

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

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

**DEFENDANTS' UNOPPOSED MOTION FOR LEAVE TO FILE REPLY IN SUPPORT
OF RENEWED MOTION TO STAY PROCEEDINGS PENDING APPEAL**

Pursuant to Local Rule 7.1(b)(3), Defendants respectfully move for leave to file the short reply attached hereto as Exhibit 1 in support of their Renewed Motion to Stay Proceedings Pending Appeal, ECF No. 325. Plaintiffs do not oppose this motion.

Good cause supports leave. Plaintiffs' opposition, ECF No. 334, presents new argument and new evidence. For example, the opposition expressly relies on Plaintiffs' intervening motion to complete the administrative records, ECF No. 330, filed last week. Events postdating the Motion also bear directly on it, including the completion of briefing in the court of appeals: Defendants filed their reply brief in No. 26-1503 on July 21, 2026, yesterday, six days ahead of schedule. A short reply addressing these developments will assist the Court in advance of the July 23, 2026 hearing, and the attached reply is confined to them.

Pursuant to Local Rule 7.1(a)(2), counsel for the parties conferred regarding this motion. Plaintiffs stated that they do not oppose the relief requested.

Defendants therefore respectfully request that the Court grant leave and accept the attached reply for filing.

July 22, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

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

July 22, 2026

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EXHIBIT 1

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

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

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

Defendants.

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

**DEFENDANTS’ REPLY IN SUPPORT OF RENEWED MOTION TO STAY
PROCEEDINGS PENDING APPEAL**

Plaintiffs’ opposition calls this motion “a transparent attempt to delay.” Opp. 1. Yet it concedes that the principal appellate briefs have been filed, that a decision appears “likely in August,” *id.*, and that a stay “would last about a month,” *id.* 5. It identifies no harm from a brief pause in the district court litigation. Indeed, an appeal Defendants expedited and that will likely be resolved soon is a strange instrument of “delay.” Contrary to Plaintiffs’ argument, that the requested stay would be brief is not a reason to deny Defendant’s motion, but to *grant* it.

There is good cause for a brief stay of proceedings. This case has consumed enormous public resources, including the time of many attorneys across two Departments. To litigate record disputes before the First Circuit resolves Defendants’ expedited appeal would require a further expenditure of resources on disputes that may be mooted (for example, if the First Circuit holds that Plaintiffs lack standing to challenge the ACIP appointments or that those appointments are not final agency action). It would also require litigating a moving target, as the First Circuit’s decision may change the contours of the district court litigation. This Motion is about sequence, not delay. Nobody pours the foundation while the zoning board decides whether the house may be built.

I. The efficiency of a stay is no longer a prediction.

In May, the work a stay would defer was hypothetical. It no longer is. The judicial economy case has two parts: what a stay defers, and what it makes possible. Plaintiffs’ authorities resist neither. *Contour Design* simply confirms the Court’s authority to proceed, 649 F.3d 31, 34 (1st Cir. 2011), which was never in doubt. The question is whether the Court should exercise its discretion to grant a brief stay of proceedings. *Marquis* explains that the Court’s discretion should be guided by good cause, reasonable duration, and balanced equities. 965 F.2d 1148, 1155 (1st Cir. 1992). That is amply satisfied here: Plaintiffs concede the pause would likely be measured in weeks, and it would preserve the Court’s preliminary relief and defer matters the appeal may moot.

Begin with what a stay defers. The scale of Plaintiffs’ motion to complete the administrative records is telling: six categorical demands spanning fifteen months, reaching back to February 14, 2025, with exhibits predating the Secretary’s tenure. ECF 330 at 8; *id.* Ex. 5. In December, counsel told this Court the record “continues to build” — a record with no end. Dkt. 165, at 5–6. The new motion describes a record with no beginning. This is not the record of a discrete agency action, and whether the APA permits review on those terms is before the First Circuit now.

Nor are the deferred disputes open questions in this Court. In January, the government stated the standard: the record is “the material the decision-maker considered in reaching the challenged decision.” The Court agreed that post-decisional meeting material falls outside it: “I think he’s right. I don’t think it would be part of the record.” Dkt. 178, at 13. And Plaintiffs’ counsel acknowledged that this Court “might have a final say in what is really the administrative record.” *Id.* at 24. The motion proceeds as if none of it was said: it applies an “all documents

related to” civil-discovery standard, ECF 330 at 20–21, that the Court already rejected. And beneath these disputes sits a question the appeal will settle: what is the agency action under review, and is fair-balance review a facial inquiry into committee composition, or a warrant to ferret through the deliberative files? Many of the disputes on this docket turn on that answer.

The opposition previews the merits, too. Defendants, it says, “will be hard-pressed to dispute” that documents were “wrongfully withheld.” Opp. 7. Not so. Many of the materials Plaintiffs say should exist may not exist. Also, internal, pre-decisional deliberations are privileged and not part of an administrative record. *U.S. Fish & Wildlife Serv. v. Sierra Club, Inc.*, 592 U.S. 261, 267–68 (2021). Nor was the “campaign” Plaintiffs purport to reveal any secret: the trade press reported it in **February 2025**, pleaded in Plaintiffs’ own complaint, and argued to this Court in January. Helen Branswell, *HHS Orders CDC to Halt Some Vaccine Ads, Saying RFK Jr. Wants Message Focused on ‘Informed Consent’*, STAT News (Feb. 20, 2025), <https://www.statnews.com/2025/02/20/cdc-vaccine-promotions-rfk-jr-informed-consent/>; Compl. ¶ 47, ECF No. 1 (Feb. 2025 cancellation of “Wild to Mild” campaign); Third Am. Compl. ¶ 7, ECF No. 139 (“[i]nformed consent is back”); Dkt. 178, at 12.

The Supreme Court has addressed demands of this character before — in a FACA case. In *Cheney v. U.S. District Court for the District of Columbia*, 542 U.S. 367 (2004), discovery (six requests) aimed at an advisory group answering to the Vice President “ask[ed] for everything under the sky.” *Id.* at 387–88. The concern here is the same, one degree removed: a categorical demand for “all documents” and extra-record discovery, aimed at the upper reaches of the Executive Branch, pressed before reviewability is settled. Separation-of-powers considerations “inform the conduct of the entire proceeding, including the timing and scope of

discovery.” *Id.* at 385 (quoting *Clinton v. Jones*, 520 U.S. 681, 707 (1997)). In *Cheney*, protecting those interests required mandamus. Here, for the moment, a brief pause suffices.

A brief stay, moreover, wastes nothing. It pays for itself however the appeal ends: reversal may end Count II; a ruling on the FACA standard will reshape proceedings on Count II; and even affirmance will provide guidance on further proceedings. The only wasteful course would be to proceed in district court while the appeal remains pending. Plaintiffs argue that reversal would not moot Count II, quoting Defendants’ acknowledgment that the agency “must still address a fair balance issue, to the extent one exists.” Opp. 5. That misses twice. If the court of appeals holds that Count II fails as a matter of law, it fails. And the acknowledgment Plaintiffs quote describes the agency’s obligation (the remand path below), not this Court’s docket. The premise of Defendants’ motion was never erasure, but clarity.

Plaintiffs treat the pendency of ECF 330 as a reason not to stay. Actually, it is the best reason for a stay. What a stay defers is the litigation that motion previews: contests over six categorical demands for “all documents,” and a wholesale attack on the deliberative-process privilege before any specific document is at issue. ECF 330 also foreshadows yet another shift in the asserted agency action. Plaintiffs now contend that everything after February 2025 is “post-decisional,” ECF 330 at 8–9.¹ Without a stay, the parties brief and the Court hears all of that in the same weeks the First Circuit decides the questions it turns on. With a stay, the same motion can be heard soon after a First Circuit decision, with answers instead of predictions. Perhaps the pause lasts a month, as Plaintiffs estimate, perhaps two. Whatever the case, there

¹ Separately, the publicly filed memorandum and exhibits to ECF 330 disclose information designated Confidential under the Protective Order. See ECF 320 ¶ 4.

should be little doubt that a brief pause furthers judicial economy—and *Cheney* practically compels it.

The second half of the economy case is what a stay makes possible: a clear path to resolution. The government’s objective deserves plain statement, because it is the opposite of the motive Plaintiffs impute. The government wants the ACIP back at work, as Defendants explained in the First Circuit reply they filed six days early. Reply Br., No. 26-1503 (1st Cir. filed July 21, 2026) (attached as Ex. A). As stated there and in the opening Motion in this Court, depending on how Count II is resolved, the government may seek a voluntary remand—a device that “allow[s] agencies to cure their own mistakes rather than wasting the courts’ and the parties’ resources.” *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993). A remand under a settled standard lets the Secretary reconstitute with confidence, mooted the appointments challenge and disputes that are now on this docket. That is judicial economy, not concealment.

Plaintiffs’ conduct made this sequence necessary. Asked in a recorded public interview whether the preliminary relief order bars new appointments to the ACIP, counsel of record answered that it “does not”—and continued: “if we see additional appointments to ACIP, you can rest assured that we will act.” Quoted in Reply Br. Part I & n.3 (Ex. A). The opposition now presses the same point in briefing: the Secretary, Plaintiffs say, “has had ample time to appoint” “new, qualified members,” or to seat ex-officio members as voters. Opp. 8. But “qualified” is at issue in the litigation. The parties do not agree on what it means, no court has stated the standard, and any slate named today draws the promised challenge, member by member. And a committee whose voting majority is ex-officio members is not what the ACIP the charter contemplates.²

² “If fewer than a quorum of ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate

Defendants have not mischaracterized the order. They have described precisely how it operates in the environment Plaintiffs have built around it. Nor do Defendants “blame this Court.” Opp.

8. They appeal an order that rests on a framework Plaintiffs urged.

In January, the Court said it was “doing everyone a service the quicker I can move this towards finality.” Dkt. 178, at 17. The sequence just described is that service in motion: committee back at work, dispute moot, no further judicial action needed. The government is not trying to prolong this case. It is trying to end it.

II. No prejudice: the flu season needs nothing from this docket.

The preliminary relief is not at issue. Plaintiffs keep what they won.

What became of Plaintiffs’ urgency? In October, during a government shutdown (and Defendants’ counsel litigating without pay) Plaintiffs pressed to lift the stay of these proceedings, telling this Court: “we cannot predict who is going to get sick and who is going to die, but those things are going to happen.” ECF No. 137 at 13. The stay lifted. On May 1, opposing a stay, Plaintiffs wrote that “for the sake of public health, this case must reach an adjudication of the merits as soon as possible.” ECF No. 309 at 1. Six weeks later, opposing expedition in the First Circuit, the same urgency became, in their words, “a contrived, manufactured sense of urgency.” ECF No. 325 at 9 (quoting Plaintiffs’ expedition opposition, Mot. Ex. B). Plaintiffs contended that “Americans will thus have access to flu shots this Fall even if this appeal is still pending.” 1st Cir. Expedition Opp. (June 15, 2026) at 2. The urgency changed sides the moment it changed forums. Now it has disappeared altogether: the new

the ex-officio members as voting members.” The charter makes the ex-officio members non-voting. The designation power is a temporary quorum device for a constituted committee, not a means of composing one. <https://www.cdc.gov/acip/about/acip-charter.html>.

opposition claims no urgency and identifies no harm from a pause. Nowhere do Plaintiffs justify the about-face, saying two different things in two different courts.

Their merits brief goes further: “there are strong reasons to believe that no such problem exists” for the 2026–27 season: strain recommendations are finalized, “federal laws do not require the ACIP to issue recommendations annually,” the June 2025 influenza vote “remains operative,” and insurers have committed to coverage “through the end of 2027.” 1st Cir. Appellees’ Br. 47–48 & nn.32–34. Their counsel’s public assessment is the same. Two weeks before that brief, he published his answer to what he called “the immediate question” — “[w]ill flu vaccines be available and covered this year?”: “We believe the answer, for the 2026-2027 season, is yes.” Richard Hughes IV & Will Walters, *A Flu Season Without ACIP: The Question for Fall*, MedPage Today (June 29, 2026) (Ex. B) (disclosure: “The authors represent the American Academy of Pediatrics . . . in litigation challenging immunization schedule changes”). Yet the article also identifies risks such as “potential noncoverage” in Medicaid and traces each to a committee that cannot meet—the concerns their expedition opposition dismissed.

Defendants see the issues differently, which is why they asked to expedite the appeal. Why Plaintiffs opposed and said something different than they told this Court is for them to explain. The Court need not resolve the discrepancy today. Under either account, the motion should be granted. If the flu season is secure, a stay costs nothing. If its legal footing turns on the committee’s status, only the expedited appeal can supply the answer. Nothing a stay defers (administrative record litigation, merits briefing) convenes a committee.

Finally, one footnote requires a response. Plaintiffs suggest that the timing of the appeal “calls into question the genuineness” of the government’s concern for the coming season. Opp.

8 n.13. These words are best answered by action: the government asked the court of appeals to expedite, shortened only its own deadlines, and prevailed.³ Plaintiffs, not Defendants, opposed.

CONCLUSION

A stay furthers judicial economy while changing nothing about the preliminary relief order and imposing no costs on Plaintiffs, as is clear from their representations to this Court, the court of appeals, and the public. The Court should grant the Motion.

July 22, 2026

Respectfully submitted,

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³ The government is eager to resolve the appeal: it cut its own briefing time on the opening brief and filed its reply 6 days early. (Plaintiffs took all 29 days for their brief.) The government took time to decide how to proceed, Opp. 8 n.13, because the quickest path to a working ACIP was not obvious given Plaintiffs' avowed opposition to the Secretary's appointments. Defendants determined that an expedited appeal that settles the ACIP appointment question is that path. Deliberation in service of ending a case is not delay.

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EXHIBIT A

[ORAL ARGUMENT REQUESTED]

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

REPLY BRIEF FOR FEDERAL DEFENDANTS-APPELLANTS

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GLOSSARY

ACIP	Advisory Committee on Immunization Practices
APA	Administrative Procedure Act
CDC	Centers for Disease Control and Prevention
EPA	U.S. Environmental Protection Agency
FACA	Federal Advisory Committee Act
FDA	U.S. Food and Drug Administration
HHS	U.S. Department of Health and Human Services
MBP	Membership Balance Plan
PI Op.	Memorandum and Order on Plaintiffs' Motion for Preliminary Injunction
SCDM	Shared Clinical Decision-Making

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs say oral argument is unnecessary. Resp. Br., Statement Regarding Oral Argument. This is an expedited appeal of preliminary structural relief against the Executive Branch, and argument would materially assist the Court. Fed. R. App. P. 34(a). But the paramount consideration is a decision before the coming flu season. The government requests argument at the Court's earliest convenience, or submission on the briefs if argument would delay decision.

INTRODUCTION

Which agency action does Count II challenge, and when did it become final? Plaintiffs never say. Their brief offers only a hedge: the reconstitution, “whether viewed as a series of individual appointments or as a reconstitution of the entire Committee.” Resp. Br. 19, 32, 34.

A party defending an APA judgment ought to be able to name the action under review, the date it became final, the injury that action causes, and how the relief entered redresses it. Plaintiffs cannot because no answer survives the record: each appointment is an unreviewable personnel selection, and the “reconstitution” is an ongoing course of conduct. But here is what their counsel did say, in December 2025, defending Count II at the motion-to-dismiss argument:

[W]ith respect to our count regarding the constitution of the ACIP, that is a claim that is one in which the facts are developing every day. . . . I think the administrative record continues to build on that claim as we go forward.

Dkt. 165,¹ at 4–5 (Dec. 17, 2025 Hr’g Tr.); Suppl. App’x 1240–41.

Those words alone should dispose of this appeal. They describe a claim with no consummated action and no fixed record. And they refute

¹ Citations to Dkt. __ refer to the district court docket below.

waiver in the same breath, because the government answered on the spot: “Your Honor, the administrative record does not continue to grow.” Dkt. 165, at 5; Suppl. App’x 1241. Issue, joined. Far from anything being waived, the confusion about this claim has never been the government’s.

Plaintiffs’ defense of the remedy for that confused claim concedes the point. Asked how the government may respond if vaccine policy must move—a new pathogen, new safety data, the annual flu cycle—their answer to this Court is that the government is “free to return to the district court to seek a modification of the stay order.” Resp. Br. 48. That is not a defense of the order below. It is an indictment. Under the arrangement Plaintiffs defend, the Executive Branch’s vaccine-advisory apparatus answers to the court: thirteen appointments held in judicial custody, the CDC Director’s authority conditioned on a committee that cannot convene, and every path forward routed through motion practice Plaintiffs have promised to oppose.

Just last Term, the Supreme Court reaffirmed that district court judges lack equitable authority to grant relief broader than necessary to provide complete relief to the plaintiffs before them. *Trump v. CASA, Inc.*, 606 U.S. 831 (2025). Complete relief here is the stay of the actions Plaintiffs say injure them—the adopted recommendations and the January 5 Memo—relief this

appeal does not disturb in the interim. The appointment stay adds nothing except to hand custody of an Executive Branch advisory committee to the courts. A universal remedy does not become permissible because it is labeled a “stay” under 5 U.S.C. § 705. If the label controlled, CASA would have decided nothing.

Even assuming everything else in Plaintiffs’ brief, the remedy stands nearly undefended. Plaintiffs offer no precedent for it and no answer to the objection that it places a FACA advisory committee under ongoing judicial control. An unprecedented remedy that its own defenders barely defend cannot survive review.

Plaintiffs open by cataloguing what the government’s brief “does not argue.” Resp. Br. 2. True enough. But an appeal directed at the vehicle, the standard of review, and the remedy concedes nothing about the merits. They also answer a position nobody argued in this case: that FACA’s fair-balance requirement is unenforceable, that *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11 (1st Cir. 2020), was wrongly decided, or that courts are “powerless.” Resp. Br. 44. Fair balance is fully enforceable through the APA’s ordinary channels—review of a *Wheeler*-type directive where one exists, and review of the downstream final actions that rely on an

imbalanced committee—exactly what Counts I, III, and IV present. What does not exist is a third channel: freestanding review of individual appointments, with structural remedies and intrusive discovery of the Executive Branch, untethered to any reviewable action. Policy concerns (such as Amici’s) may be legitimate, but every harm they identify flows from the recommendations—fully reviewable under the other counts.

The scope of this targeted appeal remains as the opening brief described it. The stay of the January 5 Memo is not challenged. The interim stay of the three adopted votes is not disturbed. What the government challenges is the FACA-based structural relief. As to that relief, the order should be reversed.

ARGUMENT

Plaintiffs ask this Court to review the order for abuse of discretion, with “considerable deference” to the district court. Resp. Br. 21. Yet every question this appeal presents—reviewability, standing, the governing FACA standard, and the scope of remedial authority—is legal and reviewed de novo. 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); Gov’t Br. 16–17. Deference has no work to do here.

The Court can resolve this appeal at the threshold: if appointments are not “agency action,” there is no APA vehicle, and the order falls. *Infra* Part II.B. Standing independently requires the same result. *Infra* Part II.A. Only if the Court disagrees on both need it reach the governing standard, *infra* Part III – and even then, the remedy cannot survive. *Infra* Part IV.

I. The Order Is an Injunction in All but Label – and the Label Concedes the Merits.

Plaintiffs first ask this Court to dismiss. The order below, they say, is not an injunction but a “stay” of “agency actions.” Resp. Br. 4 (citing *Nken v. Holder*, 556 U.S. 418, 429–30 (2009)). The argument defeats itself twice.

First, the characterization concedes the merits question Plaintiffs elsewhere insist is forfeited. A stay of agency action flows from 5 U.S.C. § 705, which authorizes a reviewing court to “postpone the effective date of an agency action” pending “review.” Calling the order a § 705 stay makes its validity turn on the appointments being reviewable agency action – the very question Plaintiffs say the government cannot raise. *Infra* Part II.B. Plaintiffs’ jurisdictional statement and their forfeiture argument cannot both be true. If

the appointments are not reviewable agency action, the order is not a § 705 stay of anything but an injunction restraining executive officers – appealable under 28 U.S.C. § 1292(a)(1), and reversible on the merits.

Second, the order is an injunction under *Nken* itself. *Nken* distinguishes a stay, which “operates upon the judicial proceeding” and temporarily suspends the effect of what has been done, from an injunction, which “is directed at someone, and governs that party’s conduct.” 556 U.S. at 428–29. The order below bars thirteen individuals from serving and concludes that the CDC Director cannot alter the immunization schedule without ACIP’s involvement. The order is directed at persons, and it governs conduct. Nor does it do what § 705 permits: a court cannot “postpone the effective date” of appointments completed months earlier. An order that unseats an already sitting committee member does not “preserve status or rights” but destroys the status quo.

The *Carson* conditions are satisfied. Gov’t Br. 4–5. Plaintiffs’ response reinforces them. The “serious, perhaps irreparable, consequence,” *Carson v. Am. Brands, Inc.*, 450 U.S. 79, 84 (1981), is the ongoing disability itself: by Plaintiffs’ own account, the government’s recourse when vaccine policy must move is to “return to the district court to seek a modification.” Resp.

Br. 48. An arrangement in which executive action requires judicial permission does not answer the irreparable-consequence showing. It is an irreparable consequence. The district court said as much, selecting its stay as “less drastic” than, “and thus preferable to, an injunction.” PI Op. 44; App. 859. An order entered as the substitute for an injunction has the practical effect of one and is immediately appealable.² If styling universal relief as a “stay” defeated appellate review, the same label would launder it past CASA’s limits on equity. See *Abbott v. Perez*, 585 U.S. 579, 594–95 (2018) (practical effect of order controls over label).

Nor is the practical effect a matter of inference. Plaintiffs assure this Court that the order “leaves the Secretary free to take a range of possible actions” to reconstitute the committee. Resp. Br. 3–4. Yet in a recorded interview immediately after the stay order issued, counsel of record explained:

INTERVIEWER: Does this decision stay any new appointments to ACIP?

² Plaintiffs assert that the district court “neither granted nor refused to grant an injunction.” Resp. Br. 4. Both verbs are wrong: adjudicating a motion for a preliminary injunction and § 705 stays, the court refused the injunction – declining to bar ACIP from meeting – and “GRANTED in part” the rest. PI Op. 5 n.11, 44–45; App. 820, 859–60. Either verb is § 1292(a)(1)’s.

COUNSEL: It does not. But *if we see additional appointments to ACIP, you can rest assured that we will act.*

INTERVIEWER: You'll file a motion to basically stay that one and make it go in circles . . .

COUNSEL: *Yeah. Yes.*³

Hence, this appeal. The government wants to reconstitute the ACIP and get it back to work. Plaintiffs tell this Court that appointing “legitimate, qualified, credible” members is a “simple solution[.]” the Secretary has “refused.” Expedition Opp. 3, 7. Their counsel elsewhere admits that if he does, “you can rest assured that we will act.” That is superintendence—the “serious, perhaps irreparable, consequence” that *Carson* holds may be challenged now.⁴

³ See <https://www.youtube.com/watch?v=l6Hm3V4433U> at 37:40–38:00 (last visited July 18, 2026) (interview of counsel of record for Plaintiffs-Appellees). The extra-record statements are offered on the question of jurisdiction, and the Court may take judicial notice of counsel’s own public statements for that purpose. See Fed. R. Evid. 201(b)(2).

⁴ *Calvary Chapel of Bangor v. Mills* is not to the contrary: it concerned the denial of a temporary restraining order—a denial that changed nothing and left the movant with other avenues of relief. 984 F.3d 21, 26–29 (1st Cir. 2020). The order here is months-long affirmative relief restraining the Executive Branch.

II. Count II Fails at the Threshold: No Standing, No Agency Action, No Finality.

A. Plaintiffs’ Injuries Trace to Adoptions, Not Appointments—and the Appointment Stay Redresses None of Them.

Standing must be established for each claim and each form of relief. *TransUnion LLC v. Ramirez*, 594 U.S. 413, 431 (2021) (standing “is not dispensed in gross”); *Davis v. FEC*, 554 U.S. 724, 734 (2008). Plaintiffs’ brief defends injuries. It never connects them to the appointments or explains what the appointment stay redresses.

1. Traceability. Plaintiffs now rest traceability on *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100 (2025), arguing that it was “predictable” that reconstituting the committee would alter recommendations and reduce vaccine uptake. Resp. Br. 28. *Diamond* involved a single, predictable market response to binding regulation: reinstate the regulation, and the regulated parties comply. 606 U.S. at 117–18. The chain here runs through independent, discretionary *government* decisions: a committee must deliberate; a majority must vote; and the Director must then decide, alone, whether to adopt, 45 C.F.R. § 147.130(a)(1)(ii). That is not predictable third-party behavior. It is the attenuated chain that *FDA v. Alliance for Hippocratic*

Medicine holds insufficient. 602 U.S. 367, 380–83 (2024). *See also Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 410–14 (2013). *Center for Biological Diversity v. EPA*, 168 F.4th 1164, 1176 (9th Cir. 2026), is farther afield still: the challenged action there was the agency’s published recommendation itself.

If appointments are agency action traceable to every downstream policy disagreement, every association that disagrees with a policy becomes a roving commission over executive appointments—armed with standing, preliminary injunctions, and intrusive discovery styled as record compilation.

Count I proves the disconnect. On the district court’s own holding, the January 5 Memo—the most consequential action here—was unlawful precisely because the Director *bypassed* ACIP entirely. A bypassed committee’s composition caused nothing. Plaintiffs cannot both maintain that the Director ignored the committee and that the committee’s membership produced their harm.

2. Redressability. Nowhere does the response explain what the appointment stay redresses that the stay of the adopted votes does not. The financial injuries Plaintiffs catalogue—unused doses, unreimbursed counseling, changed billing—flow from adopted recommendations, and

those adoptions are independently stayed. The district court itself saw the problem: vacating the committee's composition "would presumably wipe out the ACIP votes," which would "reinstate the guidance" Plaintiffs oppose. Dkt. 165, at 22; Suppl. App'x 1258; *see* Dkt. 165, at 36; Suppl. App'x 1272 (Plaintiffs' counsel: "That's what we're concerned about."). A remedy that at best returns Plaintiffs to the very actions they challenge redresses nothing.

3. The "direct interest" theory. Plaintiffs' remaining theory is that any organization with "a direct interest" in a committee's work has standing whenever fair balance is violated. Resp. Br. 30. But Plaintiffs have now disclaimed the only concrete version of that interest: they "do[] not claim" any "entitle[ment]" to a Work Group seat. Resp. Br. 31.

The contrast with *Wheeler* now appears in Plaintiffs' own filing. In *Wheeler*, the plaintiffs' members were the scientists the directive excluded – shut out of committee service and wanting in. These Plaintiffs disclaim any wish to be let in, so their asserted interest can only be in who *else* sits. An interest in the composition of a body one does not seek to join, divorced from concrete and redressable harm, is "an injury in law," not "an injury in fact." *TransUnion*, 594 U.S. at 427. Plaintiffs' pleadings confirm it: the injuries they

attribute to the committee itself – public meetings that are “a megaphone for spreading misinformation” that Plaintiffs must divert resources to “combat,” Dkt. 245 ¶¶ 3, 161–62; App. 356–57, 437; Dkt. 139 ¶¶ 122–23; Suppl. App’x 250—are the self-directed counter-speech expenditures *Alliance for Hippocratic Medicine* forecloses.

The district-court decisions Plaintiffs collect (Resp. Br. 30) – *Cardona*, *Uejio*, *Barr*—rested on seat-and-voice injuries of the exact kind Plaintiffs renounce; and *Alliance for Hippocratic Medicine* postdates each. *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), remains “an unusual case” not to be extended, and an organization “cannot spend its way into standing.” 602 U.S. at 394–96.⁵

⁵ Plaintiffs’ rhetoric outruns the record. An SCDM or individual-based recommendation does not “take away” coverage: the ACA mandates cost-free coverage of any immunization with an in-effect ACIP recommendation, 42 U.S.C. § 300gg-13(a)(2); *see* 45 C.F.R. § 147.130(a)(1)—as Plaintiffs’ own brief concedes. Resp. Br. 47 n.33. The birth dose remained covered for every family that chooses it; the asserted injury is that physicians must discuss the vaccine, not that any patient lost coverage.

B. An Appointment Is Not “Agency Action,” and the Reconstitution Became “Complete” Only When the Court Stopped It.

1. The APA does not reach everything an agency does. It reaches “agency action”: “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 category is a discrete, circumscribed exercise of regulatory power. *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 62 (2004).

The opening brief argued that an appointment to an advisory committee is none of them. Gov’t Br. 26–27. Plaintiffs never respond. Their brief argues discreteness and finality at length, but it never says which § 551(13) category an appointment occupies—rule, order, license, sanction, or relief. Plaintiffs leave the argument unanswered because there is no answer. The operative complaint’s own caption for Count II names its subject: not an action, but an entity—“The ACIP.” Discreteness is necessary but not sufficient, *Norton*, 542 U.S. at 62–64, and a personnel selection fits no category the APA enumerates.

This Court has drawn the same line: the *Wheeler* directive was reviewable because it was an agency-wide policy, “clearly not individual hiring decisions committed to discretion[.]” 954 F.3d at 18 n.5.

Plaintiffs’ effort to manufacture the missing legal consequences confirms the problem. The only “rights or obligations” their brief identifies are the *appointee’s* own: the right to attend meetings and vote, and duties of financial disclosure, outside-employment limitation, and uncompensated service. Resp. Br. 35. That is finality borrowed from someone else. The legal consequences *Bennett v. Spear* requires run outward—to parties whose legal position the action alters. 520 U.S. 154, 178 (1997). Consequences internal to the employment relationship are ordinary personnel administration, which no court reviews under the APA.

The theory also proves too much. Every federal appointment confers duties on the person appointed—an oath, ethics rules, disclosure obligations. On Plaintiffs’ theory, every appointment of every official, across roughly a thousand federal advisory committees and beyond, is final agency action reviewable at the suit of any interested bystander. The APA does not convert the Executive Branch’s staffing decisions into a docket.⁶

⁶ Plaintiffs assert that the government “does not contest” that each appointment marks a consummation. Resp. Br. 35. It does, and it did: appointments “are the beginning of a deliberative process, not its consummation.” Gov’t Br. 14.

Plaintiffs’ finality authority confirms the point. *Harper v. Werfel* applied *Bennett* to hold even a formal IRS summons non-final: a “preliminary investigative step, far upstream” of any enforcement action. 118 F.4th 100, 116 (1st Cir. 2024). Appointments sit farther upstream: before deliberation, before any vote, before the one decision with legal effect—the Director’s adoption. If the investigative step in *Harper* was non-final, staffing that precedes an advisory body’s deliberation cannot be final agency action.

Plaintiffs’ counsel said the same below: “[w]e wouldn’t be challenging an action taken by the ACIP if it hadn’t been adopted by the CDC [D]irector because it doesn’t become a final agency action.” Dkt. 260, at 51; App. 494. And their operative complaint pleads the same: the three challenged votes became “final agency actions” upon CDC adoption. Dkt. 245 ¶ 170; App. 438. Just so. Finality attaches at adoption—and the appointments sit two steps before the vote that precedes it.

2. Plaintiffs principally respond that the government raises all of this “for the first time on appeal.” Resp. Br. 33. The record refutes that. The government argued that Count II “amounts to a programmatic challenge to HHS’s vaccine policy writ large that is not cognizable under the APA” — a reviewability objection by its terms—and invoked Rule 12(h)(2): 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. Plaintiffs themselves briefed waiver below, Dkt. 229-1, at 31–32; App. 197–98, and the government responded, Dkt. 232, at 21; App. 258.

Plaintiffs’ course of litigation defeats any claim of unfair surprise. Their positions related to finality have never stood still:

Date	Plaintiffs’ position
Nov. 5, 2025	Third Am. Compl. labels “Reconstitution of the ACIP” a “justiciable final agency action[]” – no instrument, no date; twelve members seated, appointments ongoing.
Dec. 17, 2025	“[T]he facts are developing every day”; “the administrative record continues to build.” Dkt. 165, at 4–5; Suppl. App’x 1240–41.
Jan. 13, 2026	Two more members appointed.
Feb. 9, 2026	The government has “waived” any finality objection. Dkt. 229-1, at 31–32; App. 197–98.
Feb. 17, 2026	Operative complaint: Count III pleads finality expressly – CDC adoption dates, “thus making all of these votes final agency actions.” Dkt. 245 ¶ 170; App. 438. Count II pleads none. <i>Id.</i> ¶¶ 156–68.
Feb. 27, 2026	Two more members appointed; four seats remain vacant.
Mar. 4, 2026	To avoid <i>Braidwood</i> issues, the ACIP becomes “a purely advisory committee” whose recommendations are “not self-effectuating”; it “neither makes nor implements government decisions or policy”; it “is not the final decider.” Dkt. 283, at 25, 27; App. 753, 755; Dkt. 276, at 1, 4–5; App. 710, 713–14.
Mar. 16, 2026	The district court stays thirteen appointments.
July 16, 2026	“As a practical matter, the reconstitution is complete.” Resp. Br. 37.

The sequence speaks for itself. A claim pleaded with no identified final action became “developing every day” in December, a waiver argument in February, non-final again in March to avoid *Braidwood*, and “complete” in July—four months after procuring the order that halted it. The only consummating event between “developing every day” and “complete” is the injunction itself. The finality Plaintiffs assert was manufactured by the remedy they procured: they sued over an action they told the district court was still unfolding, obtained an order halting it mid-course, and now cite the halt as the consummation.

Plaintiffs’ theory reduces to this: the reconstitution became final when the district court stopped it. To state the position is to refute it. The order’s own boundary proves the point. The court expressly declined to stay the two appointments made February 27 because they “post-date the filing of this motion,” staying only the thirteen made before it. PI Op. 29 n.46; App. 844. No agency-side line separates the stayed from the spared—same official, same process, same alleged defects. The boundary is *a filing date*. The action did not consummate; it was interrupted.

The pleadings agree: Count II was ripe at twelve members, ripe again at fourteen, with two appointments and four vacancies still to come—a claim

that matures anew at each pleading challenges a program, not an action—and counsel promised the program: “we will continue to be challenging final agency actions,” because the facts “develop every day.” Dkt. 178, at 31 (Jan. 12, 2026 Status Conf. Tr.). *Lujan v. Nat’l Wildlife Fed’n*, 497 U.S. 871, 890 (1990).

Forfeiture fails for the same reason: it assumes a fixed target. The government was asked to align two moving dots. The claim moved—amended again in the middle of preliminary-injunction briefing, over the government’s objection, Dkt. 233; App. 67, to absorb the newest appointments. And the argument moved—the month after alleging forfeiture, Plaintiffs recast the committee as “purely advisory,” its recommendations “not self-effectuating,” to steer clear of *Braidwood*. The government joined issue on the claim as Plaintiffs described it; what it could not do was pin an objection to a particular final action Plaintiffs never named, or contest, in December, the finality of appointments, or a reconstitution, not yet made. Forfeiture requires a fixed target, and Plaintiffs never held one still.

Plaintiffs’ own authority holds that the APA’s finality requirement is not jurisdictional, *Nulankeyutmonen Nkihtaqmikon v. Impson*, 503 F.3d 18, 33 (1st Cir. 2007)—it is an element of Plaintiffs’ claim, theirs to plead and, on a

preliminary injunction, clearly show, *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008), and a defendant does not forfeit an element of the plaintiff's claim. They argued waiver instead. Nor could an objection to the appointment stay's predicate have been forfeited before that relief existed: no party proposed it, Dkt. 183-1; App. 141, and § 705 authorizes stays only of reviewable agency action. *Supra* Part I.

Regardless, this Court reaches new defenses where the question is purely legal, record-ready, and touches "matters of great public moment[.]" *Nat'l Ass'n of Social Workers v. Harwood*, 69 F.3d 622, 627–28 & n.6 (1st Cir. 1995) (exception ensures courts do not "poach on preserves that the Constitution reserves to other forms of oversight"). *Harwood's* defendants said nothing below. Here, the government joined issue in December.

3. Plaintiffs' own concessions strand Count II on the wrong side of *Wheeler's* line. Their brief confirms that "Plaintiffs have not challenged the Secretary's mass firing of all the ACIP members." Resp. Br. 48–49. The June 9 termination and its public announcement are the only events in this case that even resemble a *Wheeler*-style directive—dated, published, categorical. They are unchallenged. Nor is the announcement itself the missing instrument: it barred no one from service, set no eligibility criteria, and

carried no legal consequence of its own. What remains is precisely what *Wheeler* placed beyond APA review: a series of individual selections, made one by one over many months.

Biden v. Texas does not help. There, the agency issued a definitive written policy instrument, implemented in later steps. 597 U.S. 785, 793 (2022). Here, no instrument at all.

Plaintiffs warn that on the government's reading, agencies could "evade *Wheeler* by doing through appointments what they could not do through a written directive." Resp. Br. 36–37. How so? Where an agency acts through a directive, as in *Wheeler*, the directive is reviewed; and where it acts through individual selections and later relies on the committee's output, that reliance is reviewed on challenge to the downstream final action. Had the Secretary adopted a written policy that no industry-funded scientist may serve, that policy would have been reviewable the day it issued, however implemented. No conduct escapes review. What Plaintiffs seek is not review but a third channel the APA does not contain.

And consider what Plaintiffs' theory does to *Wheeler*. *Wheeler* holds that FACA is enforceable through the APA. "Through the APA" means through the APA's limits of § 551(13), *Bennett*, and *Norton*. If a plaintiff could

satisfy those limits by relabeling a series of personnel selections under the noun “reconstitution” and calling the noun agency action, that holding would mean nothing: FACA would be enforceable around the APA, not through it. *Lujan v. National Wildlife Federation* forecloses the move: the “land withdrawal review program,” a name for the agency’s continuing operations, was not “agency action” at all. 497 U.S. at 890. A label is not a rule, order, license, sanction, or relief.

4. Consider what review of individual appointments or “reconstitution” entails. An action with no instrument and no closed record must be reviewed on *some* record, and the only candidate is selection deliberations—vetting files, candidate comparisons, internal communications. Plaintiffs’ counsel described the posture below: this is “not a closed administrative record-type case”; the record “continues to build.” Dkt. 165, at 4–6; Suppl. App’x 1240–42. Record litigation continues even now. Resp. Br. 44 n.31.

The Supreme Court has warned in this precise context—a FACA dispute—against converting judicial review into civil discovery aimed at the deliberations of high-ranking executive officials. *Cheney v. U.S. Dist. Ct. for D.C.*, 542 U.S. 367, 385–90 (2004). A theory of “agency action” whose

administration requires ongoing discovery into the exercise of appointment authority is not a construction of the APA. It is a warrant for supervision the APA nowhere grants and *Cheney* and the Constitution do not tolerate.

That, in the end, is what Count II is actually about. Plaintiffs never seriously dispute that the stays of the adopted actions redress every concrete harm they allege. What Count II and the appointment stay add is not redress but control: judicial supervision of Executive Branch staffing, and judicially sanctioned discovery into agency deliberations.

III. *Wheeler* Authorizes Record Review, Not Résumé Review.

Identify the agency action, and the standard of review follows. *Wheeler* is *State Farm* review: the court examined a decision, on a record, against a stated rationale, asking whether the agency acknowledged the directive's effect on balance and "offered [a] rational reason" for it. 954 F.3d at 20. *See Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). That review was possible because there was an action to review.

Plaintiffs gave the court appointments instead – no reviewable record of a final decision. The court was left to assemble a record itself, reading résumés, building a record from the committee's website, and grading each

member against criteria of its own selection. PI Op. 28–34; App. 843–49. Member-by-member credentialing is what remains when nothing before the court is reviewable under *State Farm*. Under the correct standard, review asks whether the agency transgressed FACA’s outer boundaries—a categorical exclusion, a roster facially irreconcilable with the charter—measured on a fixed record against the agency’s stated rationale. Nothing of that kind occurred, or was found, here.

Plaintiffs’ focus on the administrative record obscures the subject of this appeal—and is revealing. This is a *preliminary-injunction* appeal; there was no administrative record to review—not because the government withheld one, but because, as Plaintiffs admitted in December, Dkt. 165, at 4–6, appointments generate no closed record at any stage. Their complaint that the government delayed producing a record that, in their counsel’s words, “continues to build,” concedes the defect rather than curing it.

Plaintiffs respond that the district court merely “appli[ed] the agency’s own standards”—the Membership Balance Plan and the outreach regulation—citing *INS v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996). Resp. Br. 39–42. *Yang* concerned settled adjudicative practice. The MBP is an internal, executive-amendable staffing document, and the requirement to maintain

one has since been rescinded, 90 Fed. Reg. 58,408 (Dec. 16, 2025), just as the outreach regulation has been revised. PI Op. 31 n.57, 32 n.58; App. 846–47.

Departure from a nonbinding internal plan is not a FACA violation. FACA’s test is the fairness of the composition that results, not the purity of the process that produced it. Plaintiffs relabel the district court’s method—“application of the agency’s own standards in the most generous possible way[,]” Resp. Br. 42. But they never defend the member-by-member footnotes themselves. Nor can they explain a stay that reached members the court never discussed and never found unqualified.

The burden inversion stands un rebutted as well. A preliminary-injunction movant must make a “clear showing” on every element. *Winter*, 555 U.S. at 22. Without a record, the court was left to find imbalance from the *absence* of evidence—reciting, member by member, that “there is no evidence in the record” of relevant expertise—while acknowledging that “there may be evidence to demonstrate” otherwise. PI Op. 29–31 & n.56; App. 844–46. An evidentiary gap of the movant’s own making is a reason to deny preliminary relief, not a basis to grant it.

Last, Plaintiffs say the separation-of-powers point was forfeited and underdeveloped. Resp. Br. 44. But the government does not press a

freestanding constitutional claim. Rather, it provides constitutional avoidance as guideposts to reading *Wheeler* and the APA. Arguments in support of a preserved position may be developed on appeal. The argument is that the district court's extension of *Wheeler* — from outer-boundary review of a directive to judicial credentialing of individual appointees — creates an Article II problem — and the reading that avoids it is also the correct one.

IV. The Remedy Is Unprecedented, Untailored, and Untethered to Any Plaintiff's Injury.

1. The district court did not stop at a fair-balance determination. Fair balance is a property of a committee's composition at a point in time.

No individual appointment is "unbalanced." Yet the court stayed *every* challenged appointment on the theory that "the appointment process, in general, and thus the full committee, was tainted." PI Op. 43–44; App. 858–59. A determination about balance became an order about people. Nor do the order's disclaimers match its operation: the court declared it "would be inappropriate" to "enjoin ACIP from meeting," yet entered a stay whose express object was that "ACIP as currently constituted cannot meet[.]" PI Op. 44; App. 859. Even under Plaintiffs' preferred abuse-of-discretion standard, that sequence cannot stand: the stay accomplishes the very result

the court had just called inappropriate. Relief must 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), and a stay that leaves no functioning committee does not cure an imbalance but inflicts a different and greater one.

2. The equitable defects escalate. Relief must be no broader than necessary. *Califano*, 442 U.S. at 702. It must have historical antecedent. *Grupo Mexicano de Desarrollo, S.A. v. All. Bond Fund, Inc.*, 527 U.S. 308, 318–19 (1999). Plaintiffs cite no case, from any court in any era, staying or vacating an individual appointment to remedy a fair-balance violation. And it must be tethered to complete relief for the parties. *CASA*, 606 U.S. at 851.

The appointment stay fails all three. This order does not merely extend relief to nonparties but awards relief that benefits no party at all. Plaintiffs' finality theory is novel, and their remedy is unprecedented. Novelty at both ends of an APA claim confirms that Count II leaves the statute behind.

The form of the relief tells the same story. Plaintiffs sought § 705 stays of the downstream Challenged Actions and an injunction against future meetings; no party sought a stay of appointments. PI Op. 5 & n.11; App. 820. The court selected that form itself, as the “less drastic” substitute for an

injunction. *Supra* Part I. The injunction this relief replaced would have had to answer *CASA*’s complete-relief limit. Styled as a § 705 stay, it never confronted that limit—and the label now serves a second purpose in this Court, deployed to defeat appellate jurisdiction. *Supra* Part I.

The mismatch between harm and remedy makes the point independently. The irreparable-harm finding below—diversion of organizational resources, PI Op. 36; App. 851—is not before this Court. But the relief erected on it is. And nothing in that finding connects to unseating thirteen appointees: a court concerned with what a reconstituted committee might someday vote—and a Director might adopt—reviews the adoption when it occurs, on an actual record, redressing an actual injury. It does not suspend the committee’s membership in the meantime.

3. Reversal does not “reinstate” anything. Plaintiffs warn that if the government prevails, the Secretary could “simply reinstate the appointments previously stayed.” Resp. Br. 3. The argument assumes its conclusion. Reversal restores the Executive Branch’s discretion, not any particular roster. Nothing suggests the Secretary will reseal the last roster rather than exercise the restored authority mindful of *FACA*’s fair-balance requirement—enforceable on review of the committee’s downstream

product, and, as the district court put it, “an agency’s job and prerogative” in the first instance. PI Op. 44; App. 859. What reversal ends is not fair-balance compliance but ongoing judicial supervision of the roster.

4. Judicial estoppel fails on its own elements. Plaintiffs say the government “proposed” appointment stays below and cannot now challenge “a variant” of its own remedy. Resp. Br. 46 (citing *Sexual Minorities Uganda v. Lively*, 899 F.3d 24 (1st Cir. 2018)). The government never proposed a remedy that stayed the ACIP out of existence. In any event, estoppel requires that the earlier position succeeded. *Lively*, 899 F.3d at 33–34. Here, the opposite happened. The government’s submission was an express alternative to keep the ACIP functioning: *if* the court found an imbalance, it should stay “only as many appointees as would be necessary” to cure it. Dkt. 232, at 51; App. 288. The court rejected that tailoring and stayed all thirteen, *including members it never found wanting*.

Plaintiffs add that the government never “flesh[ed] out” how a narrower remedy would work. Resp. Br. 46 (citing *Doe v. Trump*, 157 F.4th 36, 82 (1st Cir. 2025)). The record answers: stay only as many appointments as necessary to cure any imbalance, and let the Secretary finish filling the four open seats. Dkt. 232, at 32, 51; App. 269, 288. And the party seeking

relief, not the party restrained, bears the burden of justifying its scope. *Califano*, 442 U.S. at 702.

An order broader than the fallback the government offered in the alternative is not a “less intrusive variant.”

5. *Braidwood* is not a removal-only case. Resp. Br. 48–49. Appointment and removal are two faces of the same supervisory power. A Secretary who may remove members but whose appointments a court holds in abeyance cannot supervise the committee at all. *Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748, 760–62 (2025) (supervision of an advisory body runs through the powers to appoint, remove, and block recommendations). Plaintiffs’ observation that the *Braidwood* Task Force was not subject to FACA cuts against them: FACA committees exist “solely for advisory functions,” 5 U.S.C. § 1008(b)—a weaker case, not a stronger one, for judicial structural control. Nor does the government dispute that Congress may prescribe qualifications for advisory bodies. Resp. Br. 49. The question is who applies them to individual candidates, and *Braidwood* answers it: supervision of an advisory body’s membership belongs to the Secretary. And Plaintiffs’ non-challenge to the mass termination concedes the supervisory authority at issue. *Accord* Dkt. 165, at 29; Suppl. App’x 1265 (“the Secretary does have

discretion to appoint to an advisory committee, also to terminate”). The district court felt the same difficulty. Dkt. 283, at 23; App. 751 (“struggling with how to square that with what the Supreme Court said in *Braidwood*”).

6. Plaintiffs’ flu-season assurances confirm the point. The assurances rest on materials outside the record – agency web pages, a price list, a trade association’s press release. Resp. Br. 47–48 & nn.32–34. Taken on their own terms: national vaccine coverage now depends in part on an insurers’ association’s voluntary pledge through 2027—a stopgap for a disabled statutory process.

A committee supervised by Article II now operates by leave of Article III. And under Plaintiffs' own theory, every future appointee is separately litigable, before the same court, under no articulated standard. That is conservatorship, not judicial review.

* * *

The proper remedy remains the ordinary one: set aside the challenged final actions, if warranted, and remand for the agency to proceed properly. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985). That relief redresses every concrete injury Plaintiffs identify, without judicial staffing of the Executive Branch.

CONCLUSION

At bottom, the government seeks two things from this Court: release of the appointment power from ongoing judicial supervision, and clarification that this is an APA case, not a roving commission into the files of Executive Branch officers.

Reversal forfeits no safeguard. The pre-January 5 schedule remains in effect; the stays of the adopted actions remain in place; FACA's fair-balance requirement remains binding law; and any future adoption is subject to immediate APA review, on a record, the day it issues. Reversal does not make vaccine policy unreviewable. It returns review to where the APA locates it.

The district court confronted a novel claim on a compressed schedule, amid an urgency Plaintiffs have since disclaimed. The error lies in the framework they pressed, not the court's care. For these reasons and those in the opening brief, the Court should reverse the order below insofar as it stays the thirteen appointments, and remand, subject to the interim treatment of the stayed votes described in the opening brief.

Respectfully submitted,

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July 2026

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 6,487 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 July 21, 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

EXHIBIT B

Perspectives > Second Opinions

A Flu Season Without ACIP: The Question for Fall

— While vaccine access and coverage will mostly hold this year, that's not good enough

by Richard Hughes IV, JD, MPH, and Will Walters, JD

June 29, 2026 · 5 min read

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The U.S. is heading toward the 2026-2027 respiratory virus season without a functioning [Advisory Committee on Immunization Practices](#) (ACIP). That is no small disruption. ACIP has guided national policy on influenza vaccination since its [first meeting in 1964](#), and since 2010 has maintained a [universal annual recommendation](#) for influenza vaccination for everyone 6 months and older. The committee has been central to the evidence-review



process that translates vaccine science into clinical guidance, coverage obligations, purchasing decisions, and public communication.

Now that process has stalled. A federal district court in Massachusetts stayed the appointments of 13 ACIP members in *American Academy of Pediatrics et al. v. Kennedy et al.*, following an unprecedented move by Health Secretary Robert F. Kennedy Jr. to [fire all existing ACIP members](#). The committee has not been lawfully reconstituted nor convened. Kennedy has [issued a charter](#) that refocuses the responsibilities of the committee, but it's little more than an attempt to rewrite the rules he has broken. No season-specific federal recommendation for influenza vaccination has yet been issued for the 2026-2027 season -- and we don't believe one is imminent.

But broad access to influenza vaccination is a public health necessity: the current [off-season flu outbreak](#) among military members offers an eye to what happens when immunization rates drop precipitously.

For providers, pharmacists, payers, and the millions of Americans who receive influenza vaccines each fall, the immediate question is simple: Will flu vaccines be available and covered this year? We believe the answer, for the 2026-2027 season, is yes.

A System Running on Workarounds

Even without ACIP, the existing system for influenza vaccine production, coverage, and delivery is resilient enough to hold together for now. But that resilience should not be confused with a functioning public health infrastructure. What will carry the country through this flu season is a collection of norms, professional society guidelines, legal backstops, and payer commitments.



In the absence of a federal recommendation, the clinical standard of care is increasingly being [articulated by professional societies](#) -- and the consensus is uniform. The American Academy of Pediatrics [continues to recommend](#) annual influenza vaccination for all children beginning at 6 months of age. The American Academy of Family Physicians likewise published its own [2026 adult immunization schedule](#) through an independent internal review process. Amid a backdrop of chaotic federal vaccine policy, providers will have a source of evidence-based guidance when recommending flu vaccines this fall.

Coverage Should Mostly Hold

The [Affordable Care Act \(ACA\) requires](#) commercial health plans to cover, without cost sharing, immunizations that have "in effect" a recommendation from ACIP. A rarely noticed structural reality is that the ACA's implementing rules provide payers with a lengthy grace period to cover newly recommended vaccines. Given that make-up of antigen strains resets every year, this reveals that seasonal flu vaccine coverage has relied on payer good will.

That norm remains intact. America's Health Insurance Plans recently [renewed its members' commitment](#) to ongoing coverage of vaccines to ensure access and affordability for this respiratory virus season. Older adults, who are among the highest-priority populations for flu vaccination, are insulated from the current ACIP disruption because Medicare Part B coverage is statutorily required and does not depend on ACIP.

The [Vaccines for Children program](#), which supplies federally purchased vaccines to Medicaid-eligible, uninsured, and underinsured children through age 18, must provide free doses of vaccines chosen by ACIP to states. Any ambiguity about whether 2026-2027 influenza



vaccines will be covered by the program is resolved by [Resolution No. 10/24-1](#), adopted by ACIP in October 2024.

Because the resolution's language is agnostic to any particular season or strain, it maintains operational legitimacy.

Medicaid coverage of influenza vaccines should also remain reasonably stable in the near term. The Inflation Reduction Act requires traditional Medicaid programs to cover, without cost sharing, FDA-approved adult vaccines recommended by ACIP. No implementing rules further define these requirements, though [CMS guidance specifies](#) that coverage must be consistent with ACIP recommendations. This opens the door to potential non-coverage and deserves the attention of states and Medicaid managed care organizations toward ensuring continuity of coverage for adults covered by Medicaid during the 2026-2027 influenza season.

Pharmacists Need Clarity in Some States

One practical access concern deserves particular attention: pharmacist vaccination authority. Many states authorize pharmacists to administer vaccines by referencing ACIP recommendations or CDC immunization schedules. In those states, the absence of a current-season federal recommendation could create a technical scope-of-practice question.

The [Twelfth Amendment COVID Declaration](#) Under the Public Readiness and Emergency Preparedness Act, extended through 2029, authorizes pharmacists in all 50 states to administer seasonal influenza vaccines to individuals ages 3 and older, preempting more restrictive state laws. However, this authority is limited "according to CDC's/ACIP's standard immunization schedule."

HHS Could Fix This



The current situation is not inevitable. The HHS secretary retains authority to restore a functioning ACIP. He could appoint qualified new members. He could also designate ex officio members as voting members while a quorum is unavailable. Either step could allow the recommendation process to continue before the 2026-2027 respiratory season.

The plaintiffs in *AAP v. Kennedy* have made clear that their concern is not with merely maintaining long-standing, science-grounded vaccine recommendations. Their concern is the removal or downgrading of established recommendations without a credible scientific process.

The System Will Mostly Hold. That Is Not Good Enough.

The 2026-2027 influenza season will likely proceed without major coverage disruption. But contingencies do not make a system. Influenza is the best-case scenario for navigating a vaccine season without ACIP. It has a long history of annual guidance, a universal recommendation, broad payer support, mature manufacturing and distribution channels, and one of the deepest evidence bases in preventive medicine. If any vaccine can make it through a season on institutional memory and workarounds, it is flu.

But public health infrastructure should not depend on workarounds.

The longer the committee remains unable to function, the more likely today's manageable uncertainty becomes tomorrow's access barrier, coverage dispute, provider confusion, or decline in vaccine confidence.

Disclosures

The authors represent the American Academy of Pediatrics and other medical societies and public health groups in litigation challenging immunization schedule changes by HHS Secretary Kennedy and ACIP.



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

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

[PROPOSED] ORDER

Upon consideration of Defendants' Unopposed Motion for Leave to File Reply in Support of Renewed Motion to Stay Proceedings Pending Appeal, and good cause appearing, the Motion is GRANTED. The reply attached to the Motion as Exhibit 1, with its exhibits, is deemed filed as of the date of this Order.

IT IS SO ORDERED.

Dated: _____, 2026

Hon. Brian E. Murphy
United States District Judge