based insurance design

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

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

PRIOR PROVISIONS

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

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

EFFECTIVE DATE

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

§ 300gg–14. Extension of dependent coverage

(a) In general

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

(b) Regulations

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

(c) Rule of construction

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

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

PRIOR PROVISIONS

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

AMENDMENTS

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

EFFECTIVE DATE

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

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

(a) In general

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

(b) Requirements

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

(1) Appearance

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

(2) Language

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

(3) Contents

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

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

Title 45 —Public Welfare
Subtitle A —Department of Health and Human Services
Subchapter B —Requirements Relating to Health Care Access
Part 147 —Health Insurance Reform Requirements for the Group and Individual Health Insurance Markets

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

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

§ 147.130 Coverage of preventive health services.

(a) *Services* —

(1) *In general.* Beginning at the time described in paragraph (b) of this section and subject to §§ 147.131, 147.132, and 147.133, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for—

(i) Evidence-based items or services that have in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual involved (except as otherwise provided in paragraph (c) of this section);

(ii) Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention with respect to the individual involved (for this purpose, a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention is considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention, and a recommendation is considered to be for routine use if it is listed on the Immunization Schedules of the Centers for Disease Control and Prevention);

(iii) With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in comprehensive guidelines supported by the Health Resources and Services Administration;

(iv) With respect to women, such additional preventive care and screenings not described in paragraph (a)(1)(i) of this section as provided for in comprehensive guidelines supported by the Health Resources and Services Administration for purposes of section 2713(a)(4) of the Public Health Service Act, subject to §§ 147.131, 147.132, and 147.133; and

(v) Any qualifying coronavirus preventive service, which means an item, service, or immunization that is intended to prevent or mitigate coronavirus disease 2019 (COVID-19) and that is, with respect to the individual involved—

(A) An evidence-based item or service that has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force; or

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

(2) *Office visits.*

(i) If an item or service described in paragraph (a)(1) of this section is billed separately (or is tracked as individual encounter data separately) from an office visit, then a plan or issuer may impose cost-sharing requirements with respect to the office visit.

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

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

(iv) The rules of this paragraph (a)(2) are illustrated by the following examples:

> *Example 1.* (i) *Facts.* An individual covered by a group health plan visits an in-network health care provider. While visiting the provider, the individual is screened for cholesterol abnormalities, which has in effect a rating of A or B in the current recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit and for the laboratory work of the cholesterol screening test.
> (ii) *Conclusion.* In this *Example 1,* the plan may not impose any cost-sharing requirements with respect to the separately-billed laboratory work of the cholesterol screening test. Because the office visit is billed separately from the cholesterol screening test, the plan may impose cost-sharing requirements for the office visit.

> *Example 2.* (i) *Facts.* Same facts as *Example 1.* As the result of the screening, the individual is diagnosed with hyperlipidemia and is prescribed a course of treatment that is not included in the recommendations under paragraph (a)(1) of this section.
> (ii) *Conclusion.* In this *Example 2,* because the treatment is not included in the recommendations under paragraph (a)(1) of this section, the plan is not prohibited from imposing cost-sharing requirements with respect to the treatment.

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

recommendations of the United States Preventive Services Task Force with respect to the individual. The provider bills the plan for an office visit.
(ii) *Conclusion.* In this *Example 3,* the blood pressure screening is provided as part of an office visit for which the primary purpose was not to deliver items or services described in paragraph (a)(1) of this section. Therefore, the plan may impose a cost-sharing requirement for the office visit charge.

Example 4. (i) *Facts.* A child covered by a group health plan visits an in-network pediatrician to receive an annual physical exam described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. During the office visit, the child receives additional items and services that are not described in the comprehensive guidelines supported by the Health Resources and Services Administration, nor otherwise described in paragraph (a)(1) of this section. The provider bills the plan for an office visit.
(ii) *Conclusion.* In this *Example 4,* the service was not billed as a separate charge and was billed as part of an office visit. Moreover, the primary purpose for the visit was to deliver items and services described as part of the comprehensive guidelines supported by the Health Resources and Services Administration. Therefore, the plan may not impose a cost-sharing requirement for the office visit charge.

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

(i) Subject to paragraphs (a)(3)(ii) and (iii) of this section, nothing in this section requires a plan or issuer that has a network of providers to provide benefits for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing cost-sharing requirements for items or services described in paragraph (a)(1) of this section that are delivered by an out-of-network provider.

(ii) If a plan or issuer does not have in its network a provider who can provide an item or service described in paragraph (a)(1) of this section, the plan or issuer must cover the item or service when performed by an out-of-network provider, and may not impose cost sharing with respect to the item or service.

(iii) A plan or issuer must provide coverage for and must not impose any cost-sharing requirements (such as a copayment, coinsurance, or a deductible) for any qualifying coronavirus preventive service described in paragraph (a)(1)(v) of this section, regardless of whether such service is delivered by an in-network or out-of-network provider. For purposes of this paragraph (a)(3)(iii), with respect to a qualifying coronavirus preventive service and a provider with whom the plan or issuer does not have a negotiated rate for such service (such as an out-of-network provider), the plan or issuer must reimburse the provider for such service in an amount that is reasonable, as determined in comparison to prevailing market rates for such service.

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

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

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

(b) ***Timing.***

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

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

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

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

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

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

(d) ***Applicability date.*** The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

(e) ***Sunset date.*** The provisions of paragraphs (a)(1)(v), (a)(3)(iii), and (b)(3) of this section will not apply with respect to a qualifying coronavirus preventive service furnished on or after the expiration of the public health emergency determined on January 31, 2020, to exist nationwide as of January 27, 2020, by the Secretary of Health and Human Services pursuant to section 319 of the Public Health Service Act, as a result of COVID-19, including any subsequent renewals of that determination.

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

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al.*, Defendants.	Case No. 1:25-cv-11916-BEM

[PROPOSED] ORDER GRANTING DEFENDANTS' RENEWED MOTION TO STAY PROCEEDINGS PENDING APPEAL AND TO POSTPONE RECORD DISPUTES

Before the Court is Defendants' Renewed Motion to Stay Proceedings Pending Appeal and to Postpone Record Disputes. Having considered the motion in light of the governing standards, it is hereby ORDERED that the motion is GRANTED. Proceedings in this case are stayed pending the First Circuit's decision in Defendants' appeal of this Court's preliminary relief order.

SO ORDERED.

Dated: _____

_____
Brian E. Murphy
Judge, United States District Court