

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs,

v.

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

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

Defendants.

**BRIEF OF AMICI CURIAE ANDREA SHAW, SHANTICIA NELSON,  
DR. PAUL THOMAS, DR. KENNETH STOLLER, AND  
CHILDREN'S HEALTH DEFENSE IN OPPOSITION TO  
PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION**

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## I. INTRODUCTION AND SUMMARY OF ARGUMENT

Amici file this brief pursuant to the Court's direction at the March 4, 2026 hearing and its March 5, 2026 order. Amici are Andrea Shaw, Shanticia Nelson, Drs. Paul Thomas and Kenneth Stoller, and Children's Health Defense.

This case has generated more than 280 docket entries, a Fourth Amended Complaint, two evidentiary hearings, declarations from more than thirty witnesses, and supplemental briefing on a question of first impression under *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), and various amici briefs.

The Fourth Amended Complaint challenges four categories of government action taken between May 2025 and January 2026. Count I challenges the January 5, 2026 Decision Memo revising the childhood immunization schedule, reducing universally recommended vaccines from eighteen diseases to eleven, reclassifying six vaccines to shared clinical decision-making (“SCDM”) or risk-based categories, eliminating the second dose of the HPV vaccine, and removing the hepatitis B birth dose for infants born to hepatitis B-negative mothers.

Count II challenges the composition of ACIP, the Secretary's June 2025 removal of all seventeen members and appointment of replacements Plaintiffs allege are unfairly balanced and inappropriately influenced in violation of FACA.

Count III challenges three votes of the reconstituted ACIP: the September 2025 vote moving the COVID-19 vaccine to shared clinical decision-making, the December 2025 vote on the hepatitis B birth dose, and the June 2025 vote on thimerosal.

Count IV challenges the Secretary's May 2025 directive removing the COVID-19 vaccine from the recommended schedule for healthy children and pregnant women.

Plaintiffs' proposed preliminary injunction order (Dkt. 183-1) would reverse all six challenged actions, enjoin the government from publishing any materials reflecting the changes, and shut down ACIP entirely: no meetings of the current membership on any subject, for the duration of this litigation. If a novel pathogen surfaces in the United States next month, the federal government's vaccine advisory committee would be unavailable by court order.

Amici respectfully submit that the preliminary injunction analysis is simpler than the record suggests. The four *Winter* factors are independent. Failure on any one is dispositive. Thus the Court need not necessarily resolve every contested question to rule on this motion.

The following is a brief summary of the points in this Brief:

### **1. Reviewability**

Amici first address the threshold question whether the Court has the power to review the Secretary's actions. The government argues the Director's adoption of ACIP recommendations is committed to agency discretion and therefore unreviewable. That position is wrong, and Amici argue against it even though Amici are aligned with the government on the merits. *Braidwood* footnote 4 confirms that the Director's adoption is the act that triggers binding legal consequences. The APA provides the review standard. The government's own supplemental filing (Dkt. 279) concedes the adoption is discretionary, which supports reviewability rather than unreviewability. (Section II below). Accordingly, the Court should reject the Government's claim that it does not have the power to review the Secretary's discretionary actions.

### **2. Standing**

Amici argue that before the Court can proceed to the *Winter* factors, it must satisfy itself that Plaintiffs maintain Article III standing on the developed record — not merely on the pleadings accepted as true at the motion to dismiss stage. The evidentiary record developed since

January 6, 2026, raises a serious question whether AAP's claimed organizational injuries reflect operational disruption or issue-advocacy. Under *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), issue-advocacy does not confer standing. Amici submit that the Court should deny the motion to enjoin the next ACIP meeting, hold all other relief in abeyance, and order the parties to brief standing on the developed record.

### **3. Framework**

Having established reviewability, and assuming the Court finds continued standing on the record, the Court should begin its *Winter* analysis with irreparable harm rather than the merits. The merits questions are unusually complex: the parties have filed competing briefs on whether *Braidwood* exempts ACIP from FACA, a question of first impression no court has decided. Those questions deserve resolution on a better record. More importantly, the merits matter only if Plaintiffs can demonstrate that they will be irreparably injured. If they cannot, the motion fails without reaching the merits. (Section III).

### **4. Irreparable harm.**

Amici's primary argument is that Plaintiffs have not demonstrated irreparable harm to themselves. Every organizational injury in the record is quantifiable in dollars: staff time, hiring costs, reimbursement declines. Those are compensable, not irreparable. Plaintiffs' non-economic claims, erosion of trust, declining vaccination rates, confusion among families, are injuries to the public, not to Plaintiffs as organizations. They belong in the public interest analysis, (*Winter* factor 4), not the irreparable harm analysis.

The evidentiary record reveals something more fundamental. In its order on the motion to dismiss, this Court accepted Plaintiffs' allegation that AAP "had to divert resources to develop new infrastructures, processes, and guidance" and to publish "their own immunization

schedules.” Dkt. 168 at 5 (quoting Compl. ¶ 86). That finding was made on a pleading-stage record, as the law required. After the Court’s standing decision, AAP’s own declarant told a different story. Dr. Kressly, AAP’s immediate past President, acknowledged that AAP has its own clinical practice guidelines framework and that endorsing the CDC schedule was a historical choice within that framework. Kressly Decl. (Dkt. 185-27) ¶ 19 (“has historically endorsed”). She confirmed AAP had already “ceased its endorsement.” Id. ¶ 22

Shortly after Kressly signed her declaration, AAP published the Red Book 2026, the clinical reference AAP’s Committee on Infectious Diseases has published since 1938. Jaffe Amicus Decl. ¶¶ 8, 17; Appendix B. That schedule recommends the same vaccines, for the same children, at the same ages, on the same timetable, as AAP’s 2025 schedule. AAP did not change any clinical recommendation. It did not implement shared clinical decision-making for any of the CDC’s reclassified vaccines. It did not retrain its members. It told its 67,000 members: nothing has changed; continue to follow the Red Book; ignore the CDC.

The resources AAP spent after January 5 were spent on press releases, webinars, coalition-building with 230 organizations, and public statements that the government is wrong. Jaffe Amicus Decl. ¶ 17. That is advocacy. Section IV.

### **The Merits**

Amici address the merits to assist the Court in the event it reaches them. On the COVID-19 vaccine (Counts III and IV), every institution that examined the question reached the same result: the Biden/pre-Kennedy ACIP working group, the FDA, the manufacturers, the reconstituted ACIP. The data Plaintiffs rely on (set out by Dr. Havers) was presented to the Biden April 2025 working group and rejected by more than three-quarters of its members. On the schedule revision (Count I), the Hoeg/Kulldorff assessment is in the record as Plaintiffs’ own

Exhibit 19 (Dkt. 185). Plaintiffs dismiss it in one allegation. The document speaks for itself; Amici walk the Court through its contents because neither party has done so. On the ACIP shutdown (Count II), the proposed remedy is disproportionate, creates an irreconcilable tension in Plaintiffs' position, and would disable the nation's emergency response infrastructure for the duration of this litigation. Section VI.

**The parallel litigation.** On February 24, 2026, fourteen state attorneys general and the Governor of Pennsylvania filed suit in the Northern District of California challenging the same schedule revision, ACIP reconstitution, and ACIP votes at issue here, asserting the same APA and FACA claims. They did not move for a preliminary injunction. That decision, by fifteen sovereign officers with *parens patriae* authority over tens of millions of children, is itself evidence that emergency relief is not required. Several plaintiff states have already enacted independent regulatory solutions—Colorado by emergency rule, California by statute, New Mexico by legislation, Delaware by regulatory amendment—collapsing the claim that a federal injunction is the only mechanism available to protect children. California has delinked from the federal schedule by statute (AB 144) and claims injury from changes to that schedule, presenting the same issue-advocacy standing problem that runs through AAP's claims here. And granting a nationwide preliminary injunction on a question of first impression, on a thin preliminary record without full merits briefing or testimony, with parallel litigation pending in a sister district, risks an inconsistent resolution that binds the government before any court has fully analyzed the question. On a motion where the Court can deny on irreparable harm without touching the first-impression issues, that risk alone counsels restraint. Section VI.D.

**I-A. PRIOR RECORD INCORPORATED BY REFERENCE**

Amici have filed three prior submissions in this action: the Memorandum in Opposition to the Preliminary Injunction (Dkt. 251), the Declaration of Richard Jaffe with Exhibits A through E (Dkt. 250), and the Supplemental Declaration of Richard Jaffe with Exhibits F through H (Dkt. 264). All three are incorporated by reference. The factual record from those filings, organized by *Winter* factor and count, is set forth in the Proposed Findings of Fact and Conclusions of Law filed as Appendix A to the Declaration of Richard Jaffe in Support of Amicus Brief. Throughout this brief, parenthetical citations to “App. A ¶ \_\_” refer to specific numbered findings in that document. The following highlights are the facts from the prior record most directly relevant to this motion:

1. The cumulative childhood immunization schedule Plaintiffs ask this Court to restore has never been evaluated as a protocol. The IOM found in 2002 that no study had compared health outcomes between children who received the full schedule and those who did not, and recommended such studies. The IOM found in 2013 that those studies had still not been conducted and should be prioritized. Neither Plaintiffs nor Defendants cited either report. (App. A ¶¶ 11–14.)
2. Massachusetts requires nine or ten vaccines for school entry. The pre-January 2026 CDC schedule recommended eighteen. The revised schedule recommends eleven. Both exceed what Massachusetts requires. Six of the seven reclassified vaccines were never required for Massachusetts school entry. The difference between the two federal schedules is not a clinical difference for Massachusetts children. It is a difference in how aggressively Plaintiffs can promote uptake of vaccines the state does not require. (App. A ¶¶ 33–36.)

3. No COVID-19 vaccine is approved or authorized for any healthy child of any age. The FDA limited Moderna’s and Pfizer’s BLAs to children with underlying high-risk conditions and revoked Pfizer’s EUA for all children under five. The FDA’s Director of CBER wrote: “For healthy children that standard is not met.” (App. A ¶¶ 37–40.)
4. More than three-quarters of the pre-Kennedy ACIP COVID-19 Work Group had already concluded that universal recommendation should end, after hearing the Havers data Plaintiffs now rely upon. The formal vote was scheduled for June 2025. Kennedy acted in May. (App. A ¶¶ 46–49.)
5. The VFC enforcement mechanism made the prior COVID-19 recommendation coercive for Medicaid-enrolled children and the physicians who served them. Dr. Samara Cardenas lost her practice of 1,900 Medicaid children for declining to administer the COVID-19 vaccine to healthy children based on her clinical judgment. Preliminary relief would reimpose that mechanism. (App. A ¶¶ 54–57.)
6. Two mothers whose children died following multiple simultaneous vaccinations are among Amici. Two physicians lost their licenses for exercising the clinical judgment FDA would later vindicate. Plaintiffs’ more than twenty declarations address none of them. (App. A ¶¶ 23–28.)

Amici now address each issue in the Section I summary in turn.

## **II. THE DIRECTOR’S ADOPTION OF ACIP RECOMMENDATIONS IS REVIEWABLE UNDER THE APA**

This section argues against a position taken by the Department of Justice (“DOJ”) on behalf of the Defendants that the Director’s decision to accept, reject, or modify ACIP recommendations is committed to agency discretion and therefore unreviewable. The importance

of this issue extends beyond this case. If this Court accepts that the Director’s adoption of ACIP recommendations is unreviewable, the same argument would insulate any future Director, of any administration, who chose to add, remove, or modify vaccine recommendations for any reason, or no reason. It is the function of an amicus curiae to assist the Court. On this issue, the DOJ is wrong.

#### **A. Discretionary Does Not Mean Unreviewable.**

The APA “embodies the basic presumption of judicial review.” *Abbott Labs. v. Gardner*, 387 U.S. 136, 140 (1967). The exception for action “committed to agency discretion by law,” 5 U.S.C. § 701(a)(2), is “very narrow.” *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971). It applies only in “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.” *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 586 U.S. 9, 18–19 (2018).

Courts “could never determine that an agency abused its discretion if all matters committed to agency discretion were unreviewable.” *Weyerhaeuser*, 586 U.S. at 18–19. The government identifies the discretion correctly and then leaps to unreviewability without establishing that there is no law to apply. Section 706(2)(A) supplies the standard: the agency must “examine the relevant data and articulate a satisfactory explanation for its action.” *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 29, 43 (1983).

The absence of a statute specifying the particular factors the Director must weigh does not render the decision unreviewable. It renders the decision reviewable under the APA’s general standard.

#### **B. *Braidwood* Forecloses the Government’s Position.**

*Braidwood* eliminates any argument that the Director’s adoption falls within the narrow § 701(a)(2) exception. The Court held that when the ACA empowers an advisory body’s recommendations to trigger binding insurance obligations, the body’s function is no longer purely advisory. 606 U.S. at 766 n.3. Footnote 4 concludes that ACIP recommendations become binding only upon adoption by the Director. *Id.* at 767 & n.4.

What footnote 4 establishes is that the Director’s adoption converts a recommendation into a binding legal obligation affecting every health insurer in the country. The government’s own supplemental filing (Dkt. 279) confirms this: the government argues ACIP remains advisory because its recommendations require “affirmative adoption” by the Director. Dkt. 279 at 3. That concession supports reviewability. If the Director exercises discretion in deciding whether to adopt, that discretion is reviewable under § 706(2)(A).

The “committed to agency discretion” exception has been applied to decisions where the consequences are narrow and the standards nonexistent: prosecutorial discretion (*Heckler v. Chaney*, 470 U.S. 821 (1985)), CIA personnel decisions (*Webster v. Doe*, 486 U.S. 592 (1988)), lump-sum appropriations (*Lincoln v. Vigil*, 508 U.S. 182 (1993)). It has never been applied to a decision that triggers nationwide mandatory insurance coverage for hundreds of millions of Americans. The Director’s adoption is a regulatory act of general applicability with binding legal consequences.

The government cannot invoke the binding effect of ACIP recommendations when it wants insurers to comply and then claim the decision to make them binding is unreviewable when challenged. *Braidwood* recognized the binding character. The APA provides the review standard. The Court should reject the DOJ’s argument and proceed to decide this motion.

**C. The Discretion Footnote 4 Recognizes Has Not Been Exercised in Sixteen Years. Kennedy Exercised It**

*Braidwood*'s footnote 4 identifies the moment when ACIP recommendations become binding: the Director's adoption converts a recommendation into enforceable insurance obligations. But the same footnote identifies when they do not become binding: if the Director decides otherwise. 606 U.S. at 767 n.4. The word "until" is load-bearing. It confirms that the Director retains discretion to depart from an ACIP recommendation. That discretion is not new. It has been in the statutory structure since the ACA was enacted in 2010.

For sixteen years, no Director exercised it. Each administration's Director adopted ACIP recommendations as a matter of course. That pattern became so consistent that Plaintiffs mistake convention for legal requirement. It is not. Footnote 4 says otherwise. A rubber stamp applied consistently is still a rubber stamp.

Kennedy is the first Director in sixteen years to exercise the discretion footnote 4 recognizes. That exercise is reviewable under § 706(2)(A), as Section II.A establishes. A Director who exercises statutory discretion for the first time is not acting without authority. The authority has always been there. What the Director must do is articulate a satisfactory explanation for the exercise. *State Farm*, 463 U.S. at 43. The Hoeg/Kulldorff Assessment, the pre-Kennedy working group's own conclusions, and the FDA's BLA decisions are the record from which that explanation is drawn.

Plaintiffs' argument also proves too much. If APA notice-and-comment procedures were required to revise the schedule, they were equally required to adopt it. The childhood immunization schedule was never subjected to § 553 rulemaking. It was built through ACIP recommendations and Directors' adoption of them, without notice-and-comment, without public participation, without the procedural apparatus Plaintiffs now demand. Plaintiffs cannot invoke

procedural requirements against the revision that did not apply to the schedule's original construction.

AAP is not asking this Court to enforce the law. It is asking this Court to restore the rubber stamp.

### **III. THE COURT SHOULD SATISFY ITSELF OF STANDING BEFORE GRANTING RELIEF**

Standing is jurisdictional and must exist at every stage of the proceeding. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). A court has an independent obligation to satisfy itself of jurisdiction regardless of whether any party raises the issue. Fed. R. Civ. P. 12(h)(3). Because standing is a threshold requirement, Amici respectfully submit that the Court should address it before reaching the Winter factors. Specifically: (1) the motion for a preliminary injunction to enjoin the next ACIP meeting should be denied because there is now a serious question whether Organizational Plaintiffs maintain Article III standing on the developed record; (2) all other requested relief should be held in abeyance pending resolution of the standing question; and (3) the Court should order the parties to brief whether Organizational Plaintiffs maintain standing at the preliminary injunction stage in light of the evidentiary record developed since January 6, 2026, and permit Amici to submit a memorandum in opposition to Plaintiffs' submission.

On January 6, 2026, this Court found organizational standing on a pleading-stage record. The Court found that AAP had alleged it "had to divert resources to develop new infrastructures, processes, and guidance" and to publish "their own immunization schedules." Dkt. 168 at 5 (quoting Compl. ¶ 86). The Court specifically distinguished *Equal Means Equal v. Ferriero*, 3 F.4th 24, 30 (1st Cir. 2021), finding that AAP "plausibly allege[d] injuries that are more than just

an ‘effect of [a challenged action] on the organizations’ lobbying activities’ or purely the impairment of its ‘issue-advocacy.’” Dkt. 168 at 12 n.15. (App. A ¶ 78.)

That finding was required by the pleading standard. At the motion to dismiss stage, the Court accepted AAP’s allegations as true. Dkt. 168 at 1. There was no evidentiary record against which to test them as of the date of the Court’s standing decision. AAP had not yet responded to the schedule revision. The Red Book 2026 had not been published. The Kressly declaration had not been filed. The 230 endorsements, the webinars, the press campaigns, and the Berman and Benjamin supplemental declarations describing the actual spending did not exist.

The record that exists now is different. The difference is what AAP did, publicly, in its own name, through its own publications.

Three weeks after this Court’s order, AAP’s own declarant provided the short answer. Kressly told the Court that AAP has its own clinical practice guidelines framework and that endorsing the CDC schedule was a historical choice within it. Kressly Decl. ¶ 19 (“has historically endorsed”). She confirmed AAP had already “ceased its endorsement.” Id. ¶ 22. A few days after this declaration, AAP published the Red Book 2026 with identical clinical recommendations. Appendix B. AAP told its members nothing had changed. Appendix C. It spent its resources on press releases, webinars, and coalition-building. Jaffe Amicus Decl. ¶ 17. It did not develop new clinical infrastructure. It did not implement SCDM. It did not retrain anyone. Every dollar went to telling the world the government was wrong. That is the definition of issue-advocacy. It is what *Equal Means Equal* holds is insufficient for organizational standing. 3 F.4th at 30. (App. A ¶¶ 73–79.)

The Supreme Court’s recent guidance reinforces the concern. In *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 394–95 (2024), the Court held that organizational standing

requires the defendant's action to have "directly affected and interfered with" the organization's "core business activities." AAP's core business activity is recommending vaccines. AAP still recommends the same vaccines. The schedule change did not interfere with AAP's core activity. It created a policy divergence that AAP chose to publicize. If that confers standing, every medical society has standing to challenge every government policy it disagrees with, and the distinction this Court drew between advocacy and operational disruption in footnote 15 collapses. (App. A ¶ 79.)

Amici do not ask the Court to dismiss this action on standing based on an amicus submission. The record developed since January 6, 2026, is the basis for the request. The Court should deny the motion to enjoin the next ACIP meeting, hold all other requested relief in abeyance, and order the parties to brief whether Organizational Plaintiffs maintain Article III standing on the facts as they now exist. Amici respectfully request permission to submit a memorandum responding to Plaintiffs' submission.

#### **IV. WHY THE COURT SHOULD PROCEED TO IRREPARABLE HARM BEFORE THE MERITS**

Having established that the challenged actions are reviewable, and assuming arguendo continued standing, the question is whether Plaintiffs have met the standard for preliminary relief. "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." *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008). Factors 3 and 4 merge when the government is the opposing party. *Nken v. Holder*, 556 U.S. 418, 435 (2009). The four *Winter* factors are independent, and failure on any one is dispositive.

The merits questions are unusually complex. The parties have filed competing briefs on whether *Braidwood* exempts ACIP from FACA (Dkt. 276; Dkt. 279), a question of first impression. The arbitrary-and-capricious analysis under Count I turns on the Hoeg/Kulldorff assessment and the other assessment recently proffered by the DOJ. The COVID claims require evaluation of FDA regulatory actions and the pre-Kennedy working group’s deliberative process. These questions will benefit from full merits briefing (and probably discovery), and the deliberation that novel legal questions deserve.

But the merits issues only become relevant if Plaintiffs can demonstrate irreparable harm, and because the harm issue is most developed in the record and the clearest part of this case, that is the place to begin (and end) given the extremely short decisional time frame.

## **V. PLAINTIFFS HAVE NOT DEMONSTRATED IRREPARABLE HARM**

### **A. The Legal Standard.**

Irreparable harm under *Winter* means harm to the movant that cannot be remedied by monetary damages. *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004); *Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 18–19 (1st Cir. 1996) (“a denial of interim injunctive relief would cause irreparable harm squarely upon the movant”). Factor 2 is distinct from Factor 4. *Winter* separates them; the movant must show that “he is likely to suffer irreparable harm” (Factor 2) and that “an injunction is in the public interest” (Factor 4). 555 U.S. at 20. *Nken* merged Factors 3 and 4 in government cases, but left Factor 2 independent. 556 U.S. at 435. If harm to the public satisfied Factor 2, Factor 4 would be redundant. Amici respectfully suggest that in analyzing the evidence of irreparable injury, the Court limit its consideration to the proven harm to the plaintiffs. (App. A ¶ 83.)

### **B. Plaintiffs’ Organizational Injuries Are Economic.**

Plaintiffs' declarants describe the following injuries from the schedule revision. Dr. Berman reports ten additional minutes per patient visit for SCDM counseling, hiring an additional nurse practitioner at \$130,000, approximately \$52,000 in excess annual costs, and an 8% decline in reimbursement. Dkt. 274-2. Dr. Benjamin reports staff diverted from core mission activities to emergency mitigation work. Dkt. 274-1. Dr. Goldman reports staff redirected to independent literature review and member inquiries. Dkt. 274-5. (App. A ¶¶ 84–86.)

Every one of these injuries is quantifiable in dollars. Additional staff time can be calculated. Hiring costs are known. Reimbursement declines are measurable. Diverted organizational resources can be valued. These injuries may be substantial, and Amici do not minimize them. But they are economic. They are compensable. Under *Winter* and *Charlesbank*, they are not irreparable. (App. A ¶ 82.)

#### **C. Plaintiffs' Non-Economic Claims Belong in Factor 4, Not Factor 2.**

Plaintiffs also assert broader harms: erosion of trust between physicians and patients, confusion among families, declining vaccination rates. These are public health concerns, not organizational injuries. They may be real, but they are not injuries to AAP or APHA or ACP as organizations. They are injuries to the public. They belong in the public interest analysis under Factor 4, where they must be weighed against the public interest in maintaining a functioning ACIP, in not ordering uptake of products the FDA declined to approve for healthy children, and in not reimposing the VFC disparity that AAP's own former committee chair flagged as problematic. Jaffe Suppl. Decl. (Dkt. 264 ¶ 12. (App. A ¶ 83.)

#### **D. AAP's Resource Expenditures Were Advocacy, Not Operational Adaptation.**

AAP's Committee on Infectious Diseases ("COID") has published clinical vaccine guidance through the Red Book since 1938. *AAP Red Book: Report of the Committee on*

*Infectious Diseases (31st ed. 2018–2021)*, at xxii. This is twenty-six years before ACIP was created (in 1962). CDC, Advisory Committee on Immunization Practices: History, <https://www.cdc.gov/acip/about/history.html>.

Every three years, COID independently issues updated vaccine recommendations covering “the most recent U.S. Food and Drug Administration-licensed vaccines for infants, children, and adolescents.” *AAP Red Book (31st ed. 2018–2021)* at xxi. In January 1995, AAP, ACIP, and AAFP published the first unified childhood immunization schedule. *Recommended Childhood Immunization Schedule — United States, January–June 1995*, 44 MMWR RR-5, at 1 (Jan. 27, 1995). For thirty years, the three organizations jointly published a unified schedule. Jaffe Amicus Decl. ¶ 8. That harmonization ended in January 2026. AAP’s core business — independently setting and publishing pediatric clinical standards on a triennial cycle keyed to FDA licensure — was not disrupted by the Kennedy schedule changes. It was already operating when ACIP was created, and it continues to operate now.

On January 26, 2026, AAP published its 2026 immunization schedule through Red Book Online. Jaffe Amicus Decl. ¶ 17; Appendix B. AAP stated: “At this time, the AAP no longer endorses the recommended childhood and adolescent immunization schedule from the Centers for Disease Control and Prevention.” The 2026 schedule recommends the same vaccines, for the same children, at the same ages, on the same timetable, as the 2025 edition. Jaffe Amicus Decl. ¶ 17. AAP did not change a single vaccine recommendation for a single disease for a single age group. (App. A ¶¶ 73–75.) The only significant substantive change/addition was the above quoted sentence.

AAP did not implement shared clinical decision-making for any reclassified vaccine. It did not develop new clinical protocols for SCDM conversations. It did not retrain its members. It

instructed them to continue vaccinating universally. Jaffe Amicus Decl. ¶ 17. At a January 28–29 webinar, AAP’s Committee on Infectious Diseases chair told pediatricians: “You all create the trust with the patient, not the federal government.” Appendix C.

More than 230 organizations endorsed the AAP schedule. Jaffe Amicus Decl. ¶ 17. The resources Organizational Plaintiffs expended after January 5 were spent publicizing AAP’s disagreement with the government: press releases, webinars, coalition-building, and public statements that the CDC schedule is wrong. Jaffe Amicus Decl. ¶ 17. None were spent adapting clinical operations to the revised schedule. AAP’s medical guidance is unchanged. The infrastructure AAP claims it needs a preliminary injunction to build already exists. The Red Book is that infrastructure. (App. A ¶ 76.)

This is not the record that was before the Court on January 6. This Court cited two injuries in finding organizational standing: that AAP had to develop “new infrastructures, processes, and guidance” and that AAP had to publish “their own immunization schedules.” Dkt. 168 at 5 (quoting Compl. ¶ 86). The developed record addresses both. As to the first: the Red Book 2026 demonstrates that AAP’s clinical guidance is unchanged, that no new clinical infrastructure was developed, and that the resources expended were advocacy. Kressly herself acknowledged that endorsing the CDC schedule was a historical choice within AAP’s own clinical practice guidelines framework (Kressly Decl. ¶ 19 “has historically endorsed”), and that AAP had already “ceased its endorsement” before the Red Book 2026 was published (Kressly Decl. ¶ 22 .

As to the second: AAP’s Committee on Infectious Diseases has published its own immunization schedule through the Red Book since 1938. Publishing independently is what AAP did for 57 years before harmonization began in 1995. Disharmonization returned AAP to

its default state. The harmonization was the departure, not the return to independence. An organization that already possesses a comprehensive clinical reference, that published a 2026 edition with identical recommendations, that told its members to follow it and ignore the federal schedule, and that spent its resources on a public campaign to reject the government’s policy rather than adapt to it, has not demonstrated harm “that cannot be remedied by an award of monetary damages.”

The costs of that campaign are the costs of issue-advocacy. Compensable, not irreparable. (App. A ¶¶ 77–79)

#### **E. Berman’s Injuries Are Self-Inflicted.**

Dr. Berman practices in Crossville, Tennessee. Tennessee has never required for school entry any of the six vaccines the revised schedule reclassified to shared clinical decision-making. Tenn. Comp. R. & Regs. 1200-14-01-.29(1). (App. A ¶ 36A.) The federal government no longer universally recommends them.

Dr. Berman reports spending ten additional minutes per patient visit on SCDM counseling. Dkt. 274-2. The ten extra minutes per visit are not spent on shared clinical decision-making — they are spent arguing with parents who have seen the federal schedule change and are asking why their pediatrician is insisting on vaccines their state does not require and the federal government no longer recommends. That argument is not a consequence of Kennedy’s actions. It is a consequence of AAP’s decision to override both. If these vaccines were safety-critical, Tennessee’s Department of Health would have required them. The injury is the cost of AAP’s vaccine-uptake advocacy, not operational disruption from a schedule change.

The additional time is the cost of AAP’s advocacy position. *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 416–17 (2013) (self-inflicted costs incurred in response to a speculative

threat do not establish standing). Dr. Benjamin’s APHA injuries follow the same pattern: staff spent telling members the government is wrong, not implementing the government’s guidance. (App. A ¶¶ 80–81.)

#### **F. The Transition Is Complete.**

AAP published its schedule. More than 230 organizations endorsed it. AAP’s own chair told members to follow AAP. The transition from a harmonized schedule to an independent one is complete. A preliminary injunction is designed to “preserve the relative positions of the parties until a trial on the merits can be held.” *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). Here, those positions have already shifted irrevocably. The status quo is that AAP has already decoupled. AAP is asking the Court to reverse the government’s actions after AAP has already responded to them independently. No preliminary injunction can undo what has already happened. AAP cannot simultaneously tell its members to ignore the CDC and then tell this Court that the CDC’s deviation from AAP is causing irreparable injury. Those positions are irreconcilable. (App. A ¶¶ 71–72.)

### **VI. IF THE COURT REACHES THE MERITS, THE RECORD SUPPORTS DENIAL**

Amici address the merits to assist the Court in the event it proceeds past irreparable harm and standing.

#### **A. COVID-19 (Counts III and IV): Every Institution That Examined the Question Reached the Same Result**

Counts III and IV challenge the Secretary’s May 2025 directive removing the COVID-19 vaccine from the recommended schedule for healthy children and pregnant women (Count IV), and the September 2025 ACIP vote downgrading the recommendation to shared clinical

decision-making (Count III). The proposed injunction would restore universal COVID-19 vaccination to the childhood schedule.

Five independently verifiable facts are fatal to preliminary relief on these claims:

First, no COVID-19 vaccine holds BLA approval for any healthy child of any age in the United States. The FDA specifically declined to approve it for that population. On July 9, 2025, the FDA approved Moderna's supplemental BLA for Spikevax in children six months through eleven years, but limited the approval to children with underlying high-risk conditions. On August 27, 2025, the FDA approved Pfizer's supplemental BLA for Comirnaty for children five through eleven years on the same terms. Simultaneously, the FDA revoked Pfizer's EUA for all children under five. Jaffe Suppl. Decl. (Dkt. 264 ¶¶ 8–10. (App. A ¶¶ 37–40.)

Second, more than three-quarters of the pre-Kennedy ACIP working group had already determined that universal recommendation should end. At the April 15–16, 2025 meeting, Dr. Havers presented hospitalization and severity data for children. After hearing it, the working group polled its members and scheduled a formal vote for June. Jaffe Amicus Decl. ¶¶ 10–11; Appendices D, E. Kennedy acted in May. The vote was scheduled for June. He did not override scientific consensus. He arrived at the same destination the scientific process was already heading toward. (App. A ¶¶ 46–49.)

Plaintiffs rely heavily on the Havers data. But the Secretary was not the first to weigh that data and find it insufficient. Havers' own colleagues were. They heard her presentation. They had access to every dataset she compiled. After reviewing it, more than three-quarters concluded universal recommendation should end. Then the FDA reached the same conclusion. Then Moderna reached it when it withdrew the healthy-child indication. Then the reconstituted ACIP reached it unanimously. Plaintiffs are asking this Court to be the only institution in the country to

conclude that Havers' data compels universal COVID-19 vaccination for healthy children. (App. A ¶¶ 50–51.)

Dr. Goldman's supplemental declaration (Dkt. 274-5) states that two May 12 internal memoranda were never shared with the Work Group through the EtR process. Goldman attended the April meeting and participated in every major decision of the Work Group. Dkt. 274-5 ¶¶ 8–9. The Work Group, working through the EtR process Goldman describes, reviewing the data Goldman reviewed, without access to the two memos Goldman complains about, concluded by supermajority that universal recommendation should end. Jaffe Amicus Decl. ¶ 13. Goldman's complaint about the memos establishes that the deliberative process he trusts produced the same substantive conclusion as the memos he never saw. (App. A ¶¶ 52–53.)

Third, AAP's own members had stopped following the recommendation. In July 2025, the CDC changed VFC policy so providers are no longer required to stock COVID-19 vaccines. Dr. Jesse M. Hackell, former chair of the AAP Committee on Practice and Ambulatory Medicine, told AAP News: the new guidance "reflect[s] the reality many pediatricians have not been stocking it for quite some time now, because the demand is low and the cost is high." Jaffe Suppl. Decl. (Dkt. 264 ¶ 12; Exhibit H. (App. A ¶¶ 55–56.)

Fourth, no state has ever required COVID-19 vaccination for school entry. Not one. Jaffe Amicus Decl. ¶ 15; Appendix F. (App. A ¶ 35.)

Fifth, the only regulatory pathway for vaccinating a healthy child runs through an emergency use framework whose underlying public health emergency terminated on May 11, 2023. It has not been renewed. In revoking Novavax's EUA, the FDA stated that "the circumstances of COVID-19 are not what they previously were" and that "the infection fatality

rate is estimated to have decreased approximately 10-fold.” Jaffe Suppl. Decl. (Dkt. 264 ¶ 9. (App. A ¶¶ 41–45.)

On the balance of equities, restoring the universal recommendation restores the VFC enforcement mechanism that destroyed Dr. Cardenas’s pediatric practice when she declined to administer the COVID-19 vaccine to healthy children. Jaffe Suppl. Decl. (Dkt. 264 ¶¶ 4–6. It restores the two-tier system under which Medicaid-enrolled children were subject to compelled vaccination that privately insured families could avoid. Dr. Hackell warned that the VFC policy “could lead to treatments of the VFC-eligible and the non-VFC-eligible population differently in practice.” Id. ¶ 12. (App. A ¶¶ 54–57.)

#### **B. The Schedule Revision (Count I): The Assessment Speaks for Itself.**

Count I challenges the January 5, 2026 Decision Memo reorganizing the childhood immunization schedule. The revision reduced universally recommended vaccines from eighteen diseases to eleven, reclassifying six to shared clinical decision-making or risk-based categories. No vaccine was eliminated. No vaccine was made unavailable. All remain covered by insurance without cost-sharing. (App. A ¶¶ 29–32.)

SCDM is an ACIP recommendation. HHS has confirmed all SCDM vaccines remain covered. AHIP, representing plans covering more than 200 million Americans, confirmed its members will cover all ACIP-recommended immunizations at no cost through the end of 2026. No family that wanted any of these vaccines before the revision is unable to obtain them after it.

Massachusetts, the lead Plaintiff state, requires for school entry in grades K–6: DTaP, polio, MMR, hepatitis B, and varicella. Five diseases. Massachusetts does not require rotavirus, influenza, hepatitis A, HPV, RSV, COVID-19, or meningococcal vaccine for school entry. Six of

the seven vaccines reclassified in the revision were never required for Massachusetts school entry. (App. A ¶¶ 33–36.)

On the *Braidwood* question: the parties have filed competing supplemental briefs. Plaintiffs argue FACA applies to ACIP for reasons independent of *Braidwood* (Dkt. 276). The government agrees FACA applies but argues ACIP remains advisory (Dkt. 279). Amici take no position. The question is genuinely open, has never been decided by any court, and the existence of a contested question of first impression at the foundation of the FACA claim cuts against the “substantial likelihood of success” required for preliminary relief.

The Hoeg/Kulldorff assessment is in the record as Plaintiffs’ own Exhibit 19 (Dkt. 185). Plaintiffs allege that “neither the Decision Memo nor the Assessment discuss what other country’s best practices are or the scientific evidence that informs those best practices.” Fourth Am. Compl. ¶ 270. The assessment contains a comparative table of immunization schedules across twenty nations, vaccine-by-vaccine analysis of each reclassified vaccine, citations to country-specific rationales, and references to Cochrane systematic reviews, WHO position papers, and FDA approval records. Whether the assessment satisfies *State Farm* is a question the Court should answer after reviewing the document, not on the basis of Plaintiffs’ characterization. (App. A ¶ 65.)

The assessment addresses each reclassified vaccine individually. Hepatitis A: U.S. incidence approximately 1 per 100,000; only Greece among twenty peers recommends it universally. Rotavirus: U.S. mortality averaged 3.3 deaths per year pre-vaccine; Denmark, Belgium, and Portugal do not recommend it. Meningococcal disease: U.S. incidence 0.12 per 100,000; the WHO recommends mass vaccination only above 2 per 100,000. Influenza: the Cochrane Collaboration found no convincing evidence that vaccines can reduce mortality,

hospital admissions, serious complications, or community transmission of influenza in children; twelve of twenty peers do not recommend it for any children. Jaffe Amicus Decl. ¶ 14; Appendix G. (App. A ¶ 63.)

The assessment also acknowledges what the IOM has said since 2002: the cumulative effects of the childhood schedule have never been fully evaluated. It cites the IOM's 2013 recommendation that HHS study the overall schedule, notes "progress has been slow," and identifies specific conditions requiring investigation. Appendix G at 12–13. (App. A ¶¶ 11–14.)

**C. The ACIP Shutdown (Count II): The Remedy Is Disproportionate and Against the Public Interest.**

Proposed Order ¶ 3 (Dkt. 183-1) would enjoin ACIP from holding any future meetings until the current membership is dissolved and reconstituted. ACIP has been the federal government's sole vaccine advisory committee since 1964. The advisory infrastructure that has guided every vaccine deployment for six decades would be frozen by court order for the duration of this litigation.

*Trump v. CASA, Inc.*, 606 U.S. 831, 853 (2025) (“[I]njunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs” (quoting *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979))). Plaintiffs’ organizational injuries come from specific ACIP actions: specific votes, specific schedule changes. The remedy for those injuries is to enjoin those specific actions, which Plaintiffs have separately requested. Shutting down the committee entirely prevents it from performing functions unrelated to the challenged actions, including functions Plaintiffs themselves depend on.

Plaintiffs simultaneously ask this Court to restore the pre-May 2025 schedule and to prevent the advisory committee from meeting. Those positions cannot coexist. If the old

schedule represents the consensus Plaintiffs claim, then ACIP's function is to evaluate and update that consensus as evidence evolves. An ACIP that cannot meet cannot do that for anyone. Plaintiffs are asking the Court to freeze the schedule and then disable the mechanism by which the schedule has always been updated.

**D. The Parallel State Litigation Undermines Every Pillar of the Motion.**

At the March 4 hearing, this Court inquired about the effect of *Arizona v. Kennedy*, No. 3:26-cv-01609-VC (N.D. Cal.). Amici address it because the parallel action bears on irreparable harm, the public interest, proportionality, and the coherence of the relief Plaintiffs request.

On February 24, 2026, fourteen state attorneys general and the Governor of Pennsylvania filed suit challenging the same schedule revision, ACIP reconstitution, and ACIP votes at issue here. They asserted the same APA and FACA claims. They filed an 85-page complaint. They did not move for a preliminary injunction or a temporary restraining order. Jaffe Amicus Decl. ¶ 13.

That decision, by the public officials with direct sovereign responsibility for the health of tens of millions of children, is itself significant. If the chief legal officers of fifteen states with *parens patriae* authority over every child in their jurisdictions concluded that merits litigation was adequate, AAP's claim that only emergency judicial intervention can prevent catastrophic harm is difficult to sustain.

But the parallel complaint reveals something more damaging to Plaintiffs' position. The plaintiff states told the Northern District of California that they have independent regulatory authority over vaccination policy and are already exercising it. Colorado adopted the 2025 AAP Recommended Child and Adolescent Immunization Schedule by emergency rule. *Arizona v. Kennedy* Compl. at 55. New Mexico enacted emergency legislation changing its Health Code to address concerns about ACIP recommendations. *Id.* at 53. Delaware updated its communicable

disease regulations to remove ACIP as the source for school vaccination schedules. *Id.* Connecticut's Commissioner of Public Health determines the standard of care based on both ACIP and AAP recommendations and can adjust independently. *Id.* at 55. California, a plaintiff in the action, enacted AB 144, which requires that federal immunization recommendations in effect on January 1, 2025 serve as a baseline and authorizes the California Department of Public Health to modify the schedule independently of federal recommendations. Cal. AB 144 (2025), signed Sept. 17, 2025.

These are not hypothetical workarounds. They are completed legislative and regulatory actions taken by sovereign states exercising their police power over public health. The infrastructure AAP claims a preliminary injunction is needed to build already exists at the state level, and the plaintiff states are already using it.

This collapses the irreparable harm argument from a direction neither party has addressed. AAP's strongest claim is that the schedule revision disrupts the coordinated national public health infrastructure. But the coordinated national system AAP describes no longer exists. Twenty-four states have delinked from the CDC schedule. Colorado follows AAP, not CDC. California follows neither ACIP nor CDC for recommendations issued after January 1, 2025. The plaintiff states themselves dismantled the coordination, voluntarily, through the exercise of their sovereign authority. A federal preliminary injunction cannot reassemble what the states chose to take apart.

It also raises a question this Court may find relevant. California enacted legislation freezing the federal schedule as of January 1, 2025 and authorizing its own Department of Public Health to modify it independently. California then filed suit claiming injury from changes to the federal schedule it no longer follows. If a state can delink from the federal schedule by

legislation and still claim injury from changes to that schedule, the injury is not the schedule change. It is the policy disagreement. That is the same issue-advocacy problem that complicates Organizational Plaintiffs' standing here.

The risk of inconsistent orders reinforces the case for restraint. If this Court grants a nationwide preliminary injunction and the Northern District of California reaches a different conclusion on the *Braidwood* question or the arbitrary-and-capricious analysis, the government faces conflicting obligations. On a question of first impression that no court has decided, that risk counsels restraint rather than extraordinary relief.

Fifteen sovereign plaintiffs with *parens patriae* authority, litigating the same claims on the same legal theories, concluded emergency relief was not warranted. Several have already solved the problem through their own regulatory authority. The states' actions are the strongest evidence in the record that the infrastructure exists to protect children without a federal injunction, and that the merits process is adequate.

## VII. CONCLUSION

The motion for preliminary injunction should be denied.

Plaintiffs have not demonstrated irreparable harm to themselves. Their organizational injuries are economic and compensable. Their non-economic claims are public interest arguments that belong in Factor 4, not Factor 2. The resource expenditures went to advocacy, not operational adaptation. The Red Book, AAP's independent clinical reference since 1938, contains the same vaccine recommendations in 2026 as in 2025. AAP told its members nothing has changed. The transition to an independent AAP schedule is complete. There is nothing left for a preliminary injunction to protect.

The evidentiary record developed since January 6, 2026, raises substantial questions about whether Organizational Plaintiffs maintain Article III standing on the facts as they now exist, as opposed to the allegations this Court accepted at the pleading stage. If the Court concludes the standing question warrants development, Amici respectfully request the Court order the parties to brief it and permit Amici to submit a memorandum.

If the Court reaches the merits, the record supports denial on every *Winter* factor. On COVID, every institution that examined the question reached the same conclusion. On the schedule revision, the Hoeg/Kulldorff assessment provides the reasoned basis Plaintiffs claim is absent. The proposed ACIP shutdown remedy would disable the federal government's vaccine advisory infrastructure for the indefinite future.

What Plaintiffs are asking, stripped of the procedural framework, is to restore a federal recommendation that exceeds what every state in which they operate actually requires for school entry, so they can more effectively promote uptake of vaccines no state has mandated and that the FDA has declined to fully approve for the relevant population (for COVID). AAP is already conducting that campaign, through the Red Book, 230 endorsing organizations, 24 states, webinars, and press releases, without a court order. A preliminary injunction in this posture would not protect children from harm. It would give AAP a more powerful instrument for vaccine promotion. Preliminary injunctions are not for that purpose.

Dated: March 9, 2026

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on March 9, 2026, I electronically filed the foregoing Brief of Amici Curiae in Opposition to Plaintiffs' Motion for Preliminary Injunction, together with the Declaration of Richard Jaffe and Appendices A–G thereto, with the Clerk of the United States District Court for the District of Massachusetts using the CM/ECF system. The CM/ECF system will send notification of such filing to all counsel of record who are registered CM/ECF users.

Dated: March 9, 2026

/s/ Richard Jaffe

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