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,

/s/ Richard Jaffe
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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

Richard Jaffe (admitted pro hac vice)

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.

DECLARATION OF RICHARD JAFFE
IN SUPPORT OF AMICUS CURIAE BRIEF

I, Richard Jaffe, declare as follows:

1. I submit this declaration in support of the Amicus Brief filed herewith, to authenticate the appendices attached.. I incorporate by reference my prior declarations (Dkt. 248-4; Dkt. 261) and the filings submitted therewith.
2. This declaration authenticates the following appendices to the Amicus Brief. Each is described below with the reason for its inclusion.
3. Appendix A is the Proposed Findings of Fact and Conclusions of Law in Support of Denial of the Preliminary Injunction. Included to assist the Court in organizing the new material which the Court might consider relevant to the disposition of the pending preliminary injunction motion, and to help organize the many facts and declarations and exhibits submitted to the Court in this motion.
4. Appendix B is a true and correct copy of Sean T. O'Leary, Committee on Infectious Diseases, *Recommended Childhood and Adolescent Immunization Schedule: United States, 2026: Policy Statement*, 157 Pediatrics e2025075754 (Mar. 2026), https://publications.aap.org/pediatrics/article/157/3/e2025075754/206175. Included

because it is the primary source for the irreparable harm and standing arguments. It establishes that AAP published its own 2026 schedule with identical clinical recommendations, formally disharmonized from the CDC, and secured endorsements from more than 230 organizations.

5. Appendix C is a true and correct copy of the relevant pages from *CDC vs. AAP Vaccine Schedule*, Infectious Disease Advisor (Feb. 27, 2026), https://www.infectiousdiseaseadvisor.com/features/cdc-vs-aap-vaccine-schedule/. Included because it documents AAP's instructions to its members at the January 28–29 webinar: O'Leary told pediatricians "You all create the trust with the patient — not the federal government," and Dr. David Higgins, vice president of Colorado's AAP chapter, instructed clinicians to proceed as usual and not raise the CDC's changes unless parents asked. These statements establish that AAP told its own members their clinical practice was unaffected — which is fatal to AAP's claim of irreparable harm.
6. Appendix D is a true and correct copy of Brenda Goodman, *CDC Considers Narrowing Its Covid-19 Vaccine Recommendations*, CNN (Apr. 16, 2025), https://www.cnn.com/2025/04/16/health/cdc-considers-narrowing-covid-vaccine-recommendations/index.html. Included because it documents the pre-Kennedy working group's internal poll in which more than three-quarters favored ending universal COVID-19 recommendation. This fact is central to the argument that the Secretary did not override scientific consensus.
7. Appendix E is a true and correct copy of the relevant pages from American Academy of Pediatrics, *April 2025 ACIP Meeting Update*, 156 Pediatrics e2025072444 (Sept. 2025). Included because it is AAP's own journal confirming the working group poll: "Based on

an internal poll of the COVID-19 [Work Group], the majority support a nonuniversal (risk-based) recommendation for 2025–2026 COVID-19 vaccination."

8. Appendix F is a true and correct copy of the relevant pages from KFF, *A Look at Recent Changes to State Vaccine Requirements for School Children* (Sept. 2025), https://www.kff.org/state-health-policy-data/a-look-at-recent-changes-to-state-vaccine-requirements-for-school-children/. Included because it establishes three independent points bearing on irreparable harm and the balance of equities. First, no state has ever required COVID-19 vaccination for school entry — not even the bluest state, not even after ACIP voted unanimously to add COVID-19 to the recommended schedule in October 2022. Second, state vaccine requirement authority is independent of federal ACIP recommendations: states set their own mandates, and changes to the federal schedule do not automatically alter school entry requirements. Third, KFF documents that as of 2024–2025 the national non-medical exemption rate had already risen to 3.6% — the highest on record — before the January 5 Decision Memo, demonstrating that vaccination rate erosion predates and is not caused by Kennedy's action. Together these three points confirm that the practical harm AAP predicts from the schedule revision is speculative, pre-existing, and not caused by the challenged decision.
9. Appendix G is a true and correct copy of the Hoeg/Kulldorff Assessment dated January 2, 2026, "Assessment of United States Childhood Immunization Schedule Compared to Other Countries," https://www.hhs.gov/sites/default/files/childhood-immunization-assessment.pdf. Included because it is the scientific assessment underlying the January 5 Decision Memo. Plaintiffs dismiss it in one allegation (Fourth Am. Compl. ¶ 270). The

Amicus Brief walks through its contents. Already in the record as Plaintiffs' Exhibit 19 (Dkt. 185); attached separately to facilitate review.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct to the best of my knowledge and belief.

Executed on March 9, 2026.

/s/ Richard Jaffe
RICHARD JAFFE

TABLE OF APPENDICES

APPENDIX A

Proposed Findings of Fact and Conclusions of Law in Support of Denial of the Preliminary Injunction

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.

APPENDIX A

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW IN SUPPORT OF DENIAL OF PRELIMINARY INJUNCTION

PROPOSED FINDINGS OF FACT

I. Procedural Posture and the Claims Before the Court

1. Plaintiffs American Academy of Pediatrics ("AAP"), American Public Health Association ("APHA"), American College of Physicians ("ACP"), Infectious Diseases Society of America ("IDSA"), and three individual plaintiffs filed this action challenging four categories of government action taken between May 2025 and January 2026. Fourth Am. Compl. (Dkt. 236).
2. Count I challenges the January 5, 2026 Decision Memo revising the childhood immunization schedule. Count II challenges the composition of the reconstituted ACIP. Count III challenges three specific votes of the reconstituted ACIP: the September 19,

2025 COVID-19 vote, the December 5, 2025 hepatitis B vote, and the June 26, 2025 thimerosal vote. Count IV challenges the Secretary's May 27, 2025 directive removing the COVID-19 vaccine from the recommended schedule for healthy children and pregnant women. Fourth Am. Compl. ¶¶ 590–682.

3. Plaintiffs' proposed preliminary injunction order seeks to: (a) reverse all six challenged agency actions; (b) enjoin any materials reflecting those actions; (c) enjoin all future meetings of the current ACIP until the committee is dissolved and reconstituted; and (d) waive the bond requirement. Proposed Order ¶¶ 1–6.
4. Children's Health Defense, two physicians, and two mothers whose children died following administration of multiple simultaneous childhood vaccines moved to intervene on February 18, 2026 (Dkt. 248). The Court denied intervention on February 27, 2026, and invited amici to file a brief.

II. The Childhood Immunization Schedule Before and After the Challenged Actions

5. Prior to May 2025, the CDC childhood immunization schedule recommended universal vaccination against eighteen diseases: diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, varicella, Haemophilus influenzae type B, pneumococcal disease, hepatitis A, hepatitis B, rotavirus, influenza, human papillomavirus, meningococcal ACWY, meningococcal B, and respiratory syncytial virus. COVID-19 was moved to shared clinical decision-making in September 2025. HHS Fact Sheet, CDC Childhood Immunization Recommendations (Jan. 5, 2026).
6. The January 5, 2026 Decision Memo reorganized the schedule into three tiers. The first tier, vaccines recommended for all children, covers eleven diseases: measles, mumps,

rubella, polio, pertussis, tetanus, diphtheria, Hib, pneumococcal disease, HPV, and varicella. Id.

7. The second tier, vaccines recommended for high-risk groups, covers RSV, hepatitis A, hepatitis B, meningococcal ACWY, and meningococcal B. Id.
8. The third tier, shared clinical decision-making, covers rotavirus, influenza, COVID-19, hepatitis A, hepatitis B, and meningococcal disease. Several vaccines appear in both the second and third tiers. Id.
9. No vaccine was eliminated from the schedule. No vaccine was withdrawn from the market. No vaccine was made unavailable. The revision reclassified vaccines from "recommended for all children" to risk-based and/or shared clinical decision-making categories. Id.
10. The January 2026 revision also reduced the recommended HPV vaccination from two doses to one and removed the hepatitis B birth dose for infants born to hepatitis B-negative mothers. Id.

III. The Institute of Medicine Findings on Cumulative Schedule Safety

11. The Institute of Medicine found in 2002 that no study had compared health outcomes between children who received the full immunization schedule and those who did not, and recommended such studies using the Vaccine Safety Datalink. IOM, Immunization Safety Review: Multiple Immunizations and Immune Dysfunction at 14–15, 107–108 (2002) (Jaffe Decl. (Dkt. 248-4) Ex. C).
12. In 2013, the IOM found that "studies designed to examine the long-term effects of the cumulative number of vaccines" had never been conducted, were feasible, and should be

prioritized. IOM, The Childhood Immunization Schedule and Safety at 6 (2013) (Jaffe Decl. Ex. D).

13. Neither Plaintiffs nor Defendants cited either IOM report in their respective filings. Jaffe Decl. (Dkt. 248-4) ¶ 22. The schedule Plaintiffs ask this Court to restore has never been evaluated as a cumulative protocol.

14. The Hoeg/Kulldorff Assessment dated January 2, 2026, acknowledges the IOM's findings and notes that "progress has been slow" and "only a few of the many studies that the IOM sought and deemed feasible have been conducted." Assessment at 12–13, § 2.3 (Jaffe Amicus Decl. App. G).

IV. The Enforcement Infrastructure That Makes the Schedule Coercive in Practice

15. HEDIS quality metrics, administered by the National Committee for Quality Assurance, tie insurer reimbursement rates and physician performance ratings to vaccination rates. Providers who do not achieve target vaccination rates face reduced reimbursement and adverse performance ratings that affect contracting. Jaffe Decl. (Dkt. 248-4) ¶¶ 27–29.

16. Combination vaccines such as Pediarix bundle multiple antigens in a single injection, making it physically impossible to administer one component without the others. A parent who declines one component receives all or none. This is part of the structural design of the current schedule. Jaffe Decl. ¶¶ 27–29.

17. AAP's Red Book classifies a family history of adverse vaccine reactions as a "misperceived contraindication"—a factor the Red Book instructs providers to disregard when making vaccination decisions. Jaffe Decl. ¶ 31.

18. The catch-up schedule has no upper limit on the number of vaccines that may be administered simultaneously. The Department of Defense limits healthy adult soldiers to five vaccines in a single visit. No comparable limit applies to children under the current or prior federal schedule. Jaffe Decl. ¶¶ 24–25.

V. Shared Clinical Decision-Making as the International Norm

19. Seventeen European Union nations, the United Kingdom, and Japan use voluntary recommendation programs and achieve vaccination rates comparable to or higher than the United States: Sweden 97%, Denmark 95%, Japan 98%. Jaffe Decl. (Dkt. 248-4) ¶ 23. SCDM does not mean no vaccination. It means what most of the developed world already does.

20. The Hoeg/Kulldorff Assessment's comparative table of immunization schedules across twenty peer nations documents that the United States recommends more childhood vaccines than any peer nation, and more than twice as many doses as some European countries, yet does not achieve better health outcomes. Assessment at 5, 15–16, §§ 1, 3 (Jaffe Amicus Decl. App. G).

VI. The 1986 National Childhood Vaccine Injury Act and the Missing Reports

21. The National Childhood Vaccine Injury Act of 1986 requires the Secretary to report to Congress every two years on the progress made in the implementation of a vaccine safety research program. 42 U.S.C. § 300aa-27(c). Congress expressly conditioned the liability protections the 1986 Act extended to vaccine manufacturers on this ongoing safety monitoring obligation.

22. HHS disbanded the task force responsible for vaccine safety monitoring, and there is no public record of any biennial report having been filed with Congress. Jaffe Decl. (Dkt. 248-4) ¶ 26. The public interest is not served by restoring a schedule that expanded without the safety oversight Congress mandated as the condition for the liability protections the industry now enjoys.

VII. The Physicians on the Other Side of the Schedule

23. Dr. Paul Thomas, a pediatrician in Portland, Oregon, published a peer-reviewed study comparing health outcomes between vaccinated and unvaccinated children in his practice—the type of study the IOM had recommended in 2002 and 2013. His medical license was suspended within days of publication. Jaffe Decl. (Dkt. 248-4) ¶ 6.
24. Dr. Kenneth B. Stoller used genetic testing to identify children at elevated risk of adverse vaccine reactions and adjusted their vaccination protocols accordingly. His medical license was revoked for deviating from ACIP guidelines. Jaffe Decl. ¶ 7.
25. If this Court restores the prior federal schedule, the individualized clinical approach for which both physicians lost their licenses will again constitute professional misconduct under the enforcement frameworks that destroyed their practices.

VIII. The Families on the Other Side of the Schedule

26. Andrea Shaw's fraternal twins, Dallas and Tyson, died on May 1, 2025, eight days after receiving their 18-month vaccines. Mrs. Shaw had warned the pediatrician about a family history of adverse vaccine reactions. The pediatrician dismissed the warning. AAP's Red

Book classifies family history of adverse vaccine reactions as a "misperceived contraindication," directing providers to disregard it. Jaffe Decl. (Dkt. 248-4) ¶¶ 8, 31.

27. Shanticia Nelson's daughter Sa'Niya Carter died on March 27, 2025, less than twelve hours after receiving six injections containing twelve antigens in a single catch-up visit. Sa'Niya was ill at the time. Her mother expressed concern. Clinic staff told her it was safe to proceed. Jaffe Decl. ¶ 9.

28. Plaintiffs filed more than twenty declarations. Not one is from a parent whose child was harmed by the schedule Plaintiffs seek to restore. Not one addresses the IOM's findings. Jaffe Decl. (Dkt. 248-4) ¶¶ 1, 10.

IX. SCDM Vaccines Remain Covered by Insurance Without Cost-Sharing

29. The Affordable Care Act requires health plans to cover without cost-sharing vaccines recommended by ACIP that have been adopted by the CDC Director. 42 U.S.C. § 300gg-13(a)(2).

30. SCDM is an ACIP recommendation. HHS has confirmed that all vaccines on the revised schedule, including those in the SCDM category, remain covered by insurance without cost-sharing. HHS Fact Sheet (Jan. 5, 2026).

31. AHIP, the trade group representing health insurance plans covering more than 200 million Americans, confirmed that its members will continue to cover all ACIP-recommended immunizations at no cost to patients through the end of 2026, including vaccines recommended through SCDM.

32. No family that wanted any reclassified vaccine before the schedule revision is unable to obtain it after the revision. The vaccines are the same. The manufacturers are the same.

The coverage is the same. What changed is the default clinical posture: SCDM vaccines require a conversation between physician and parent rather than routine administration without discussion.

X. State Vaccine Requirements

33. Massachusetts, the forum state and home to the lead organizational plaintiff, requires the following vaccines for school entry in grades K–6: DTaP, polio, MMR, hepatitis B, and varicella. Massachusetts does not require for school entry: rotavirus, influenza, hepatitis A, HPV, RSV, COVID-19, or meningococcal vaccine. Meningococcal ACWY is not required until grade 7.

34. Six of the seven vaccines reclassified in the January 2026 revision were never required for Massachusetts school entry. The one exception, hepatitis B, remains in both the high-risk and SCDM categories. It was not eliminated.

35. No state in the United States requires COVID-19 vaccination for school entry. No state requires rotavirus vaccination for school entry. No state requires influenza vaccination for school entry. No state requires RSV immunization for school entry. KFF, A Look at Recent Changes to State Vaccine Requirements for School Children (Sept. 2025) (Jaffe Amicus Decl. App. F).

36. The federal immunization schedule is a recommendation. It has never been a mandate. States set their own school-entry requirements independent of the federal schedule.

36A. Dr. Berman practices in Crossville, Tennessee. Tennessee requires seven vaccine categories for school entry: diphtheria, pertussis, tetanus, polio, measles/mumps/rubella, hepatitis B, and varicella. Tenn. Comp. R. & Regs. 1200-14-01-.29(1). None of the six

vaccines reclassified to shared clinical decision-making under the revised schedule is required for school entry in Tennessee. Under subsection (4), Tennessee's regulation expressly adopts the ACIP schedule by reference: "the Department adopts the recommended immunization schedule … published by the Advisory Committee on Immunization Practices (ACIP)." Tenn. Comp. R. & Regs. 1200-14-01-.29(4). Tennessee does not follow the AAP schedule.

XI. The Regulatory Status of the COVID-19 Vaccine for Children

37. On July 9, 2025, the FDA approved Moderna's supplemental Biologics License Application for Spikevax in children six months through eleven years, limited to children with at least one underlying condition placing them at high risk for severe COVID-19 outcomes. Moderna had revised its application on June 19, 2025, removing the indication for healthy children. FDA, CBER Center Director Decisional Memorandum (July 9, 2025). Jaffe Suppl. Decl. (Dkt. 261) ¶ 8.

38. Dr. Vinayak Prasad, Director of the FDA's Center for Biologics Evaluation and Research, wrote: "FDA has a regulatory duty to only grant marketing authorization in settings where we have substantial certainty the benefits outweigh the risks. For healthy children that standard is not met." Id.

39. On August 27, 2025, the FDA approved Pfizer's supplemental BLA for Comirnaty for children five through eleven years, limited to those with at least one underlying high-risk condition. Simultaneously, the FDA revoked Pfizer's Emergency Use Authorization for all children under five. Jaffe Suppl. Decl. ¶ 9.

40. As of August 27, 2025, no COVID-19 vaccine manufactured by any company is approved or authorized for healthy children of any age in the United States. Jaffe Suppl. Decl. ¶ 10.

XII. The Emergency Use Authorization Framework

41. The BLA standard requires a showing that a biological product is "safe, pure, and potent." 42 U.S.C. § 262(a)(2)(C)(i). The COVID-19 vaccine for healthy children has never been evaluated under this standard.

42. The EUA standard requires the lesser showing that "it is reasonable to believe" the product "may be effective." 21 U.S.C. § 360bbb-3(c)(2)(B). This is the only regulatory standard that has ever applied to the COVID-19 vaccine for healthy children.

43. EUA authority requires a determination by the HHS Secretary that "there is a public health emergency, or a significant potential for a public health emergency." 21 U.S.C. § 360bbb-3(b)(1)(C).

44. The Section 319 public health emergency for COVID-19 was terminated on May 11, 2023. It has not been renewed. 88 Fed. Reg. 16,644 (Mar. 15, 2023).

45. In revoking Novavax's EUA on August 27, 2025, the FDA stated: "the circumstances of COVID-19 are not what they previously were," "the risk of severe outcomes from COVID-19 has decreased dramatically," and "the infection fatality rate is estimated to have decreased approximately 10-fold." FDA Revocation Memorandum (Aug. 27, 2025). Jaffe Suppl. Decl. ¶ 9.

XIII. The Pre-Kennedy ACIP Working Group Had Already Abandoned Universal COVID-19 Recommendation

46. At the April 15–16, 2025 ACIP meeting, the last meeting of the pre-Kennedy committee, the COVID-19 Work Group reported the results of an internal poll. More than three-quarters of the working group favored moving to a risk-based (nonuniversal) recommendation for COVID-19 vaccination. The group planned to bring the recommendation to a formal vote at the June 2025 ACIP meeting. Brenda Goodman, CDC Considers Narrowing Its Covid-19 Vaccine Recommendations, CNN (Apr. 16, 2025) (Jaffe Amicus Decl. App. D).

47. AAP's own journal confirmed the finding: "Based on an internal poll of the COVID-19 [Work Group], the majority support a nonuniversal (risk-based) recommendation for 2025–2026 COVID-19 vaccination." American Academy of Pediatrics, April 2025 ACIP Meeting Update, 156 Pediatrics e2025072444 (Sept. 2025) (Jaffe Amicus Decl. App. E).

48. Kennedy issued the May 27, 2025 directive removing the COVID-19 vaccine from the recommended schedule for healthy children and pregnant women. The pre-Kennedy working group's formal vote was scheduled for June 2025.

49. On September 19, 2025, the reconstituted ACIP voted unanimously to move COVID-19 vaccination to shared clinical decision-making for all individuals six months and older.

XIV. The Havers Data and the Goldman Declaration

50. Dr. Fiona Havers, a former CDC senior adviser on vaccine policy, presented hospitalization and severity data for COVID-19 in children at the April 15–16, 2025

ACIP meeting. Plaintiffs rely on her declaration and this presentation to argue that the Secretary's May 2025 directive was arbitrary.

51. The pre-Kennedy working group heard Havers' presentation. They had access to all datasets she compiled: hospitalization rates, severity data, pediatric ICU admissions, outcomes in children without comorbidities. After reviewing her data, more than three-quarters of the working group concluded that universal recommendation should end.

52. Dr. Goldman, President of the American College of Physicians and ACIP COVID-19 Work Group member since 2020, states that two May 12, 2025 internal memoranda supporting the Secretary's directive were never shared with the Work Group through the established Evidence to Recommendation process. Goldman Suppl. Decl. (Dkt. 274-5) ¶¶ 11–13. Goldman first saw these memos on March 1, 2026, when produced as litigation exhibits.

53. Goldman attended the April 15–16, 2025 meeting and participated in every major meeting and decision of the COVID-19 Work Group. Goldman Suppl. Decl. ¶¶ 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 more than a three-quarters supermajority that universal recommendation should end. Goldman's complaint about the memos establishes that the deliberative process he trusts produced the same substantive conclusion as the memos he never saw.

XV. The VFC Enforcement Mechanism and the Cardenas Experience

54. Dr. Samara Cardenas operated a pediatric practice in Anaheim, California, serving approximately 1,900 Medicaid children. She declined to administer the COVID-19

vaccine to healthy children based on her professional judgment. The VFC program refused to process any of her vaccine orders because her orders did not include the COVID-19 vaccine. CalOptima terminated her contract and reassigned all 1,900 patients. Dr. Cardenas closed her practice. Jaffe Suppl. Decl. (Dkt. 261) ¶¶ 4–6; Exhibit F.

55. Effective July 1, 2025, the CDC changed VFC program policy so that providers enrolled in the VFC program are no longer required to routinely stock COVID-19 vaccines. Jaffe Suppl. Decl. ¶ 11; Exhibit G.

56. Dr. Jesse M. Hackell, former chair of the AAP Committee on Practice and Ambulatory Medicine, told AAP News that the new VFC 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. ¶ 12; Exhibit H. Dr. Hackell further warned that the relaxed stocking requirement "could lead to treatments of the VFC-eligible and the non-VFC-eligible population differently in practice." Id.

57. Private-pay or commercially insured families could access pediatricians outside the VFC program who exercised individualized clinical judgment regarding the COVID-19 vaccine. Medicaid families could not. VFC providers were required to order and administer every ACIP-recommended vaccine or lose access to the entire VFC program. Jaffe Suppl. Decl. ¶ 8.

XVI. The Hoeg/Kulldorff Assessment and the January 5 Decision Memo

58. On December 5, 2025, President Trump issued a Presidential Memorandum directing HHS and CDC to examine how peer developed nations structure their childhood vaccination schedules and to evaluate the scientific evidence underlying those practices.

59. On January 2, 2026, Dr. Tracy Beth Hoeg, Acting Director of FDA's Center for Drug Evaluation and Research and FDA's ex officio member to ACIP, and Dr. Martin Kulldorff, Chief Science and Data Officer at HHS, in consultation with officials at CDC, FDA, NIH, and CMS, completed a 25-page scientific assessment of U.S. childhood immunization practices.

60. On January 5, 2026, Acting CDC Director Jim O'Neill signed the Decision Memo accepting the assessment's recommendations.

61. The assessment compared U.S. childhood immunization practices with those of twenty peer nations. It found that the United States recommends more childhood vaccines than any peer nation, more than twice as many doses as some European countries, yet does not achieve better health outcomes. Assessment at 5, 15–16, §§ 1, 3.

62. The assessment documents that U.S. childhood vaccination trust declined from 71.5% to 40.1% between 2020 and 2024, and that MMR uptake declined from 95.2% to 92.7% during the same period. Assessment at 3, 6, § 1.1.

63. The assessment addresses each reclassified vaccine individually. Hepatitis A: U.S. incidence approximately 1 per 100,000, mortality 1 per 10 million, only Greece among twenty peers recommends universally. Assessment at 19–20, § 4.4. Rotavirus: U.S. mortality averaged 3.3 deaths per year pre-vaccine among all children under 15; Denmark, Belgium, and Portugal do not recommend it. Assessment at 20–21. Meningococcal disease: U.S. incidence 0.12 per 100,000; WHO recommends mass vaccination only above 2 per 100,000. Assessment at 21–23. Influenza: Cochrane 2018 systematic review found no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza in

children; twelve of twenty peer nations do not recommend it for any children. Assessment at 23–24. COVID-19: all peer nations have removed universal recommendation. Assessment at 24–25.

64. Plaintiffs attached the Hoeg/Kulldorff assessment as their Exhibit 19 (Dkt. 185) but dismiss it in a single allegation (Fourth Am. Compl. ¶ 270). Neither party has walked the Court through its contents. Amici attach it as Appendix G to the Amicus Brief and address its contents in detail.

65. 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 against international practice, country-specific rationales, Cochrane systematic reviews, WHO position papers, and FDA approval records.

XVII. AAP's Disharmonization From the CDC Schedule

66. AAP's Committee on Infectious Diseases first published vaccine guidance in 1938, twenty-six years before ACIP was established in 1964. AAP, ACIP, and AAFP first published a unified immunization schedule in January 1995. CDC, MMWR (Jan. 6, 1995).

67. In January 2026, AAP published its own 2026 immunization schedule through Red Book Online, explicitly stating: "At this time, the AAP no longer endorses the recommended childhood and adolescent immunization schedule from the Centers for Disease Control and Prevention." Sean T. O'Leary, Committee on Infectious Diseases, Recommended

Childhood and Adolescent Immunization Schedule: United States, 2026, 157 Pediatrics e2025075754 (Mar. 2026) (Jaffe Amicus Decl. App. B).

68. More than 230 medical organizations endorsed AAP's independent 2026 schedule.

69. Dr. Sean T. O'Leary, chair of AAP's Committee on Infectious Diseases, told pediatricians: "You all create the trust with the patient—not the federal government." Infectious Disease Advisor (Feb. 27, 2026) (Jaffe Amicus Decl. App. C).

70. Twenty-eight states no longer use HHS/CDC as their source for vaccine recommendations. KFF, State Recommendations for Routine Childhood Vaccines: Increasing Departure from Federal Guidelines (Jan. 22, 2026), https://www.kff.org/state-health-policy-data/state-recommendations-for-routine-childhood-vaccines-increasing-departure-from-federal-guidelines/.

71. AAP's 2026 immunization schedule recommends the same vaccines for the same children at the same ages that AAP was recommending on January 4, 2026, before the Decision Memo was signed. The Red Book did not change. AAP's clinical guidance to its members did not change. What changed is that AAP stopped co-signing the CDC's version of the schedule and began publishing independently, which is what AAP did for the first 57 years of the Red Book's existence, from 1938 until harmonization began in 1995.

72. AAP did not develop new clinical recommendations in response to the January 5 schedule revision. It did not commission new research. It did not create a new reference guide. AAP issued a policy statement announcing deharmonization and instructed its members to follow the Red Book as they had been. Deharmonization returned AAP to its default state. The harmonization was the departure, not the return to independence.

XVIII. The Absence of Operational Change: Why There Is No Irreparable Harm and No Standing at the PI Stage

73. AAP's 2026 immunization 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 a single vaccine recommendation for a single disease for a single age group in response to the January 5, 2026 schedule revision. AAP's Red Book clinical guidance on rotavirus, influenza, hepatitis A, hepatitis B, and meningococcal disease is: vaccinate universally. That was the guidance before January 5, 2026. It remains the guidance after January 5, 2026.

74. The only new content in the Red Book 2026 is the disharmonization statement: "At this time, the AAP no longer endorses the recommended childhood and adolescent immunization schedule from the Centers for Disease Control and Prevention." O'Leary, 157 Pediatrics e2025075754. All clinical recommendations remain unchanged from prior editions.

75. AAP's Red Book does not implement SCDM for any reclassified vaccine. It does not instruct pediatricians on how to conduct shared clinical decision-making conversations. It instructs pediatricians to vaccinate universally, in direct contradiction of the CDC schedule. The Red Book rejects the schedule change rather than adapts to it.

76. The resources AAP and other Organizational Plaintiffs expended after January 5, 2026, were spent publicizing their disagreement with the government's policy: press releases, webinars, coordination with 230 organizations and 24 states, and public statements that the CDC is wrong. These expenditures were not spent on clinical re-education, re-training

staff, developing new protocols, or adapting operations to a changed regulatory environment. Jaffe Amicus Decl. ¶ 17.

77. Dr. Sarah Kressly, AAP's immediate past President, acknowledged in her declaration 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) ¶ 43 ("has historically endorsed"). She confirmed AAP had already "ceased its endorsement." Id. ¶ 50.

78. This Court found organizational standing at the motion to dismiss stage based on AAP's allegation that it had to "devote significant time and resources to respond to the Challenged Actions," including developing new infrastructures and publishing independent guidance. Dkt. 168 at 10–12. The Court distinguished Equal Means Equal v. Ferriero, 3 F.4th 24, 30 (1st Cir. 2021), finding AAP's spending went "beyond mere advocacy." Dkt. 168 at 12 & n.15. Those were allegations accepted as true at the pleading stage. The evidentiary record tells a different story.

79. The evidentiary record now shows: AAP's medical guidance is unchanged; AAP's clinical recommendations are unchanged; the "new infrastructure" AAP built is a public campaign disagreeing with federal policy; and AAP instructed its members to continue doing what they had always done. Under Alliance for Hippocratic Medicine, 602 U.S. 367, 394–95 (2024), organizational standing requires that the defendant's action "directly affected and interfered with" the organization's "core business activities." AAP's core business activity is recommending vaccines. AAP is still recommending the same vaccines.

80. Dr. Berman's injuries, including ten additional minutes per visit and confrontational parents, do not flow from implementing SCDM. They flow from Dr. Berman's decision to follow AAP's universal vaccination guidance rather than the CDC's SCDM framework. An injury generated by the plaintiff's own decision to oppose the challenged action rather than adapt to it is neither fairly traceable to the defendant nor redressable by injunctive relief. Clapper v. Amnesty Int'l USA, 568 U.S. 398, 416–17 (2013). Berman Suppl. Decl. (Dkt. 274-2). Dr. Berman practices in a state that has never required any of the reclassified vaccines for school entry and that follows the ACIP schedule by regulation. Tenn. Comp. R. & Regs. 1200-14-01-.29(4). The parents questioning her are not confused by the federal schedule change. They are asking why their pediatrician insists on vaccines Tennessee does not require and the federal government no longer universally recommends.

81. Dr. Benjamin's APHA injuries, including staff diverted to communications, webinars, and member briefings, were not spent helping members implement SCDM. They were spent telling members that SCDM is wrong and that prior universal recommendations should continue. Benjamin Suppl. Decl. (Dkt. 274-1).

82. Every organizational injury described in the declarations is quantifiable in dollars: staff time, hiring costs, reimbursement declines, counseling minutes, materials revision, website redesign. Injuries compensable in damages are not irreparable. Charlesbank Equity Fund II v. Blinds To Go, Inc., 370 F.3d 151, 162 (1st Cir. 2004).

83. AAP's claimed non-economic injuries, including erosion of public trust and declining vaccination rates, are injuries to the public, not to AAP as an organization. They belong in the public interest analysis under Winter Factor 4, not the irreparable harm analysis

under Factor 2. Winter v. Natural Resources Defense Council, 555 U.S. 7, 20 (2008). If harm to the public satisfied Factor 2, Factor 4 would be redundant.

XIX. Plaintiffs' Claimed Injuries

84. Dr. Suzanne Berman, a pediatrician in Crossville, Tennessee (70–75% Medicaid patient population), reports ten additional minutes per patient visit for SCDM counseling, the hiring of an additional nurse practitioner at $130,000, approximately $52,000 in excess annual costs, and an 8% decline in reimbursement. Berman Suppl. Decl. (Dkt. 274-2).

85. Dr. Georges Benjamin, Executive Director of the American Public Health Association, reports staff diverted from core mission activities to emergency communications, updated materials, and member inquiries. An APHA mobile clinic member reports approximately three additional minutes of counseling time per patient encounter and mandatory motivational interviewing training for staff. Benjamin Suppl. Decl. (Dkt. 274-1).

86. Dr. Goldman reports that ACP must "independently review available literature," "respond to member inquiries," and "divert staff and physician leadership" from other activities. Goldman Suppl. Decl. (Dkt. 274-5) ¶¶ 14–17. Goldman's organization, ACP, endorsed AAP's independent 2026 schedule.

87. Plaintiffs' COVID-specific injuries are asserted through three Jane Doe declarations: two alleging difficulty accessing the vaccine during pregnancy, one alleging difficulty vaccinating teenage sons at a pharmacy.

XX. The Parallel State Litigation and the Parens Patriae Distinction

88. On February 24, 2026, fourteen state attorneys general and the Governor of Pennsylvania filed Arizona v. Kennedy, No. 3:26-cv-01609-VC (N.D. Cal.), challenging the same schedule revision, ACIP reconstitution, and challenged votes at issue in this litigation.

89. The plaintiff states did not move for a preliminary injunction. They did not seek a temporary restraining order. They did not ask to enjoin any ACIP meeting. They did not ask any court to freeze the schedule. They are litigating on the merits.

90. No plaintiff state in that action requires COVID-19 vaccination for school entry. No plaintiff state requires rotavirus vaccination. No plaintiff state requires influenza vaccination. No plaintiff state requires RSV immunization.

91. States possess parens patriae authority over the welfare of children within their borders. The fifteen plaintiff states and the Governor of Pennsylvania examined the same challenged actions, represent the populations Plaintiffs claim are harmed, and concluded that preliminary relief was not necessary. AAP is a private membership organization. It does not possess parens patriae authority. The judgment of fifteen sovereign plaintiffs about the urgency of the relief AAP demands is entitled to weight in the balance of equities.

92. Several plaintiff states in Arizona v. Kennedy have independently enacted regulatory solutions that insulate their immunization programs from the federal schedule change, demonstrating that the infrastructure to protect children exists without a federal injunction. Colorado's State Board of Health adopted, via an emergency rule, regulations incorporating the 2025 AAP Recommended Child and Adolescent Immunization Schedule. 6 CCR 1009-2. Arizona v. Kennedy Compl. at 55.

93. New Mexico's Legislature enacted significant changes to its Health Code during an emergency session in 2025 to address concerns related to ACIP recommendations. 2025 N.M. Laws, 1st Spec. Sess., ch. 5, §§ 1–6. Arizona v. Kennedy Compl. at 53.

94. Delaware's Division of Public Health updated its Communicable Disease Regulations in Fall 2025, removing ACIP as the sole source for school vaccination schedules and adding references to AAP, AAFP, and ACOG. 27 Del. Reg. 863. Delaware also updated its school enrollment statutes to remove references to ACIP. Del. Code tit. 14, § 131. Arizona v. Kennedy Compl. at 53–54.

95. Connecticut's Commissioner of Public Health determines the standard of care for children based on the recommended immunization schedules published by ACIP, the AAP, and the AAFP, and can adjust independently. Conn. Gen. Stat. § 19a-7f(a). Arizona v. Kennedy Compl. at 55.

96. California enacted AB 144 (signed September 17, 2025), which authorized the California Department of Public Health to base immunization guidance on credible independent medical organizations in lieu of the CDC, effectively decoupling California from the federal schedule. Cal. AB 144 (2025). CDPH implemented AB 144 by adopting the AAP schedule. California then filed suit in Arizona v. Kennedy claiming injury from changes to the federal schedule it had already legislated around.

97. 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. The plaintiff states themselves have already used it.

98. The risk of inconsistent orders is concrete. 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. This Court would be the first court in the country to resolve the Braidwood/FACA question, doing so on a preliminary injunction record—competing declarations, no testimony, no full merits briefing—rather than on a developed record after trial. On a question of first impression that no court has decided, that risk counsels restraint.

XXI. The Parties' Positions on Reviewability

99. Defendants argue that the Director's decision to accept, reject, or modify ACIP recommendations is committed to agency discretion and therefore unreviewable under 5 U.S.C. § 701(a)(2).

100. At oral argument, when pressed by the Court, Defendants conceded that under their unreviewability theory, the Secretary could hypothetically order physicians to infect children with measles and the action would be unreviewable. This concession undermines Defendants' position and is inconsistent with the presumption of judicial review. Abbott Labs. v. Gardner, 387 U.S. 136, 140 (1967).

101. Plaintiffs placed the Hoeg/Kulldorff assessment in the record as their Exhibit 19 (Dkt. 185) but dismissed it in a single allegation. Defendants did not present the BLA/EUA regulatory status of the COVID-19 vaccine for children. Defendants did not present the pre-Kennedy working group's internal poll.

PROPOSED CONCLUSIONS OF LAW

I. Legal Standard

1. A preliminary injunction is "an extraordinary remedy never awarded as of right." Winter v. Natural Resources Defense Council, 555 U.S. 7, 24 (2008). The movant must demonstrate: (1) a substantial likelihood of success on the merits; (2) a likelihood of irreparable harm absent injunctive relief; (3) that the balance of equities tips in the movant's favor; and (4) that the injunction serves the public interest. Id. at 20.
2. In the First Circuit, the movant bears the burden on all four factors. Charlesbank Equity Fund II v. Blinds To Go, Inc., 370 F.3d 151, 162 (1st Cir. 2004). Irreparable harm is harm "that cannot be remedied by an award of monetary damages." Id. The four Winter factors are independent; failure on any one is dispositive.

II. Standing

3. Standing is jurisdictional and must exist at every stage of the litigation, including at the preliminary injunction stage. Arizonans for Official English v. Arizona, 520 U.S. 43, 67 (1997). 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). The party invoking federal jurisdiction bears the burden of establishing standing "with the manner and degree of evidence required at the successive stages of the litigation." Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992). At the preliminary injunction stage, that burden is not satisfied by the pleading-stage standard of accepting allegations as true. TransUnion LLC v. Ramirez, 594 U.S. 413, 431 (2021).

4. For organizational standing, the defendant's actions must have "directly affected and interfered with" the organization's "core business activities." FDA v. Alliance for Hippocratic Medicine, 602 U.S. 367, 394–95 (2024) (citing Havens Realty Corp. v. Coleman, 455 U.S. 363, 379 (1982)). Costs incurred in issuing competing guidance, publishing communications to members, or conducting issue-advocacy in response to a policy change do not satisfy this standard. Id. at 394–95. The distinction between operational disruption and issue-advocacy is dispositive: organizations "cannot spend their way into standing" by expending resources on advocacy activities they would have undertaken regardless of the challenged government action. Id.

5. On January 6, 2026, this Court found organizational standing on a pleading-stage record, accepting as true AAP's allegation that it "had to divert resources to develop new infrastructures, processes, and guidance." Dkt. 168 at 15–16. The evidentiary record developed since January 6 raises a serious question whether those allegations survive scrutiny under Alliance for Hippocratic Medicine. Three weeks after this Court's order, AAP's own declarant testified that AAP has its own clinical practice guidelines framework and that endorsing the CDC schedule was a "historical choice" within it. Kressly Decl. (Dkt. 185-27) ¶ 50. Seven days earlier, AAP published the Red Book 2026 with clinical recommendations identical to those in the 2025 edition it claims to have been forced to abandon. AAP's core business — setting and publishing pediatric clinical standards — is unaffected. (Findings ¶¶ 55–72.)

6. Because the standing question is jurisdictional, the Court should resolve it before proceeding to the Winter factors. Amici respectfully submit that the Court should: (1) deny the motion for a preliminary injunction to enjoin the next ACIP meeting, on the

ground that there is a serious unresolved question whether Organizational Plaintiffs maintain Article III standing on the developed record; (2) hold all other requested preliminary relief in abeyance; and (3) order the parties to brief whether Organizational Plaintiffs maintain Article III standing at the preliminary injunction stage in light of the evidentiary record developed since January 6, 2026, and permit Amici to submit a memorandum on that question. See Steel Co. v. Citizens for a Better Environment, 523 U.S. 83, 94–95 (1998) (courts must resolve jurisdictional questions before proceeding to the merits).

III. Likelihood of Success on the Merits

7. On Counts III and IV (COVID-19 vaccine), Plaintiffs cannot demonstrate a substantial likelihood of success. Even assuming procedural irregularity in the Secretary's May 2025 directive and the September 2025 ACIP vote, Plaintiffs cannot show that a proper process would have reached a different result. The pre-Kennedy ACIP working group's own internal poll showed more than three-quarters favoring risk-based recommendation. The FDA independently declined BLA approval for healthy children. Moderna withdrew the healthy-child indication. The reconstituted ACIP voted unanimously. Procedural irregularity without outcome-determinative effect does not establish likelihood of success. (Findings ¶¶ 46–53.)

8. On Count I (schedule revision), the Braidwood Management, Inc. v. Becerra, 606 U.S. 756, 767 n.4 (2025), question of first impression regarding ACIP's status under FACA creates genuine legal uncertainty that cuts against likelihood of success. ACIP has the identical ACA empowerment the Supreme Court found dispositive for USPSTF. Whether FACA applies to ACIP is an open question no court has decided. (Findings ¶¶ 5–10.)

9. On Count II (ACIP composition), Amici take no position on the merits of the FACA fair-balance claim. This is a question for trial.

10. The Director's adoption of ACIP recommendations is reviewable under the APA notwithstanding Defendants' unreviewability argument. The adoption triggers binding insurance-coverage obligations under § 300gg-13(a)(2) for hundreds of millions of Americans. It is the paradigm case for APA review. The review standard is § 706(2)(A): arbitrary, capricious, abuse of discretion. (Findings ¶¶ 92–93.)

IV. Irreparable Harm

11. Plaintiffs' organizational injuries are the costs of publishing competing medical guidance in response to a government policy change. AAP's clinical recommendations are unchanged. The resources Organizational Plaintiffs expended were advocacy expenditures. Expenditures on issue-advocacy in response to a government action the organization opposes are not irreparable harm. Equal Means Equal v. Ferriero, 3 F.4th 24, 30 (1st Cir. 2021). (Findings ¶¶ 73–83.)

12. Dr. Berman's claimed injuries flow not from the schedule change but from her decision to follow AAP's universal vaccination guidance rather than the CDC's SCDM framework. An injury generated by the plaintiff's own choice to oppose the challenged action rather than adapt to it is self-inflicted and neither fairly traceable to the defendant's action nor redressable by judicial relief. Clapper v. Amnesty Int'l USA, 568 U.S. 398, 416–17 (2013). (Findings ¶ 80.) Dr. Berman practices in Tennessee, which requires seven vaccine categories for school entry — none of the six reclassified vaccines among them — and which adopts the ACIP schedule by regulation. Tenn. Comp. R. & Regs. 1200-14-

01-.29(1), (4). Her additional counseling time flows from her decision to override both the federal schedule and her own state's regulatory framework at AAP's direction.

13. Every organizational injury described in the declarations is quantifiable in dollars. Economic injuries compensable in damages are not irreparable. (Findings ¶ 82.)

14. Plaintiffs' COVID-specific injuries through the Jane Doe declarations are access injuries flowing from FDA's BLA and EUA decisions, not the schedule change. Even if this Court restores the recommendation, Pfizer's EUA for children under five remains revoked and Moderna's BLA still excludes healthy children. (Findings ¶¶ 37–40.)

15. AAP cannot simultaneously instruct its members to disregard the CDC schedule and then claim irreparable injury from the CDC's deviation. (Findings ¶¶ 67–72.)

V. Balance of Equities

16. On the COVID-19 vaccine, restoring the universal recommendation restores the VFC enforcement mechanism that destroyed Dr. Cardenas's practice and the Medicaid/private-pay disparity that AAP's own former committee chair flagged as problematic. (Findings ¶¶ 54–57.)

17. On the schedule revision, the Hoeg/Kulldorff assessment provides a detailed, disease-by-disease scientific rationale grounded in evidence the government's own Institute of Medicine has urged it to act on since 2002. (Findings ¶¶ 58–65.)

18. The equities include the families and physicians on the other side of the schedule: the mothers whose children died following multiple simultaneous vaccinations, the physicians whose practices were destroyed for exercising clinical judgment the FDA would later vindicate, and the Medicaid-enrolled children subject to compelled vaccination that wealthier families could avoid. (Findings ¶¶ 23–28, 54–57.)

19. Fifteen sovereigns with parens patriae authority over the affected children examined the same challenged actions and concluded preliminary relief was not necessary. That judgment bears on the balance of equities. (Findings ¶¶ 88–98.)

20. The parallel state litigation in Arizona v. Kennedy, No. 3:26-cv-01609-VC (N.D. Cal.), bears on the balance of equities and the public interest in three independent respects. First, fifteen sovereign plaintiffs with parens patriae authority examined the same challenged actions and concluded that preliminary relief was not necessary; that judgment is entitled to weight in the balance of equities. Second, several plaintiff states have already enacted independent regulatory solutions—Colorado by emergency rule (6 CCR 1009-2), New Mexico by emergency legislation (2025 N.M. Laws, 1st Spec. Sess., ch. 5, §§ 1–6), Delaware by regulatory and statutory amendment (27 Del. Reg. 863; Del. Code tit. 14, § 131), and California by statute (Cal. AB 144 (2025))—demonstrating that children can be protected without a federal injunction. Third, granting a nationwide preliminary injunction on a question of first impression, on a thin record without full merits briefing or testimony, with parallel litigation pending in the Northern District of California, risks an inconsistent resolution binding the government before any court has fully analyzed the controlling legal questions. (Findings ¶¶ 88–98.)

VI. Public Interest

21. The public interest in drug safety runs through the FDA. The FDA has determined that for healthy children, the benefit-risk standard for COVID-19 vaccination "is not met." A court order restoring universal recommendation for a product that meets only the "may be effective" emergency use standard, for a population the FDA has determined does not

meet the threshold for full approval, during an emergency that ended nearly three years ago, does not serve the public interest. (Findings ¶¶ 37–45.)

22. Proposed Order ¶ 3 would shut down the nation's vaccine advisory committee for the duration of this litigation, preventing ACIP from meeting to address any subject, including emerging infectious disease threats. The public interest in maintaining a functioning federal vaccine advisory infrastructure outweighs Plaintiffs' organizational interests.

23. The public interest is not served by restoring a schedule that expanded without the biennial safety monitoring Congress mandated in the 1986 Act as the condition for the liability protections it extended to vaccine manufacturers. (Findings ¶¶ 21–22.)

24. Courts do not order increased uptake of products the responsible regulatory agency has declined to approve for the population at issue.

VII. Conclusion and Relief Requested

25. Plaintiffs have not carried their burden on any of the four Winter factors. The motion for preliminary injunction should be denied.

26. The evidentiary record developed since the motion to dismiss raises substantial questions about whether Organizational Plaintiffs maintain Article III standing. AAP's medical guidance is unchanged. The resources AAP expended were directed at publicizing its disagreement with the government's policy rather than adapting its operations to it. Under Equal Means Equal v. Ferriero, 3 F.4th 24, 30 (1st Cir. 2021), and Alliance for Hippocratic Medicine v. FDA, 602 U.S. 367, 394–95 (2024), issue-advocacy expenditures do not establish organizational injury-in-fact. (Findings ¶¶ 73–83.)

27. If the Court concludes that the standing question warrants further development, Amici respectfully request that the Court order the parties to brief whether Organizational Plaintiffs maintain Article III standing at the preliminary injunction stage in light of the evidentiary record, and that Amici be permitted to submit a memorandum in connection therewith.

Dated: March 9, 2026

Respectfully submitted,

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APPENDIX B

O'Leary, Recommended Childhood and Adolescent Immunization Schedule: United States, 2026 — Red Book 2026

Source: https://publications.aap.org/pediatrics/article/157/3/e2025075754/206175

POLICY STATEMENT Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Recommended Childhood and Adolescent Immunization Schedule: United States, 2026: Policy Statement

Sean T. O'Leary, MD, MPH, FAAP and the Committee on Infectious Diseases

The 2026 recommended childhood and adolescent immunization schedule has been published by the American Academy of Pediatrics (AAP). The schedule is revised annually to reflect current recommendations for the use of vaccines licensed by the US Food and Drug Administration. At this time, the AAP no longer endorses the recommended childhood and adolescent immunization schedule from the Centers for Disease Control and Prevention.

Members of the AAP Committee on Infectious Diseases participated in the immunization work groups of the Advisory Committee on Immunization Practices through May of 2025. The Evidence to Recommendations framework was used by the work groups and informed the 2026 pediatric recommendations.[1]

The **cover page** includes a table with an alphabetical listing of vaccines and other immunizing agents, approved abbreviations for each agent, and trade names.

Table 1 contains the recommended immunization schedule from birth to 18 years of age.

Table 2 is the catch-up immunization schedule for persons 4 months to 18 years of age who start late or who are more than 1 month behind the recommended age for vaccine administration.

Table 3 lists the immunizations that may be indicated for children and adolescents 18 years of age or younger on the basis of medical conditions.

The **Notes** provide additional information and are presented in alphabetical order of the vaccine or other immunizing agent.

The **Appendix** provides conditions when vaccines and other immunizing agents are contraindicated or not recommended or when precautions should be considered.

The **Addendum** summarizes new and updated AAP recommendations that occur after the 2026 immunization schedule is published.

The **Endorsements** list the logos of the medical and health organizations endorsing the AAP schedule.

All authors contributed substantially to the conception and design; review and interpretation of relevant literature; drafting and revisions; and final approval of the published version.

All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors. Author disclosures are provided at the end of this article. The American Academy of Pediatrics has neither solicited nor accepted any commercial involvement in the development of the content of this publication.

Policy statements from the American Academy of Pediatrics benefit from expertise and resources of liaisons and internal (AAP) and external reviewers. However, policy statements from the American Academy of Pediatrics may not reflect the views of the liaisons or the organizations or government agencies that they represent.

To cite: O'Leary ST; American Academy of Pediatrics, Committee on Infectious Diseases. Recommended Childhood and Adolescent Immunization Schedule: United States, 2026: Policy Statement. *Pediatrics*. ;157(3):e2025075754

The following changes have been made since the publication of the original 2025 schedule in November 2024:

OVERALL SCHEDULE

- Where relevant, webpage resources were changed from federal websites to trusted webpage resources from AAP and partners. Where federal webpage resources are listed, "Accessed on" dates were added.

COVER PAGE

- In the table listing immunization names and abbreviations, Enflonsia, Penmenvy and Flublok were added.
- Other information was updated on the page, including:
  - Added information on 12 medical and health organizations endorsing the AAP schedule.
  - Added information on how to report clinically significant adverse events for RSV-mAb products to MedWatch, a reporting system that supports the Food and Drug Administration (FDA)'s postmarketing safety surveillance for drugs and therapeutic biologics.
  - Changed Questions or comments contact to an AAP submission form.
  - Updated link for the current Vaccine Information Statements.
  - Updated QR code and immunization schedule landing page.

TABLE 1

Recommended Child and Adolescent Immunization Schedule by Age

- **Legend** colors and text were updated as follows:
  - Blue: Range of recommended ages for all children.
  - Purple: Range of recommended ages for catch-up vaccination.
  - Orange: Range of recommended ages for certain high-risk groups or populations.
  - Blue with dots: A new legend was added for recommended vaccination for those who desire protection.
  - Blue with diagonal lines: Recommended vaccination based on shared clinical decision-making.
  - Legends for recommended vaccination can begin in this age group and no guidance/not applicable were removed.
- **Respiratory syncytial virus (RSV) monoclonal antibody (mAb):** Added clesrovimab[2] to RSV immunizations. To provide additional clarity, the overlying text for birth through 7 months for all children was changed to "1 dose during RSV season depending on maternal RSV vaccination status (See Notes)" and for 8 months through 19 months for high risk groups was changed to "1 dose nirsevimab during RSV season (See Notes)."
- **Influenza:** Combined rows for IIV3, ccIIV3 and LAIV3 into one row for simplicity.
- **Human papillomavirus (HPV):** Changed HPV age range for recommendation to 9–12 years, to align with AAP policy.[3]
- **COVID-19:** Updated COVID recommendations to align with updated AAP policy.[4]
  - Universal recommendation for all children 6–23 months of age.
  - Risk-based recommendation for children 2–17 years of age.
  - Recommendation for those 2–17 years of age who desire protection.
  - See notes for full details.
- **RSV vaccine:** Added "if not previously vaccinated" to overlying text for clarity.

TABLE 2

Recommended Catch-up Immunization Schedule for Persons 4 Months to 18 Years of Age

- No updates were made to Table 2.

TABLE 3

Recommended Schedule by Medical Indication

- **Legend** colors and text were updated as follows:
  - Blue: Recommended for all age-eligible children who lack documentation of a complete immunization series.
  - Orange: Not recommended for all children, but recommended for some children based on increased risk for severe outcomes from disease.
  - Purple: Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications.
  - Pink with diagonal red lines: Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction.
  - Gray legend for No Guidance/Not Applicable was removed, and table is blank where no guidance is provided.
- **RSV-mAb:** Added clesrovimab to immunizing agents. For clarification, added a blue legend with overlying text "1 dose clesrovimab or nirsevimab during 1st RSV season depending on maternal RSV vaccination status (See Notes)." Added "nirsevimab" in purple legend to clarify only nirsevimab is recommended for 2nd RSV season for high risk individuals.

- **COVID-19:** Added an asterisk for pregnancy with a link to the American College of Obstetricians & Gynecologists (ACOG) practice advisory that states: *For more information, refer to https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care.

NOTES

- **COVID-19:**
  - This section has been updated with new recommendations per AAP policy[4] and to reflect the change in FDA approval of Pfizer-BioNTech Comirnaty from children 6 months of age and older to children 5 years of age and older and addition of Moderna mNEXSPIKE for age 12 + years.
  - The AAP's COVID-19 Vaccine Dosing Guide was added for reference. Dosing guidance was updated for 6–23-month old who has previously received 1 dose prior formulation of Pfizer-BioNTech vaccine and for age 6 months–4 years moderately or severely immunocompromised who has previously received 1 dose prior formulation of Pfizer-BioNTech vaccine.
  - New references were added for revaccination guidance for children with hematologic malignancy post-hematopoietic cell transplant or CAR T-cell therapy.
- **Dengue:** Added a note that dengue vaccine distribution in the US was discontinued September 2025 (with a shelf life up to September 2026).[5]
- **Hepatitis B:** Removed recommendations for PreHevbrio since it was discontinued.[6]
- **HPV:** Updated language to align with AAP policy.[3]
- **Influenza:** Updated dates to reflect 2025–2026 season and added a link to AAP influenza vaccine recommendations.[7]
- **Measles, mumps, and rubella (MMR):** Updated note to align with AAP policy[8] that the AAP expresses no preference between MMR plus monovalent varicella vaccine or MMRV for toddlers receiving their first immunization of this kind.
- **Meningococcal serogroup A, C, W, Y Vaccination:**
  - Moved recommendations on MenACWY-TT/MenB-FHb and MenACWY-CRM/MenB-4C to new notes section on Meningococcal serogroup A, B, C, W, Y.
  - Clarified language for military recruits and first-year college students who live in residential housing.
  - Added product Penmenvy to note about Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day.
  - Added chronic GVHD as an additional example of functional asplenia.
- **Meningococcal serogroup B:** Moved recommendations on MenACWY-TT/MenB-FHb and MenACWY-CRM/MenB-4C to new notes section on Meningococcal serogroup A, B, C, W, Y and added chronic GVHD as an additional example of functional asplenia.
- **Meningococcal serogroup A, B, C, W, Y:** Added a new notes section with recommendations on the use of MenACWY-TT/MenB-FHb and MenACWY-CRM/MenB-4C.
- **RSV Immunization:** Added clesrovimab as an available product for infants <8 months[2] and updated notes to align with AAP policy,[9] including the removal of guidance on palivizumab.
- **RSV Vaccination:** Added clesrovimab under Routine vaccination to "Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab or clesrovimab is recommended to prevent severe RSV disease in infants," and under Subsequent pregnancies, "Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab or clesrovimab."
- **Varicella:** Updated note to align with AAP policy[7] that the AAP expresses no preference between MMR plus monovalent varicella vaccine or MMRV combination vaccine for toddlers receiving their first immunization of this kind.

APPENDIX (CONTRAINDICATIONS AND PRECAUTIONS)

- **Meningococcal ABCWY:** Added Penmenvy product and added contraindications for MenACWY-CRM/MenB-4C and MenACWY-TT/MenB-FHbp.

The AAP's 2026 version of Tables 1 through 3, notes, appendix, and addendum are available on the American Academy of Pediatrics website (https://aap.org/ImmunizationSchedule). A parent-friendly vaccine schedule for children and adolescents is available at http://www.healthychildren.org/immunizationschedules. Clinically significant adverse events that follow vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a Vaccine Adverse Event Reporting System form can be obtained at http://www.vaers.hhs.gov or by calling 800-822-7967. For RSV-mAb products, clinically significant adverse events should be reported to MedWatch Adverse Event Reporting program at www.accessdata.fda.gov/scripts/medwatch/index.cfm. If RSV-mAb is co-administered with other products, then report to VAERS.

Additional information can be found in the *Red Book* and at *Red Book Online* (https://publications.aap.org/redbook). Information on new vaccine releases, vaccine supplies, and interim recommendations resulting from vaccine shortages and statements on specific vaccines can be found at https://publications.aap.org/redbook.

ABBREVIATIONS

AAP: American Academy of Pediatrics
ACIP: Advisory Committee on Immunization Practices
aIIV3: adjuvanted inactivated influenza vaccine, trivalent
ccIIV3: cell-culture inactivated influenza vaccine, trivalent
CDC: Centers for Disease Control and Prevention
DTaP: diphtheria and tetanus toxoids and acellular pertussis vaccine
HD-IIV3: high-dose inactivated influenza vaccine, trivalent
Hib: *Haemophilus influenzae* type b vaccine
IPV: inactivated poliovirus vaccine
MenB: meningococcal serogroup B vaccine
MMR: measles, mumps, and rubella vaccine
MMRV: measles, mumps, rubella, and varicella vaccine
PCV: pneumococcal conjugate vaccine
PPSV23: pneumococcal polysaccharide vaccine, 23-valent
RSV: respiratory syncytial virus
RSV-mAb: respiratory syncytial virus monoclonal antibody
Td: tetanus toxoid, reduced diphtheria toxoid

The guidance in this statement does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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APPENDIX C

AAP vs CDC: Expert Insights on Prioritizing Routine 2026 Vaccines
("Nothing Has Changed" Webinar) — Infectious Disease Advisor, Feb. 27, 2026

Source: https://www.infectiousdiseaseadvisor.com/features/cdc-vs-aap-vaccine-schedule/

Infectious Disease ADVISOR

AAP vs CDC: Expert Insights on Prioritizing Routine 2026 Vaccines

Olivia Stern | February 27, 2026

Credit: Getty Images

In response to updated Centers for Disease Control and Prevention (CDC) guidance that transitioned several routine vaccine recommendations to “shared clinical decision-making,” the American Academy of Pediatrics (AAP) released its 2026 immunization schedule on January 26, reaffirming its support for routine vaccination against respiratory syncytial virus (RSV), hepatitis A virus (HAV), hepatitis B virus (HAB), rotavirus, influenza, and meningococcal disease.[1, 2]

To clarify these recommendations and address practical questions from clinicians, the AAP, in collaboration with Common Health Coalition, hosted a webinar on January 29 featuring experts from both organizations who discussed strategies for approaching immunization recommendations with patients and families.[3]

The AAP's immunization schedule has been endorsed by over 230 medical associations and health care organizations, including the American Medical Association, American College of Obstetricians and Gynecologists, the Infectious Disease Society of America, American Academy of Family Physicians, and the Pediatric Infectious Diseases Society.[4]

Sean O'Leary, MD, MPH, FAAP; chair of the AAP's committee on infectious diseases, explained the process that was formerly in place between the CDC and AAP. For decades, the CDC and AAP collaborated to create a unified set of recommendations but have since parted ways and subsequently released separate immunization schedules this year. While the CDC introduced changes to 6 different vaccines, the AAP's recommendations remain largely unchanged from the previous year.

> "Routine vaccination is far more effective than identifying risk groups."

AAP Recommendations

The largest discrepancy in immunization schedules between the 2 organizations involves vaccinations for RSV, HAV and HAB, rotavirus, influenza, and meningococcal disease. The CDC transitioned most of these vaccines to a "shared clinical decision-making" category rather than maintain their status as routine. Of note, the agency advised RSV vaccination for certain high-risk groups or populations and modified their human papillomavirus (HPV) vaccine recommendation to a single dose for patients aged 11 years.[3,5]

Under the new AAP schedule, RSV immunization remains recommended for all infants younger than 8 months during the respiratory virus season depending on maternal vaccination status. Influenza immunization is recommended for infants starting at 6 months of age. Dr O'Leary emphasized that among 280 pediatric influenza-related deaths reported this year, 89% occurred in patients who were incompletely vaccinated, while also highlighting this past influenza season as the most severe in over 15 years.[3,6]

Vaccination against HAV is recommended for children aged 12 to 23 months. Dr O'Leary noted that the low disease burden of HAV is attributable to vaccine uptake, as well as established herd immunity rendering the disease as rare in pediatric populations. In regard to HAB vaccination, an initial dose is recommended for all infants within 24 hours of birth.

Universal birth-dose vaccination remains the most effective option for disease prevention as infants born to HAB-positive mothers face higher risk for perinatal infection. Data show approximately 15% of pregnant individuals do not undergo HBV screening.[3]

“Routine vaccination is far more effective than identifying risk groups,” Dr O’Leary said.

Rotavirus immunization is recommended starting at 2 months of age and must be initiated prior to 15 weeks. Prior to widespread vaccination, rotavirus accounted for an estimated 50,000 annual hospitalizations, however, infant hospitalization is now rare because of community protection through vaccination.[7]

The quadrivalent meningococcal conjugate vaccine (MenACWY) is recommended as a 2-dose series, with the first dose administered between 11 and 12 years of age and a booster dose at 16 years.[3]

The AAP recommended HPV vaccination as a 2-dose series for patients aged 9 to 12 years, or as a 3-dose series for patients aged 15 years and older at the time of the first dose. However, the organization’s review of HPV vaccination data with the Advisory Committee on Immunization Practices (ACIP) was cut short following the dismissal of all 17 ACIP members in June 2025. The AAP and Vaccine Integrity Project are currently undergoing an independent evidence review and updated recommendations are anticipated after further analysis of available data.[3]

Shared Clinical Decision-Making

Dr O'Leary expressed concern regarding the implications of transitioning several vaccines into a shared clinical decision-making category.

"It implies these vaccines are less important," Dr O'Leary noted, adding that tiered recommendations may create confusion for parents and clinicians. The availability of these vaccines also poses a risk if they are no longer classified as routine.[3]

"Clinicians really don't like tiered recommendations. They want clear recommendations. Having the 'shared clinical decision-making' label creates a tiered recommendation. The fact is that for routinely recommended vaccines, clinicians already do shared decision-making when parents have questions," Dr O'Leary said.

Addressing Patient/Parent Concerns

David Higgins, MD, MPH, MS; vice president of Colorado's AAP chapter, reassured clinicians that families continue to view their pediatrician as a primary source of expertise, honesty, and consistency, as well as someone they can trust.

He advised clinicians to only address the CDC's changes to routine vaccine recommendations if parents raised questions to avoid introducing new concerns. Dr Higgins suggested clinicians proceed as usual and continue to inform parents when their child is due for routine vaccinations per AAP guidelines, along with providing their personal recommendation as a trusted provider.

"Shared decision-making does not require neutrality," Dr Higgins said.

Leading with empathy and partnership, using digestible, credible explanations, and keeping the focus on the child's health are key, Higgins noted. If clinicians are concerned about their patients' parents seeing misinformation online about vaccines, Dr Higgins stressed that clinicians avoid trying to "win a debate."

"When parents bring up something they see online, I thank them for sharing it with me, ask if I can share why it is misleading, and help them understand the lie," he said. Continuing, Dr Higgins added that "[Trying to win a debate] can backfire and lead to a hardened belief."

Ultimately, the clinicians emphasized that by remaining focused on patient-centered care, pediatricians can successfully incorporate the AAP-recommended immunization schedule into shared clinical decision-making and provide evidence-based guidance to families.

"You all create the trust with the patient — not the federal government," Dr O'Leary concluded.

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APPENDIX D

Brenda Goodman, CDC Considers Narrowing Its Covid-19 Vaccine Recommendations — CNN, Apr. 16, 2025

Source: https://www.cnn.com/2025/04/16/health/cdc-risk-based-covid-19-vaccine-recommendation

CDC considers narrowing its Covid-19 vaccine recommendations

By Brenda Goodman, CNN

4 min read · Updated 4:49 PM EDT, Wed April 16, 2025

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Under a risk-based recommendation, the CDC would continue to recommend two doses of Covid-19 vaccines each year for older adults and to anyone with weakened immune function. Eric Lee/The Washington Post/Getty Images

(CNN) — The US Centers and Disease Control and Prevention is considering recommending annual Covid-19 shots to those who are older or who have compromised immune function,

also doesn't routinely recommend annual Covid-19 vaccines for healthy adults under 65 or healthy children.

RELATED VIDEO
'A walking experiment': Hear what happened to man who got 217 Covid shots

On Tuesday, a panel of independent experts that advises the CDC on its vaccine recommendations, called the Advisory Committee on Immunization Practices, weighed the pros and cons of moving the US away from a blanket recommendation that most people get an updated Covid-19 shot every year and toward a more nuanced, risk-based recommendation.

Members of the Covid-19 vaccine work group said they began studying the policy change in November.

Under a risk-based recommendation, the CDC would continue to recommend two doses of Covid-19 vaccines each year for older adults — those over 65 — and to anyone with weakened immune function.

It may also consider recommending annual vaccination for adults and children who are at high risk of Covid-19 disease because they have a higher risk of being exposed to it. Those groups could include people like health-care workers or children in day care.

There was also strong support for a statement in the recommendation to say that anyone who wanted to get a Covid-19 vaccine could still get one, even if they didn't fit into a higher-risk category.

A risk-based recommendation would be more complicated to communicate to the public and potentially trickier to implement than a universal recommendation, and some members of the full committee said they'd be against it for that reason.

"I guess I'm surprised that we're considering a risk-based recommendation, which in general, we have not had a lot of success with implementing in the US," said committee member Dr. Denise Jamieson, dean of the Carver College of Medicine at the University of Iowa.

or lung diseases.

An analysis of data based on the CDC's list of conditions that increase the risk for severe disease from a Covid-19 infection found that 74% of adults have at least one health condition that puts them at risk.

And even though Covid is no longer causing the same kind of punishing waves of illness and death as it once did, it was still the 10th leading cause of death among adults in 2023. From September 2023 through August 2024, it caused roughly 40,000 deaths in the US.

RELATED ARTICLE
An Idaho health department isn't allowed to give Covid-19 vaccines anymore. Experts say it's a first

"Covid is still a fairly dangerous disease and very, very common," said committee member Dr. Jamie Loehr, who runs a family practice clinic in Ithaca, New York.

Loehr said he wondered how feasible it might be to implement a risk-based recommendation and what message it might send to the public.

"Even though I'm in favor of a risk-based recommendation, I still have my hesitations," he said.

Others worried that exempting healthy adults might make long Covid more common. Studies have shown that vaccination cuts the risk of developing the condition, which affected more than 9 million adults and children in 2023, according to national surveys.

"What I would like to see is modeling around long Covid," said committee member Dr. Oliver Brooks, the chief medical officer of Watts Healthcare Corp. in Los Angeles. "My primary concern through all of this at this point is long Covid."

Though there was concern that risk-based recommendations would decrease vaccination, others pointed out there's no proof that's true.

"There's not clear evidence at all that risk-based approaches are less effective," said committee member Dr. Noel Brewer, a professor of public health at the University of North Carolina. "The data supporting that claim are not really there."

they don't plan to formally vote on the policy change until the next meeting, which is scheduled for June.

Up next

Measles is not the only disease on the rise. Mumps also may be making a comeback

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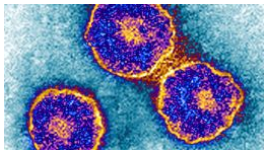

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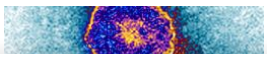

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APPENDIX E

April 2025 ACIP Meeting Update: Influenza, COVID-19, HPV, RSV and Other Immunizations — AAP Pediatrics (2025) 156(3):e2025072444

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SPECIAL ARTICLES | AUGUST 14 2025

April 2025 ACIP Meeting Update: Influenza, COVID-19, HPV, RSV and Other Immunizations FREE

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The Advisory Committee on Immunization Practices (ACIP), a group of medical and public health experts that provides advice to the Centers for Disease Control and Prevention, normally meets 3 times per year to develop US vaccine recommendations for use. The ACIP Work Groups conduct an in-depth review of the available scientific information regarding specific US Food and Drug Administration (FDA)–licensed vaccines or important vaccines in advanced stages of clinical development that are under consideration for FDA licensure and then present the information and their recommendation to the ACIP for a vote. If a recommendation receives a majority vote, it moves to the Centers for Disease Control and Prevention (CDC) Director for approval and, if approved, it is published in the CDC *Morbidity and Mortality Weekly Report*. At that point, the ACIP recommendation represents the official CDC recommendation for US immunizations. The ACIP met April 16–17, 2025, to discuss influenza vaccines, chikungunya vaccines, COVID-19 vaccines, respiratory syncytial virus (RSV) immunizations, meningococcal vaccines, Human Papillomavirus (HPV) vaccines, Mpox vaccines, and cytomegalovirus vaccines. This update summarizes the proceedings of these meetings, with an emphasis on topics that are most relevant to the pediatric population. Major updates for pediatric clinicians include information regarding HPV and

Subjects: Federal Policy, Vaccine/Immunization

Topics: immunization, vaccines, covid-19, advisory committee on immunization practices, covid-19 vaccines, influenza, human papillomavirus, monkeypox, chikungunya virus vaccine

Human Papillomavirus Vaccines

The Human Papillomavirus (HPV) Working Group (WG) presented information to frame 2 questions for upcoming policy votes : (1) Should the recommended age of initiation for HPV vaccination be lowered to 9 years? and (2) Should the number of doses be reduced? Currently, the recommended age for routine HPV vaccination starts at 11 years, with a note that it may be given as early as age 9 and that 2 doses complete the series if started before the 15th birthday. The WG felt that the main benefits to this change in wording would be to make the recommendation clearer by removing the “optional” language and that it would provide flexibility for those stakeholders interested in starting at age 9. The main concern discussed by the WG was that removal of the first HPV dose from the “adolescent platform” of recommended immunizations at 11 to 12 years of age, which includes HPV; tetanus, diphtheria, and pertussis; and pentavalent meningococcal conjugate vaccine (MenACWY), could result in decreased immunization overall. The WG anticipates bringing a recommendation to the June Advisory Committee on Immunization Practices (ACIP) meeting for vote. Notably, since 2018, the American Academy of Pediatrics (AAP) Red Book has recommended starting the HPV series between ages 9 and 12 years, and the HPV Vaccination Roundtable/American Cancer Society also encourages providers to vaccinate at age 9.

The WG also presented data that could support a reduction in

and older (decreased from 3 doses) and a 1-dose schedule for those aged 9 to 14 years (from 2 doses). The WG presented clinical trial data from Costa Rica, India, Kenya, and Tanzania, countries where there is no current routine recommendation for HPV immunization. The published trials from Costa Rica, India, and Tanzania generally reported similar, although slightly lower, efficacy and seropositivity following 1 HPV dose compared witg multiple dose regimens. Vaccine effectiveness (VE) against HPV16/18 infection in the IARC-India Trial was 92% for 1 dose and 94.8% for 2 doses at a median follow-up of 12 years,[1] and the Tanzanian trial reported 93% to 100% seropositivity 5 years after a single HPV dose.[2] Randomized controlled trial (RCT) data from the Kenyan single-dose HPV trial (KEN SHE) reported VE of 98.9% against HPC infection at approximately 4.5 years after a single dose.[3] Population-based health modeling of single-dose HPV using both base-case estimates (VE 98%) and worst-case estimates (VE 90%) against HPV16/18 infection predicted a similar reduction in HPV infection and cancer incidence as 2 doses. The WG anticipates returning to the June 2025 meeting with additional data and specific language to vote on both changing the recommended lower age and number of total HPV doses.

RSV Immunizations

The Centers for Disease Control and Prevention (CDC) recommends that all infants should be protected against severe respiratory syncytial virus (RSV) disease with either maternal RSV vaccine administered between 32 and 36 weeks gestation or monoclonal antibody infusion, nirsevimab, for all infants younger than 8 months. Clesrovimab (Merck) is the second long-acting anti-RSV monoclonal, with an anticipated FDA decision on

competition, and decrease the risk of shortages. The RSV WG presented the Evidence to Recommendations (EtR) framework assessing the following question: should clesrovimab be recommended for all infants younger than 8 months born during or entering their first RSV season? Unlike nirsevimab, clesrovimab would not be indicated for children aged 8 through 19 months at increased risk for severe RSV entering their second RSV season. WG reviewed vaccine efficacy estimates against RSV-associated medically attended lower respiratory tract infection (LRTI) (VE = 60.4%), LRTI with hospitalization (VE = 90.5%), and LRTI with intensive care unit (ICU) admission (VE = 100%); these data were reported in more detail in the October 2024 ACIP update.[4] Although clesrovimab has a shorter half-life than nirsevimab (42 vs 71 days), sustained efficacy against severe RSV through 150 days was demonstrated. Clesrovimab has a favorable safety profile with no observed increase in serious adverse events (AEs) or local or systemic reactions, including fever in 3.7% of recipients.

Clesrovimab is supplied as a single-dose, manufacturer-filled syringe for intramuscular injection, 105 mg/0.7 mL, and the dose is the same for all infants regardless of weight. Clesrovimab can be given simultaneously with routine vaccines, with target administration from October through March in most of the continental United States (as early as possible in the season).

Pending FDA licensure, the WG anticipates recommending clesrovimab for all infants younger than 8 months during their first RSV season with a vote at the June 2025 ACIP meeting. In review of clinical consideration, the WG noted there are circumstances when RSV antibody may be considered for infants born to vaccinated mothers: infants born to mothers who may

HIV infection); infants who have procedures leading to loss of maternal antibodies (eg, cardiopulmonary bypass, extracorporeal membrane oxygenation, exchange transfusion); and infants with substantially increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, ICU admission with oxygen requirement at discharge).

Finally, although there was not a vote regarding clesrovimab use in the pediatric population at this meeting, it is worth noting that, separately, the ACIP voted and passed a recommendation that all adults aged 50 to 59 years who are at increased risk of severe RSV disease receive a single RSV vaccine dose (Table 1).

TABLE 1. Advisory Committee on Immunization Practices (ACIP) Policy Questions and Votes from the April 2025 Meeting

Vaccine	Vote Date	Vote Result	Policy Questions/ Recommen
HPV	*Anticipated June 2025*[a]	N/A	1) *Should the recommended age of initiation for HPV vaccination be lowered to 9 years of age?*[a] 2) *Should the number of HP vaccine doses be reduced?*[a]
RSV	April 16, 2025	Passed: 14–0 (1 abstention)	1) ACIP recommends adult 50–59 years of age who are increased risk of severe RS disease receive a single do of RSV vaccine. Note: CDC will publish Clinical Considerations that describe ch medical conditions and risk fac

Meningococcal	April 16, 2025	2 Votes, Passed: 15–0	1) ACIP recommends GSK's MenABCWY vaccine may b used when both MenACWY and MenB are indicated at same visit. 2) ACIP recommends the Meningococcal Vaccines VF resolution be updated to include the recommendati for use of GSK's MenABCW vaccine.
Mpox	*Anticipated June 2025*[a]	N/A	1) *Should the 2 dose JYNNEC vaccine series be recommen for persons in 12–17 years o age at risk for mpox during mpox outbreak?*[a] 2) *Should routine vaccinatio with the 2 dose JYNNEOS vaccine series be recommen for persons aged 12–17 year risk for mpox?*[a]

Chikungunya	April 16, 2025	3 Votes, Passed: 14–0 (1 abstention)	1) ACIP recommends the virus-like particle chikungu vaccine for people aged ≥12 years traveling to a country or territory where there is a chikungunya outbreak. In addition, the virus-like particle chikungu vaccine may be considered people aged ≥12 years who are traveling or moving to a country or territory withou outbreak but with elevated risk for US travelers if planning travel for an extended period of time, e months or more.[b] 2) ACIP recommends the virus-like particle chikungu vaccine for laboratory worl with potential for exposure chikungunya virus.[b] 3) ACIP recommends the li attenuated chikungunya vaccine for people aged ≥18 years traveling to a country or territory where there is a chikungunya outbreak. In addition, the l attenuated chikungunya vaccine may be considered people aged ≥18 years traveling or moving to a country or territory withou outbreak but with elevated risk for US travelers if planning travel for an extended period of time, e months or more.

			due to newly reported safety e age ≥65 was previously listed a precaution for use for CHIK-LA.

a Policy questions which have been established by ACIP Working Groups and are anticipated to be put up for vote at upcoming meetings are *italicized*.

b Indicates that these recommendations have been adopted by the CDC Director or HHS Secretary (in the absence of a CDC Director) and are considered "official".

Meningococcal Vaccines

The Meningococcal WG's presentation focused on 1 topics: (1) the EtR and recommendations for an additional FDA-approved pentavalent ABCWY meningococcal vaccine and (2) a review of the data on MenQuadFi, a quadrivalent meningococcal vaccine, in children younger than 2 years. Penmenvy (GlaxoSmithKline [GSK]), a pentavalent meningococcal vaccine was licensed by the FDA in February 2025 for use in individuals aged 10 to 25 years. This vaccine is a combination of 2 previously licensed GSK meningococcal vaccines, Menveo (MenACWY-CRM) and Bexsero (MenB-4C). There are no data comparing the 2 pentavalent vaccines (Penmenvy and Pfizer's Penbraya) and, as such, the goal of the WG was to harmonize recommendations across products if possible. The WG favored a single recommendation: GSK's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit.

The WG presented data comparing immunogenicity and safety of the GSK pentavalent vaccine to Bexsero (MenB-4C) at a 2-dose 0,6-month schedule, which is a recent change (from 0,1 month) to the MenB vaccination schedule as of August 2024 based on new immunogenicity data.[5] The immunogenicity against

when dosed 0,2 months and 2 of 4 reference strains with 0,6-month schedule. Notably, the hSBA response to the reference strain PorA was not demonstrated to be noninferior for pentavalent vaccine, which is important because PorA represents the outer membrane and has bearing on cross-protection to other strains. Antibody titers in general, including against ACWY serotypes, were lower following MenABCWY vaccination compared with MenB or MenACWY alone, but there is no established correlate level of protection. The safety profile for the pentavalent vaccine is similar to that of MenB and MenACWY, with a slightly higher incidence of AEs with the pentavalent vaccine. Other data presented by the WG included an updated cost-effectiveness analysis, which demonstrates cost-savings when MenABCWY is used in place of MenACWY + MenB at the same visit.

In harmony with previous pentavalent vaccine recommendations, the ACIP voted to allow GSK's MenABCWY to be used when both MenACWY-CRM and MenB-4C are indicated at the same visit (typically ages 16 to 23) and for those individuals age ≥10 year and older who are at increased risk of meningococcal disease (**Table 1**). This policy recommendation, and the corresponding Vaccines for Children resolution, were approved unanimously (15–0) by the committee.

Following discontinuation of Menactra in June 2022, there has only been 1 quadrivalent MCV available for children younger than 2 years who are at increased risk of meningococcal disease (Menveo, GSK). To provide additional options for this patient population, Sanofi-Pasteur is seeking expansion of MenQuadFi (ACWY-TT) indication, specifically a change in minimum age from 2 years to 6 weeks. The FDA is currently reviewing clinical trial

of their clinical considerations. Proposed dosing for MenQuadFi would be based on age at initiation:

- 6 weeks through 5 months: 4 doses at 2, 4, 6, and 12 to 18 months

- 6 months through 23 months: 2 doses, with second dose given after 12 months and 3 months or more after the first dose

- 24 months or older: single dose

The WG presented safety and immunogenicity data from 3 different phase 3 clinical trials conducted in healthy infants and toddlers, with no children who would be considered high risk for meningococcal disease (the target population) included. Two of the phase 3 trials assessed safety and/or immunogenicity in infants aged 6 weeks to 11 months receiving MenQuadFi coadministered with routine immunizations at 2, 4, 6, and 12 to 18 months and the third assessed a 2-dose series in infants and toddlers aged 6 months to 23 months. With respect to immunogenicity, similar immune responses were seen in all studies and were similar or higher in the MenQuadFi groups vs the comparison. Although the incidence of AEs was similar between groups, with grade 3 (severe) local and systemic AEs occurring in approximately 10% of each group, there was an imbalance in febrile and nonfebrile seizures, with 19 patients in the MenQuadFi group (0.9%) compared with 1 (0.1%) in the comparison group reporting a seizure. On review, 87.5% of the cases had confounding factors (ie, history of febrile seizures) and only 8% met Brighton criteria as true seizures (febrile or otherwise). There were also 4 deaths that occurred more than 7 days after MenQuadFi immunization (cardiac arrest,

higher proportions of seizures (both febrile and nonfebrile), SAEs and deaths, the majority of which were not considered related to the vaccine. The WG continues to feel that the benefits of another vaccine option may outweigh the potential risks, but additional evaluation and the full EtR and Grading of Recommendations Assessment, Development, and Evaluation analysis will be presented at an upcoming ACIP meeting.

Influenza Vaccines

The influenza session had 2 primary objectives: to review the preliminary VE estimates for the 2024–2025 season and to provide an update on live-attenuated influenza vaccine (LAIV) (FluMist) for self or caregiver administration for the 2025–2026 season.

For the 2024–2025 influenza season, preliminary VE estimates were available from CDC Influenza surveillance networks and the California Department of Public Health (DPH). For the 2024–2025 season, Influenza A (H3N2) was the most common subtype, followed by Influenza A (H1N1)pdm09. Vaccination with a 2024–2025 influenza vaccine reduced the risk for medically attended influenza outpatient visits and hospitalizations among children, adolescents, and adults. Pediatric VE (age 6 months through 17 years) from the CDC networks was reported at 32% to 60% for prevention of outpatient clinic encounters and 63% to 78% effective against hospitalization.[6] VE against A(H1N1)pdm09–associated hospitalizations was slightly greater than that for A(H2N3), 63% vs 55%, respectively. The California DPH estimated VE was against medically attended (outpatient and inpatient) events and found a VE = 50% for children younger than 18 years. A subanalysis evaluated VE in a small subset of pediatric patients

On September 20, 2024, FDA approved LAIV for self or caregiver administration. It is anticipated that FluMist will be available for self or caregiver administration for the 2025–2026 influenza season. Several issues were discussed, including systems to support eligible patients and state by state variability in regulations. During launch year, the vaccine will be available through health care insurance without option to pay out of pocket. “FluMist Home,” a new web-based program sponsored by AstraZeneca, will be an online pharmacy service supporting ordering, delivering, and documentation of self/caregiver administration. Additionally, they will offer a return shipment program, which provides materials and instructions to safely dispose of the FluMist dispenser following use. The ACIP will vote on recommendations for use of FluMist at the same time as other seasonal influenza vaccines for the 2025–2026 season, likely in June.

Covid-19 Vaccines

The COVID-19 session focused on a review of data on Moderna’s next-generation COVID-19 vaccine, for which FDA licensure is anticipated in May 2025, updates to COVID epidemiology and adult VE, as well as WG considerations regarding continued universal immunization recommendations vs a shift to a risk-based recommendation.

The WG presented data comparing Moderna’s next-generation COVID-19 vaccine (mRNA-1283) to the original mRNA-1273 vaccine (Spikevax). Instead of coding for the full-length spike protein, the investigational mRNA-1283 vaccine encodes only the spike protein N-terminal domain and receptor-binding domain via a 7–amino acid linker, which allows for a decreased amount

immunogenicity compared with the currently available mRNA-1273. In children aged 12 to 17 years, the neutralizing antibody geometric mean concentrations solicited by the investigational mRNA-1283 vaccine were similar to those from the original mRNA-1273 vaccine, 3561 vs 3388, respectively. Using the CDC definition for symptomatic COVID-19 cases (polymerase chain reaction–positive and at least 1 symptom), the relative VE in patients aged 12 to 17 years was similar for both vaccines, although with a very wide CI due to a low number of observed COVID-19 cases in this population. A post hoc analysis in all participants aged 12 years and older found a relative VE against severe COVID-19 of 38%.

The remainder of the session focused on WG considerations for the future of COVID-19 vaccine recommendations. Specifically, the group weighed the benefits, risks, and epidemiological considerations of continuing with universal COVID-19 vaccine recommendations for everyone aged 6 months and older vs transitioning to a risk-based recommendation for groups at increased risk of severe COVID-19. The WG also reviewed recommendations in other countries (United Kingdom, Canada, Australia) and the World Health Organization, noting that the United States is the only country that currently has a universal COVID-19 vaccine recommendations for children.

Although COVID-19 was one of the top 10 causes of death in the United States for children aged 17 years and younger in 2021–2022, rates of COVID-19–associated hospitalizations and mortality have been declining in all age groups. During the 2023–2024 season, there were more deaths in children aged 1 year and younger because of COVID-19 than influenza (53 vs 18); however, the converse was true in older children. The number of

of the pandemic, the incidence of influenza- and RSV-associated hospitalizations in children aged 0 to 17 years was greater than that for COVID-19. During the 2024–2025 COVID season, pediatric patients accounted for approximately 4% of hospital admissions, and within pediatrics, the highest incidence remains among infants younger than 6 months. Hospitalization of infants younger than 6 months due to COVID peaked in August, at approximately 12 hospitalizations per 100 000 population. Over half (59%) of children aged 6 months through 17 years hospitalized with COVID-19 had 1 or more underlying condition and 1 in 5 were admitted to the ICU. Fewer than 5% of pediatric patients hospitalized with COVID-19 during 2023–2024 had received the most recently recommended COVID-19 vaccine.

Acute complications related to COVID-19 illness have also declined. Multisystem Inflammatory Syndrome in Children incidence has significantly declined since 2021, with 79 cases reported in 2024. It is worth noting that of those 79 cases, 74% were unvaccinated and the remaining 26% were all more than 12 months out from their last COVID-19 vaccine.

Long COVID also continues to be a significant public health threat. Data from the 2023 National Health Interview Survey indicate at least 1.4% of all US children have experienced long COVID; other studies, including structured observational trials and electronic medical record data suggest that this number may be as high as 10% to 20% of children infected with SARS-CoV-2.[8,9] Among children aged 5 to 17 years, COVID-19 vaccination prior to infection is associated with reduced likelihood of long COVID symptoms, with 72% reduction in long COVID respiratory symptoms.[10] As of March 2025, COVID-19 immunization rates remain low in children younger than

2026 COVID-19 vaccination. Next steps at the end of the session included an anticipated vote during the June ACIP meeting on recommended use for 2025–2026. Of note, approximately 1 month after the April ACIP meeting, the FDA Commissioner published a new stance on COVID-19 vaccine approval, noting that the FDA anticipates making a favorable determination and presumed approval only for COVID vaccines for use in adults older than 65 years and individuals with risk factors for severe COVID above the age of 6 months.[11]

Cytomegalovirus Vaccine

More than 16 000 children are born with congenital cytomegalovirus (cCMV) in the United States every year, or approximately 4.5 per 1000 live births, and there is no currently available CMV vaccine. Moderna presented adult phase 1 and 2 clinical trials data of their CMV vaccine (mRNA-1647). This 3-dose mRNA CMV vaccine codes for 6 total CMV proteins, including the 5 components of the pentamer required for CMV cell entry and glycoprotein B, which mediates host-virus cell fusion and is necessary for infectivity. Phase 1 and 2 results reported a generally well-tolerated vaccine, with no identified safety concerns, that was highly immunogenic with neutralizing antibodies persisting up to 3 years postvaccination in both CMV-seronegative and seropositive patients. The target population for this vaccine, pending results of a fully enrolled phase 3 trial, includes nonpregnant female patients aged 16 to 40 years to prevent primary infection in CMV-seronegative female patients and potentially boost protection in those seropositive. The WG acknowledged that there are a number of outstanding questions, including efficacy against vertical transmission, cCMV infection, and/or disease.

Mpox Vaccine

The Mpox Clade II outbreak has been ongoing in the United States since May 2022 but has waned significantly, with a current 7-day moving average case count of 1 to 3 Mpox cases per day. There has also been a new Clade 1 outbreak in the Democratic Republic of Congo and surrounding countries since mid-2024. Currently, ACIP recommends use of JYNNEOS (MVA-BN) vaccine in adults aged 18 years and older at risk of Mpox during outbreaks, who identify as "gay, bisexual or other MSM or someone who has sex with MSM with one of the following in the past 6 months: new diagnosis of STI, more than 1 sex partner, sex at a commercial venue, sex in association with a large public event where Mpox is known to be circulating; sexual partners of anyone who experiences any of the above and anyone anticipating any of the above exposures." There were 147 Mpox cases in children and adolescents in the United States between May 2022 and March 2025, mostly in adolescents aged 12 to 17 years (N = 92, 63%). As there were no previous data to evaluate the immunogenicity of JYNNEOS in children younger than 18 years, a National Institutes of Health trial was completed last year in adolescents aged 12 to 17 years (DMID 22–0020, "DoSES") compared with adult reference data. The WG plans to vote on 2 policy recommendations at the June 2025 meeting:

1) ACIP recommends the 2-dose JYNNEOS vaccine series for persons aged 12 to 17 years at risk for Mpox during an Mpox outbreak

2) ACIP recommends routine vaccination with the 2-dose JYNNEOS vaccine series for persons aged 12 to 17 years at risk for Mpox

of the 2-dose subcutaneous vaccine regimen in 315 adolescents aged 12 to 17 years compared with adults aged 18 to 50 years. Participants were generally healthy but excluded if they had known history of myocarditis or heart disease. Injection-site reactions were comparable to those in adults, with pain being most common (60%). Systemic AEs were reported in 65% and most common reactions were headache and fatigue. Injection-site nodules and discoloration were reported in 37% and 17% of adolescents, respectively; these were also a frequent finding in adults, reported in 59% and 28%. Eight adolescents reported dizziness with immunization (3%), which was more frequent than adults. No SAEs or adverse events of special interest (AESIs), including myocarditis, were observed.

Immunogenicity data demonstrated higher neutralizing antibody titers in adolescents compared with adults, clearly meeting noninferiority criteria. Overall, JYNNEOS (MVA-BN) appears to be safe and immunogenic in adolescents aged 12 through 17 years.

The WG reviewed the EtR for both outbreak and routine immunization of at-risk individuals. In addition to the DoSES study safety data, information from vaccine safety surveillance systems was reviewed for all individuals younger than 18 years who received JYNNEOS under emergency use authorization during the 2022–2023 United States outbreak. Vaccine Adverse Event Reporting System reported 1245 vaccinees, with 1 report of syncope and 3 unspecified mild local and systemic reactions; Vaccine Safety Datalink reported 88 vaccines with no AESIs and 57 vaccines were given through single-patient expanded-access investigational new drug protocol with no SAEs. The WG felt that benefits of prevention of Mpox disease during an outbreak outweighs risks based on surveillance and study safety data.

JYNNEOS vaccination in at-risk adolescents during an Mpox outbreak.

Regarding the question of routine immunization of at-risk adolescents in nonoutbreak settings, modeling studies have shown that more than 50% of at-risk populations need to be immunized/immune to significantly decrease the risk of large outbreaks. Taking this into consideration, WG considered that a routine vaccination strategy for at-risk individuals could be a powerful tool in preventing future outbreaks. The vaccine has been demonstrated to be well-tolerated and immunogenic in this population, so the WG felt that the desirable consequences of routine JYNNEOS vaccination in at-risk adolescents probably outweigh undesirable consequences in most settings, but a general lack of data on the use of JYNNEOS outside of outbreak settings raised the level of uncertainty. There are ongoing studies of JYNNEOS vaccination in Africa that may be informative in the future.

Chikungunya Vaccines

There are 2 chikungunya vaccines licensed by FDA: Live-attenuated (LA) vaccine licensed in November 2023 (Valneva) and virus-like particle (VLP) vaccine licensed on February 14, 2025 (Bavarian Nordic). Both vaccines are licensed based on neutralizing antibody responses estimating protection and safety, with pending clinical efficacy and expanded safety postlicensure studies. CHIK-VLP is a single-dose vaccine indicated for use in persons aged 12 years and older and the LA vaccine is approved for adults aged 18 years and older. The WG presented 2 policy questions for vote at this meeting. The first policy question was: Should CHIK-VLP be recommended for use in

and older. There were similar rates of AEs in vaccine and placebo groups, including postvaccination arthralgia in 7% of CHIK-VLP vs 6% placebo. The WG also recommended that CHIK-VLP vaccine may be considered for persons aged 12 years and older traveling or taking up residence in a country or territory without an outbreak but with elevated risk for US travelers if planning travel for an extended period, eg, 6 months or more.

The second policy question was: Should CHIK-VLP vaccine be recommended for laboratory staff at risk for chikungunya virus infection? The ACIP approved all policy questions related to CHIK-VLP (**Table 1**). Finally, although not immediately relevant to the pediatric population, it is important to note that based on new safety reports of multiple adults over the age of 60 requiring hospitalization for cardiac and neurologic events following vaccination with the live-attenuated chikungunya vaccine (CHK-LA or "Ixchiq"), the ACIP/CDC and FDA have recommended a pause on use of CHIK-LA in adults 60 years and older pending additional investigation.

All authors conceptualized and designed the manuscript, collaboratively drafted the initial manuscript, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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as Liaison to ACIP for the Pediatric Infectious Diseases Society and participates in COVID-19 and RSV vaccine trials sponsored by Pfizer, Sanofi and Moderna and his institution receives funds to conduct these trials.

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AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices
AE	adverse event
AESIs	adverse events of special interest
AI/AN	American Indian and Alaska Native
CDC	Centers for Disease Control and Prevention
CHKV-LA	live-attenuated chikungunya vaccine
CMV	cytomegalovirus
EtR	Evidence to Recommendations
FDA	US Food and Drug Administration
GSK	GlaxoSmithKline
hSBA	human complement serum bactericidal assay
ICU	intensive care unit
LRTI	lower respiratory tract infection
MenABCWY	pentavalent meningococcal conjugate vaccine
MenB	serogroup B meningococcal vaccine

PCV20	20-valent pneumococcal conjugate vaccine
PPSV23	23-valent pneumococcal polysaccharide vaccine
RSV	respiratory syncytial virus
VAERS	Vaccine Adverse Event Reporting System
VE	vaccine effectiveness
VLP	virus-like particle
VSD	Vaccine Safety Datalink

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Comments

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APPENDIX F

KFF: A Look at Recent Changes to State Vaccine Requirements for School Children (Sept. 2025) — No State Mandates COVID

Source: https://www.kff.org/state-health-policy-data/a-look-at-recent-changes-to-state-vaccine-requirements-for-school-children/

KFF The independent source for health policy research, polling, and news.

A Look at Recent Changes to State Vaccine Requirements for School Children

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Routine vaccination rates for kindergarten children have declined since the COVID-19 pandemic began, while exemptions from school vaccination requirements, particularly non-medical exemptions, have increased. These trends coincide with shifting attitudes toward childhood vaccination likely fueled in part by vaccine misinformation. The past few years have seen more skepticism and confusion among the public about the safety and effectiveness of vaccines, a decline in trust of health authorities, and a growing partisan divide. Shifts in vaccine attitudes are reflected in recent state level policy changes, with state lawmakers introducing more than 2,500 vaccine-related bills since 2021, with almost half targeting vaccine requirements. In addition, Florida officials recently announced plans to eliminate all school vaccination requirements. Despite these changes, recent KFF polling found that public confidence in the safety of routine vaccines like MMR remains high and about eight in ten (81%) parents overall as well as large majorities of parents who identify as Democrats, independents, and Republicans support current state vaccine requirements, saying students should be required to be vaccinated against measles and polio to attend public schools with some exceptions. This policy watch examines recent state policy changes to school vaccine requirements and the extent to which they may impact vaccination trends.

States and local jurisdictions, not the federal government, set vaccine requirements for daycare and school entry. The federal government does, however, have a long-standing, evidence-based system for approving and recommending vaccines for the public, including the childhood vaccination schedule. The childhood vaccination schedule is set by the Centers for Disease Control and Prevention (CDC) based on recommendations from the Advisory Committee on Immunization Practices (ACIP). ACIP's recommendations are used by many states to develop school vaccine requirements. HHS Secretary Robert F. Kennedy Jr. (RFK Jr.), who has long record of opposing immunizations and spreading vaccine misinformation, has led recent efforts to re-examine the federal childhood vaccine schedule, replace members of ACIP, and restrict COVID-19 vaccines and mRNA vaccine research. In addition, the Trump administration recently released a report that calls for a new vaccine framework that includes reevaluating the childhood vaccine schedule and addressing vaccine injuries.

All states currently require children to be vaccinated against certain diseases in order to attend public schools. School vaccination requirements are an important tool for reducing the spread of diseases and increasing vaccination coverage rates. Required vaccinations across every state and D.C. include MMR, DTaP, polio, and varicella; some states also require hepatitis A, hepatitis B, meningococcal, and/or HPV vaccines. At this time, no states require the COVID-19 vaccine for school entry. While it has yet to be enacted, Florida's plan to eliminate all school vaccination requirements would make them the first and only state to do so. However, as the divide between red and blue states on health policy grows, more states may consider moving this direction.

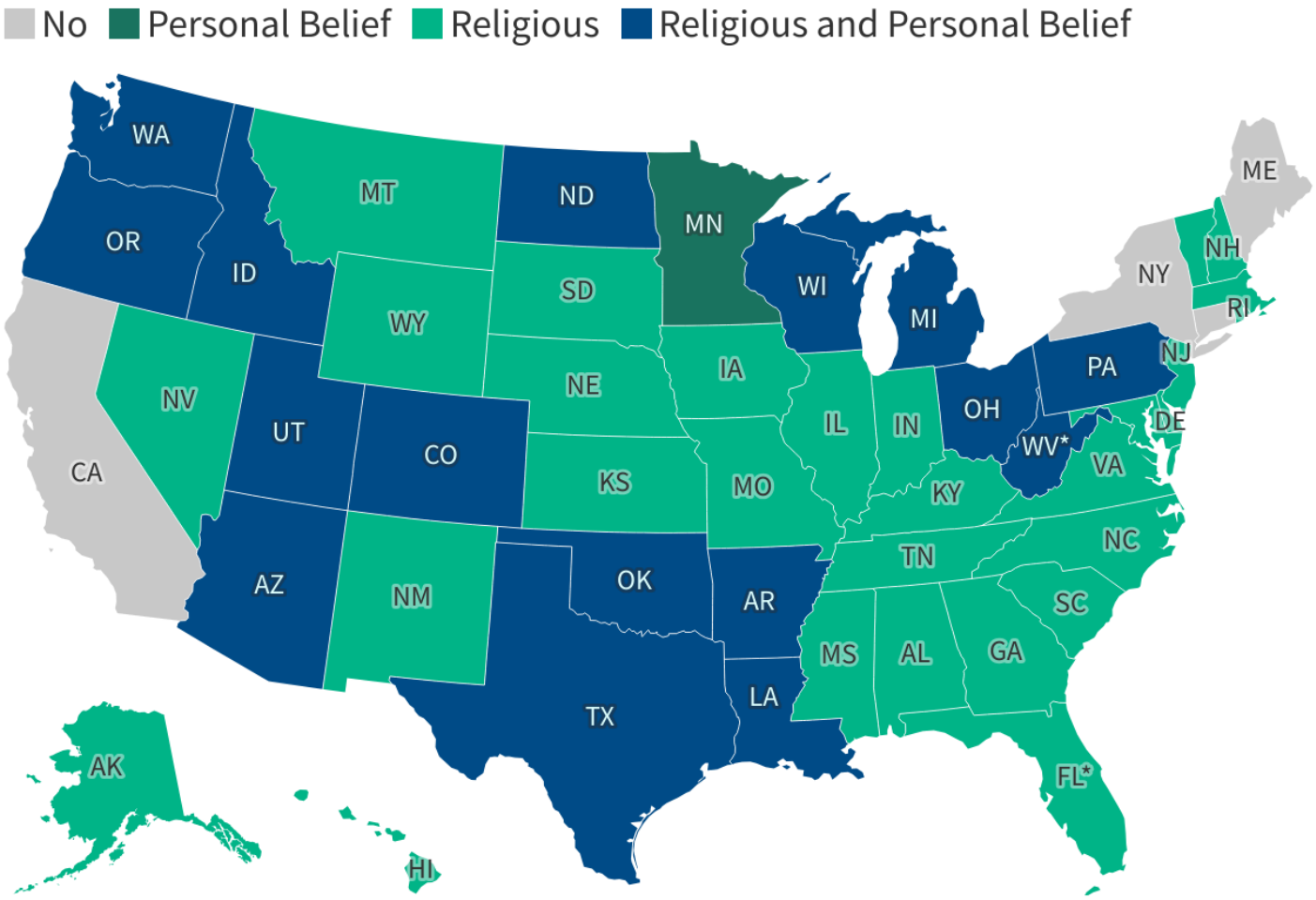
All states allow exemptions from school vaccination requirements for medical reasons and almost all states (47 including D.C.) allow exemptions for religious and/or personal beliefs (Figure 1). This leaves four states (California, Connecticut, Maine, and New York) that only allow medical exemptions. Studies have shown that higher exemption rates from school vaccination requirements are associated with lower vaccination coverage rates and increased risk for disease outbreaks. In the 2024-2025 school year, the share of children claiming an exemption from vaccination

requirements from one or more vaccinations rose to 3.6%, the highest national exemption rate to date, up from 2.5% in 2019-2020. Increases in non-medical exemptions accounted for the recent increases, with non-medical exemptions increasing from 2.2% to 3.4% over the period. Vaccination rates and exemption rates vary significantly by state, with the share of children claiming an exemption from one or more vaccinations during the 2024-2025 school year ranging from 0.1% in California to 15.4% in Idaho.

Figure 1

47 States Allow Exemptions From School Vaccination Requirements for Religious and/or Personal Beliefs

Type of non-medical exemption(s) from school vaccination requirements permitted by state



Note: Count includes D.C. *Florida has announced that they plan to eliminate school vaccine requirements but have not enacted any legislation. West Virginia Governor Patrick Morrisey signed an executive order in January 2025 allowing religious and personal belief exemptions. The West Virginia Board of Education, however, still encourages families to act in accordance with the state's vaccination legislation, which only permits medical exemptions. Litigation is ongoing.

Source: KFF Tracking of State Laws

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At least 10 states so far this year have enacted or issued changes related to routine vaccine requirements for children (Table 1). In the years following the pandemic,

states saw an increase in vaccine-related policy proposals. The pandemic spurred increased state legislative activity initially focused on state-level authority to require COVID-19 vaccines. However, over time, as the response to COVID-19 became more politicized, states began limiting COVID-19 vaccine mandates as well as focusing more broadly on routine vaccination requirements (and exemptions to those requirements) in schools. Notably, most of the vaccine-related bills introduced by legislators since the pandemic began have not passed, but ten states in the past year have enacted or issued policy changes related to school or child care vaccination requirements.

Almost all states (nine out of 10 states with recent changes) made changes that could result in more students claiming a non-medical exemption, which could reduce vaccination rates. Many of the recent changes (described in Table 1) will make it easier for families with children in childcare settings or school to obtain a non-medical vaccine exemption. Notably, the governor of West Virginia signed an executive order allowing religious and personal belief exemptions in January 2025, though litigation is ongoing. Prior to 2025, West Virginia was one of five states (now four states) that only allowed medical exemptions and had the highest vaccination rates and lowest exemption rates in the country during the 2023-2024 school year (the latest available data for the state). In addition, Idaho, the state with the lowest vaccination rates and highest exemption rates during the 2024-2025 school year, transferred control of required vaccines to the legislature and restricted medical mandates (likely weakening school vaccine requirement enforcement). These changes, in addition to broader state efforts to scale back immunization outreach and promotion, changes to vaccine recommendations at the federal level, and reduced support from the federal government for state and local health departments, could further increase the number of exemptions requested and drive down vaccination rates among children. Florida's plan to eliminate all school vaccination requirements goes beyond expanding exemptions and would mark a major shift in state vaccination requirements, though the issue will have to be taken up by the state legislature.

At the same time, one state has made a change that could maintain or increase children's routine vaccination rates. Colorado recently passed a law allowing the consideration of vaccine recommendations from outside groups like the American Academy of Pediatrics (AAP), not only ACIP, when developing school vaccine requirements. More states may move in this direction depending on the outcome of ACIP's upcoming meeting on vaccine recommendations and potential further changes by RFK Jr. to the ACIP panel. In addition, the AAP also recently reaffirmed their support for eliminating non-medical exemptions amid rising exemption rates, and some states, such as Massachusetts and Hawaii, are proposing eliminating non-medical exemptions, though these changes have not been enacted. While the appointment of RFK Jr. in early 2025 likely spurred additional efforts to loosen vaccine requirements in many states this year, other states are working to ensure vaccine access amid changes at the federal level.

Table 1

At Least 10 States So Far This Year Have Enacted or Issued Changes Related to School Vaccination Requirements for Children

Enacted legislation or administrative actions related to child care or school routine vaccination requirements in 2025 by state

State	Text	Change to Vaccine Requirements	Non-Medical Exemption Rate Among Kindergartners, 2024-2025
Recent changes that could reduce children's routine vaccination rates:			
Idaho	2025 ID SB 1210	The Medical Freedom Act prohibits medical intervention mandates, including vaccines. Schools can still block sick children from attending but cannot block healthy unvaccinated children from attending during an outbreak.	15.1%
Idaho	2025 ID HB 290	Transfers control of vaccine requirement regulation from the Department of Health and Welfare to the Idaho Legislature, removes most uses of the word "required" from state law on immunization.	15.1%

Iowa	2025 IA HB 299	Requires schools to disclose vaccine exemption information on their websites and include it in information given to parents and guardians when registering children for school.	3.8%
Kansas	2025 KS HB 2045	Codifies and expands the definition of religious exemptions for child care settings.	3.3%
Montana	DPHHS Immunization Directive	Requires child care centers to accept religious exemptions.	NR
New Hampshire	2025 NH HB 10	The Parental Bill of Rights prohibits schools from infringing on parents' right to exempt their children from receiving immunizations because of religious beliefs.	3.9%
Tennessee	2025 TN S 827	Prohibits the state board of education from requiring a private school that provides a fully online, self-paced educational program to comply with vaccination requirements.	3.7%

Texas	2025 TX HB 1586	Allows parents to print the non-medical exemption form rather than be required to submit a written request for the form to the state's health department.	4.0%
Utah	2025 UT HB 228	Makes a student's vaccine exemption form a part of their permanent school record, allowing the form to remain valid even if a student transfers schools.	10.0%
West Virginia	EO 7-25	Governor Patrick Morrisey signed an executive order in January 2025 allowing religious and personal belief exemptions. West Virginia did not permit non-medical exemptions before the executive order.	NR
Recent changes that could maintain or increase children's routine vaccination rates:			
Colorado	2025 CO HB 1027	Modifies language on where and how the state board of health should seek guidance for vaccine requirements. The board should now take	4.1%

		into consideration, rather than base decisions on, the recommendations of ACIP as well as three physician groups.

Note: State exemption rates available here.

Source: KFF Tracking of State Laws and Administrative Activity

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