IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

PLANTIFFS' OPPOSITION TO MOVANTS'
MOTION FOR STAY OF PRELIMINARY INJUNCTION PENDING APPEAL

With their Motion for Stay of Preliminary Injunction Pending Appeal ("Motion to Stay"), Children's Health Defense ("CHD"), Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (collectively, "Movants"), seek relief that they have no standing to seek. Accordingly, their Motion to Stay should be denied.

PERTINENT FACTS

The Court is well aware of the procedural history, facts, and claims in this case. Accordingly, Plaintiffs do not repeat them here but instead recite facts pertinent only to Movants' Motion to Stay.

Five days after the first preliminary injunction hearing in this case on February 13, 2026, Movants filed an emergency motion to intervene. (ECF 249, 2/18/26). Both Plaintiffs *and Defendants* opposed the Movants' intervention. (ECF 267 and 268). The Court denied Movants' request to intervene but stated that Movants were "welcome to file a brief as amicus curiae." (ECF

271, 2/27/26). Movants subsequently filed an amicus brief opposing Plaintiffs' request for injunctive relief. (ECF 281, 3/9/26).

In an Order dated March 16, 2026, the Court granted in part Plaintiffs' Motion for Preliminary Injunction (ECF 181, 182), staying "(i) the January 2026 Memo revising the CDC's childhood immunization schedule"; "(ii) the appointments of thirteen ACIP members"; and "(iii) all votes taken by the now-stayed ACIP." (ECF 291) ("March 16 Order"). In the March 16 Order, the Court expressly addressed issues raised in Movants' *amicus* brief:

> Amici Children's Health Defense raises concerns about the safety of many of the vaccinations at issue. *See generally* Dkt. 281. While the vaccinations may pose some health risk to some individuals, Children's Health Defense's proffered evidence does not demonstrate that the risks outweigh the broader benefits of the vaccines. On the record currently before the Court, the Court finds Plaintiffs' and the other amici's evidence more compelling on the public health risks.

(ECF 291 at 41, n. 75).

Although Movants' attempt to intervene and become parties to this case was denied, Movants nonetheless filed a Notice of Appeal purporting to appeal from both the Intervention Order and the March 16 Order. (ECF 297, 3/25/26). They then filed "Appellants' Emergency Motion Under FRAP 8(a)(2)(A)(ii), For Relief Pending Appeal" with the First Circuit on April 4, 2026,[1] which the First Circuit summarily denied, noting that "such a motion should be filed in the district court in the first instance. Accordingly, the motion is denied, without prejudice to movants-appellants' pursuit of relief in the district court in the first instance."[2]

This motion followed. Movants assert that the March 16 Order should be stayed because "the Secretary filed a renewed ACIP charter pursuant to the mandatory biennial renewal provision of FACA, 5 U.S.C. § 1013(d)." (ECF 303, p.1). Movants assert in their motion that the "factual

[1] This motion is attached to the Declaration of James J. Oh as Exhibit 1.
[2] The First Circuit's April 9 Order is attached to the Oh Declaration as Exhibit 2.

predicate for this Court's FACA analysis at least in part no longer exists. No party has presented this changed circumstance to this Court." (*Id*., p. 2).

MOVANTS HAVE NO STANDING TO SEEK A STAY OF THE MARCH 16 ORDER

One sentence in Movants' Motion to Stay compels the denial of this motion. On page 9, Movants admit that they "***are not parties to this action."*** (Emphasis added).

The Supreme Court has established that "an amicus curiae is not a 'party' to the case" for purposes of seeking review of a district court or appellate court decision. *International Union, United Auto., Aerospace and Agr. Implement Workers of America AFL-CIO, Local 283 v. Scofield*, 382 U.S. 205, 209 (1965). District courts have discretion in determining the scope of amicus participation. Traditional amicus status typically permits filing memoranda and briefs on motions, participating in oral arguments on dispositive motions, and receiving notice and service of documents. *Alliance of Automobile Mfrs. v. Gwadowsky*, 297 F.Supp.2d 305, 308 (D. Maine 2003). Courts have denied requests for expanded "amicus curiae plus" status that would allow amici to do such things as call witnesses, cross-examine witnesses, or conduct discovery, finding such participation would "seriously compromise judicial efficiency." *Verizon New England v. Maine Public Utilities Commission*, 229 F.R.D. 335, 338 (D. Maine 2005).

The law in this Circuit is well-established that amici cannot raise arguments for the first time that the parties have not raised. Because amici are not parties, the "customary praxis in this circuit is to eschew arguments raised only by amici and not by the parties." *Ryan v. U.S. Immigration and Customs Enforcement*, 974 F.3d 9, 33 n. 10 (1st Cir. 2020); *Upper Blackstone Water Pollution Abatement District v. EPA,* 690 F.3d 9, 29 n.25 (1st Cir. 2012) *cert. denied* 569 U.S. 972 (2013) ("amicus is not a party and we do not engage those arguments"); *In re Sony BMG Music Ent*., 564 F.3d 1, 3 (1st Cir. 2009) *cert. denied sub nom Tenenbaum v. Sony BMG Music Ent.*, 558 U.S. 933 (2009) ("We ordinarily do not entertain arguments raised by amici and not by

parties" unless the issue relates to subject-matter jurisdiction); *Lane v. First Nat'l Bank of Bos.*, 871 F.2d 166, 175 (1st Cir. 1989) ("We know of no authority which allows an amicus to interject into a case issues which the litigants, whatever their reasons might be, have chosen to ignore.").

Here, Plaintiffs, to be sure, have no intention of ignoring the new ACIP Charter, since it appears to be an attempt by Defendants to do an end-run around the Court's March 16 Order granting preliminary relief. Plaintiffs will address the new Charter at an appropriate time and reserve the right to do so. However, simply because Plaintiffs have yet to challenge the new Charter, or Defendants have not sought a stay of the March 16 Order, does not mean Movants can interject and litigate the new Charter into this case as grounds for a stay. It is not their place.[3]

CONCLUSION

The Motion to Stay should be denied.

Dated: May 4, 2026

Respectfully submitted,

By: */s/ James J. Oh* (IL Bar No. 6196413)
James J. Oh (admitted *pro hac vice*)
Kathleen Barrett (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
227 W. Monroe Street, Suite 4500
Chicago, IL 60606
Tel: 312.499.1400
Fax: 312.845.1998
Email: joh@ebglaw.com
kbarrett@ebglaw.com

Elizabeth J. McEvoy (BBO No. 683191)
Gianna Costello (BBO No. 715031)
EPSTEIN BECKER & GREEN, P.C.
One Financial Center, Suite 1520
Boston, MA 02111
Tel: 617.603.1100
Fax: 617.249.1573
Email: emcevoy@ebglaw.com

[3] Because Movants do not have standing to seek a stay of the March 16 Order, there is no need to address the test for a stay pending an appeal set forth in *Nken v. Holder,* 556 U.S. 418, 427 (2009).

gcostello@ebglaw.com

Richard H. Hughes IV (admitted *pro hac vice*)
Robert Wanerman (admitted *pro hac vice*)
William Walters (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
1227 25th Street, N.W., Suite 700
Washington, DC 20037
Tel: 202.861.0900
Fax: 202.296.2882
Email: rhhughes@ebglaw.com
rwanerman@ebglaw.com
wwalters@ebglaw.com

Jeremy A. Avila (admitted *pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
57 Post Street, Suite 703
San Francisco, CA 94104
Tel: 415.398.3500
Fax: 415.398.0955
Email: javila@ebglaw.com

Daniella R. Lee (*pro hac vice* pending)
EPSTEIN BECKER & GREEN, P.C.
201 East Kennedy Blvd., Suite 1260
Tampa, FL 33602
Tel: 813.367.9454
Fax: 813.367.9441
Email: dlee@ebglaw.com

CERTIFICATE OF SERVICE

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

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

c/o Leah Belaire Foley, US Attorney
Michael L. Fitzgerald
Office of the US Attorney for the District of Massachusetts
1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210
michael.fitzgerald2@usdoj.gov

Jay Bhattacharya, MD, PhD, in his official capacity as Acting Director Centers for Disease Control and Prevention

c/o Isaac Belfer
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
Isaac.C.Belfer@usdoj.gov

James W. Harlow
DOJ-Civ
Consumer Protection Branch
P.O Box 386
Washington, D.C. 20044
James.w.harlow@usdoj.gov

/s/ James J. Oh
James J. Oh

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM) District Judge: Hon. Brian E. Murphy

DECLARATION OF JAMES J. OH

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the following is true and correct:

1. I am lead trial counsel for Plaintiffs in the above-titled action.

2. Attached hereto as Exhibit 1 is "Appellants' Emergency Motion Under FRAP 8(a)(2)(A)(ii), For Relief Pending Appeal" filed by Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller with the First Circuit Court of Appeals on April 4, 2026.

3. Attached hereto as Exhibit 2 is the order from the First Circuit Court of Appeals dated April 9, 2026, denying the motion identified above.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 4, 2026.

/s/ James J. Oh
James J. Oh

EXHIBIT 1

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

No. 26-1325

ANDREA SHAW, SHANTICIA NELSON, DR. PAUL THOMAS,
DR. KENNETH STOLLER, and CHILDREN'S HEALTH DEFENSE,

Appellants,

v.

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs-Appellees,

v.

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

Defendants.

On Appeal from the United States District Court
for the District of Massachusetts, No. 1:25-cv-11916-BEM

APPELLANTS' EMERGENCY MOTION UNDER FRAP 8 (a)(2)(A)(ii),
FOR RELIEF PENDING APPEAL

Appellants respectfully request that this Court resolve this motion within twenty-one days of filing to preserve the possibility of further review during the Supreme Court's October Term 2025, which concludes in late June 2026.

The lower court denied Appellants' emergency motion to intervene in a short order entered February 27, 2026 (Ex. 1), without analysis or findings.

A SINGLE DISTRICT JUDGE HAS SHUT DOWN THE FEDERAL GOVERNMENT'S VACCINE APPARATUS

The statute is called the Federal *Advisory* Committee Act. Advisory. It provides that advisory committees exist "solely for advisory functions" and that "determinations of policy shall be made solely by the President or an officer of the Federal Government." 5 U.S.C. § 1008(b). Judge Murphy's March 16 order inverts that statutory command by holding that the CDC Director cannot initiate changes to the childhood immunization schedule without prior origination by the Advisory Committee on Immunization Practices ("ACIP). The order also stayed the appointments of thirteen new ACIP members, leaving the committee without a quorum, and thus unable to act.

The result is a Catch-22. The Director cannot act because the court held only ACIP can originate. ACIP cannot act because the court stayed nearly its entire membership, eliminating the quorum necessary to deliberate or vote. If a novel pathogen emerges tomorrow, the federal government has no committee to convene, no director authorized to act, and no secretary empowered to respond. That condition persists for the duration of this litigation.

One preliminary injunction, entered at the request of seven medical trade organizations, has done what no pathogen, no budget crisis, and no prior administration has done: taken the federal government out of the vaccine business entirely. And the framework is self-perpetuating: even if ACIP is eventually reconstituted, every future CDC action AAP dislikes will produce another amended complaint, another preliminary injunction motion, or a contempt proceeding under the same origination requirement. The court's order is a permanent leash on federal vaccine policy.

The court's holding has no basis in the statutory text. No statute requires the CDC Director to consult ACIP before acting on the immunization schedule. FACA says these committees advise. *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), footnote 4, recognizes the Director's discretion in "adopting" ACIP recommendations, and "adopting" presupposes independent authority. CDC's own ACIP Policies and Procedures confirm it: the Director "may adopt or reject" recommendations, with a structured disagreement pathway including internal decision memos and Federal Register notice. An ACIP recommendation, standing alone, has no legal force. It acquires binding effect[1] only when the Director adopts it.

The downstream statutes the court cited, the ACA's preventive care mandate, VFC, Medicaid, all trigger on the Director's adoption, not on ACIP's recommendation. Congress made the Director's act consequential. That is an argument for the Director's authority, not against it.

No court has ever imposed an ACIP origination requirement under FACA. The CDC Director is a Senate-confirmed officer who commands thousands of full-time scientists and public health professionals.[2] Under the court's reading, that entire apparatus cannot initiate vaccine policy. All origination authority belongs to fifteen Special Government Employees under 18 U.S.C. § 202(a) who meet three times a year for a total of six days. ACIP does not advise

[1] The Director's adoption triggers mandatory insurance coverage under the ACA, 42 U.S.C. § 300gg-13(a)(2); VFC provider obligations; and Medicaid eligibility. State vaccine mandates are set independently, though more than 600 state statutory provisions reference ACIP or the CDC schedule. See Ex. 6 (Proposed Answer ¶ 87).

[2] NCIRD, the center that manages the immunization schedule, runs the Vaccines for Children program, and staffs ACIP's own meetings, alone has five divisions and twenty-two branches. CDC, NCIRD Organizational Chart (approved July 17, 2024), https://www.cdc.gov/about/divisions-offices/ncird.html. Its Immunization Services Division has eight branches. NCIRD is one of three national centers at CDC devoted entirely to infectious disease.

under this framework; it holds the exclusive power to originate, at least according to the court. The statute says no such thing.

The court converted the CDC's directors' historic voluntary deference into a binding legal requirement. Director O'Neill changed vaccine recommendation which he was permitted to do; the Federal Advisory Committee Act is not a Federal Mandatory Advisory Committee Origination Act.

Because ACIP recommendations have no binding effect until the Director adopts them, and because no statute requires the Director to obtain ACIP origination before acting, there is no likelihood of success on the merits of the statutory claim on which the preliminary injunction rests. The preliminary injunction fails on the first *Winter* factor. *Winter v. Natural Resources Defense Council*, Inc., 555 U.S. 7, 20 (2008).

BACKGROUND

Seven medical associations led by the American Academy of Pediatrics sued the Secretary of Health and Human Services and CDC officials to block revisions to the childhood immunization schedule. The Fourth Amended Complaint challenges the Secretary's removal of the COVID-19 vaccine recommendation for healthy children, the reconstitution of ACIP, three ACIP votes, and the January 2026 memorandum reorganizing the schedule into three tiers. No vaccine was eliminated. The revision reclassified six vaccines from universal recommendation to risk-based or shared clinical decision-making categories.

Director O'Neill made the January 5 decision after consulting the NIH, the FDA, and experts across federal agencies. The United States recommended more childhood vaccines than any peer nation. AAP alleged in paragraph 34 of its complaint that the childhood immunization

schedule is "rigorously tested." The Institute of Medicine found the opposite in 2002 and again in 2013: the cumulative schedule has never been tested for safety. Ex. 5 (Jaffe Decl. ¶¶20-22; Exs. C, D).

No party cited the IOM reports.

The January 2026 revision recommended vaccination against eleven diseases for all children. Massachusetts, where AAP filed this case, requires immunization against nine diseases for grades K-6 and ten for older children. California requires ten. AAP called the revised eleven-vaccine schedule "a very dark day for children" but has never sued Massachusetts or California. Ex. 5 (Jaffe Decl. ¶8).

The court's stay of the January Memo restores universal COVID-19 recommendation for healthy children. No COVID-19 vaccine is approved or authorized for healthy children. AAP's own members had already stopped stocking the vaccine. Ex. 9 (¶¶13-16; Exs. G, H). The restored recommendation is enforced through a VFC mechanism that binds only physicians serving Medicaid children. AAP published its own 2026 immunization schedule with identical clinical recommendations to the 2025 edition and instructed its members to continue vaccinating as before. Ex. 11 (App. A, ¶¶67-79).

DOJ argued the schedule changes were entirely unreviewable, never presented the scientific basis for them, and never challenged "rigorously tested." The government lost on every issue.

Appellants moved to intervene on February 18, 2026. Ex. 3. They are two mothers whose children died under the prior schedule, two physicians whose licenses were revoked for questioning it, and Children's Health Defense. They filed three declarations and twenty exhibits

presenting the evidence no party would introduce: the IOM reports, the enforcement infrastructure, the FDA's determination on the COVID vaccine, and a 30-page set of Proposed Findings of Fact demonstrating the PI should have been denied on every Winter factor. Exs. 5, 9, 11.

The court denied intervention on February 27 in a one-sentence order with no analysis. Ex. 1. The court acknowledged Appellants' evidence in a single footnote of its PI opinion and dismissed it without adversarial testing. Ex. 2 at 41 n.75.

PROCEDURAL HISTORY

A. The Intervention Motion and Declarations

On February 18, 2026, Appellants moved to intervene as defendants and counterclaim plaintiffs under Rules 24(a)(2) and 24(b)(1)(B). Ex. 3. They are Andrea Shaw, whose fraternal twins died eight days after receiving their 18-month vaccines; Shanticia Nelson, whose daughter Sa'Niya Carter received twelve antigens in a single catch-up visit and died twelve hours later; Dr. Paul Thomas, whose license was suspended after publishing a vaccinated-versus-unvaccinated study; Dr. Kenneth Stoller, whose license was revoked for issuing exemptions beyond ACIP-recognized contraindications; and Children's Health Defense, co-plaintiff in Shaw v. AAP, No. 1:26-cv-00171 (D.D.C.).

The Jaffe Declaration (Ex. 5) presented evidence no party had introduced: the Institute of Medicine's 2002 and 2013 findings that the cumulative schedule has never been tested for safety, the enforcement infrastructure that converts recommendations into mandates, and international evidence on shared clinical decision-making. Ex. 5 (¶¶8, 20-23, 28-30).

A Supplemental Declaration (Ex. 9, filed Feb. 23) presented the COVID-specific record, including the Cardenas case: a pediatrician serving 1,900 Medicaid children who lost her practice and all patients for declining to administer the COVID vaccine to healthy children. The VFC program refused to process any of her vaccine orders because she would not order the COVID shot. Ex. 9 (¶¶3-5; Ex. F).

The Director of the FDA's Center for Biologics Evaluation and Research ("CBER") 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." Ex. 9 (¶¶11-13).

The Amicus Declaration (Ex. 11, filed Mar. 9) authenticated seven appendices, including a 30-page set of Proposed Findings of Fact and Conclusions of Law. Ex. 11 (App. A, ¶¶55-83).

B. The Oppositions, Reply, and Denial

The government opposed in 7 pages. It argued it shared the "same ultimate goal" as Appellants. Ex. 12 at 3.

AAP opposed in 22 pages filed by nine attorneys from Epstein Becker & Green. It argued this is "an APA process case, not a schedule safety case" and that Appellants' evidence was "irrelevant." Ex. 13 at 14.

Appellants' reply (Ex. 8) mapped AAP's own complaint paragraph by paragraph: "rigorously tested" (¶34), "serious illness and death" (¶2), 744 deaths from delayed hepatitis B (¶86(e)), 7,000 child hospitalizations and 152 deaths from COVID (¶98), "medically dangerous and ethically indefensible" (¶128).

Hours after the reply was filed on February 27, the court denied intervention in one sentence: "Motion denied. The proposed intervenors are welcome to file a brief as amici curiae." Ex. 1.

No analysis. No findings on any Rule 24 factor. The identical form language used for Jose Perez, a pro se individual, applied without modification to five represented intervenors with dead children, revoked licenses, and a pending RICO action.

C. The Amicus Brief and Proposed Findings

Appellants filed an amicus brief on March 9 with a third declaration (Ex. 11) authenticating seven appendices, including a 30-page alternative analysis of all four Winter factors. Ex. 11 (App. A, ¶¶55-83). The court did not cite the amicus brief, the Proposed Findings, or any appendix in its opinion.

D. The Court's PI Order

On March 16, the court granted the PI. Ex. 2. The opinion is relevant in five respects. First, the government lost on every issue it contested. The court rejected unreviewability, found the schedule changes arbitrary and capricious, and noted the only justification offered was compliance with a Presidential Memorandum. Ex. 2 at 20-22.

Second, AAP's "process case" characterization collapsed. The court's irreparable harm findings rested on substantive health consequences. Its balance of equities turned on public health outcomes. Ex. 2 at 35-44.

Third, the court acknowledged irreparable harm was "a close call" and reached its finding only by applying the sliding scale. Ex. 2 at 40 n.73. The court weighed AAP's harms against nothing because no party presented countervailing evidence.

Fourth, footnote 75 acknowledged Appellants' safety evidence and dismissed it in one sentence: "Children's Health Defense's proffered evidence does not demonstrate that the risks outweigh the broader benefits of the vaccines." Ex. 2 at 41 n.75. [3]

---

[3] The district court therein also declared the new ACIP members unqualified. The government mounted no meaningful defense of their credentials or the Secretary's policy judgment supporting their appointments. These Special Government Employees deserved better.

The Secretary's decision to reconstitute ACIP with experts drawn from outside the traditional vaccine-policy establishment was a deliberate high-level policy choice. It responded to the well-documented reality that the United States administers more routine childhood vaccines than any peer nation yet suffers the highest rates of chronic childhood illness among developed countries. Secretary Kennedy's explicit rationale, reflected in the Make America Healthy Again Commission materials and his public statements, was that the advisory apparatus had for decades been shaped by individuals and institutions with deep financial and professional ties to vaccine manufacturers, payers, and administrators, whose primary goal is to upsell vaccine.

The new members included Dr. Robert W. Malone, M.D., a molecular biologist and expert in vaccine biology; Dr. Retsef Levi, Ph.D., a professor of operations management at MIT Sloan School of Management whose career centers on risk analytics and healthcare decision-making models; and Dr. Catherine M. Stein, Ph.D., an epidemiologist and professor at Case Western Reserve University with more than two decades of research experience on infectious diseases. See HHS/CDC announcements of June–September 2025 appointments.

Dr. Levi's expertise in risk management directly addresses the very gap the Institute of Medicine identified twice (2002 and 2013) when it told CDC to study cumulative vaccine effects and vaccinated-versus-unvaccinated outcomes, the core risk-benefit analysis the old ACIP had never performed. Secretary Kennedy's inclusion on ACIP of an expert on risk management decision making in healthcare was much needed and long overdue.

Dr. Stein is an infectious disease epidemiologist with 115 peer-reviewed publications whose career has been devoted to studying why some individuals exposed to infectious disease get sick and others don't: identifying the genetic, environmental, and immunological risk factors that differentiate outcomes across populations. (Case Western Reserve University Faculty Profile, https://case.edu/medicine/pqhs/about/people/primary-faculty/catherine-m-stein-phd.) That is the analytical framework underlying what the field now calls adversomics: identifying which individuals are genetically susceptible to adverse outcomes from interventions applied universally. The cumulative childhood schedule was built without that expertise. The Secretary's appointment of Dr. Stein to ACIP was forward-thinking and long overdue. The district court stayed it.

Fifth, footnote 74 faulted the government for failing to "respond to Plaintiffs' and amici's evidence on the current risk to public health." Ex. 2 at 41 n.74. The government could not argue the schedule it endorsed for decades was unsafe. Nobody presented that response as a party.

THE EXCLUDED EVIDENCE DEMONSTRATES THE PI ORDER IS SUBSTANTIVELY FLAWED

A. The "Close Call" Was Decided on a One-Sided Record.

The court weighed AAP's harms against no countervailing evidence. The Shaw twins died eight days after their 18-month vaccines. Ex. 5, ¶12. Sa'Niya Carter received twelve antigens in one visit and died twelve hours later. The catch-up protocol has no upper limit on simultaneous vaccines and is part of the schedule Plaintiffs sought to restore. Ex. 5, ¶¶13, 24.

The Vaccine Injury Compensation Program has paid over $5 billion in awards. Ex. 8, 13.

The Proposed Findings demonstrated that every organizational injury AAP described is quantifiable in dollars and therefore not irreparable under *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). Ex. 11, App. A, ¶¶73-83.

AAP published an independent 2026 schedule with identical clinical recommendations to the 2025 edition and instructed its members to continue vaccinating as before. At a January webinar, AAP's Committee on Infectious Diseases chair told pediatricians: "You all create the trust with

---

The court implicitly credited general pediatricians and former ACIP members as qualified while declaring Dr. Malone unqualified to advise on vaccines. By that logic, the production-line workers who vaccinate chickens have more relevant experience than a molecular biologist who has studied vaccine biology for thirty plus years.

Dr. Malone resigned from ACIP on March 24, 2026, citing uncompensated labor, public hostility, and internal friction after the district court's order. His departure, and the unjustified and all but outrageous professional ridicule the new members endured, only underscore the cost of DOJ's failure to defend the Secretary's well-reasoned and long overdue changes to ACIP's composition.

the patient, not the federal government." A chapter VP told doctors to proceed as usual and not raise the CDC's changes unless parents asked. Ex. 11, App. A, ¶¶67-72; App. C.

The resources AAP spent after January 5 were advocacy expenditures: press releases, webinars, coordination with 230 organizations, public statements that the CDC was wrong. Not irreparable under *Charlesbank.*

The court's irreparable harm analysis contains a structural flaw. The court credited AAP's claim that the schedule changes impose uncompensated counseling time because parents now require reassurance about vaccine safety. But the stay cannot undo the public awareness the schedule revision created. The court's order changes what the CDC website says. It does not restore the parental trust the court found disrupted. An injury that persists with or without the injunction does not satisfy the irreparable harm requirement.

B. The Court Accepted "Rigorously Tested" Without Challenge.

AAP alleged in ¶34 of its complaint that vaccine safety is "rigorously tested." No party challenged the claim.

The IOM reports establish that it is false. The IOM found in 2002 that no study had compared health outcomes between fully vaccinated and unvaccinated children, and confirmed in 2013 that cumulative-effects studies had never been conducted. Ex. 5, Exs. C, D.
The Hoeg/Kulldorff Assessment acknowledges that "progress has been slow" and "only a few of the many studies that the IOM sought and deemed feasible have been conducted." Ex. 11, App. G.

C. The Court's Order Restores a COVID Recommendation the FDA Rejected and AAP's Members Had Abandoned.

The court's stay of the January Memo restores the entire pre-Kennedy schedule. That includes universal COVID-19 recommendation for healthy children, for whom no COVID vaccine is currently approved.

The CBER Director said the benefit-risk standard "is not met" for healthy children. The pre-Kennedy working group polled three-quarters in favor of ending universal recommendation. Ex. 11, App. D, E.

AAP's own members had already stopped stocking the vaccine. AAP's former committee chair told AAP News the VFC policy change "reflects the reality many pediatricians have not been stocking it for quite some time now, because the demand is low and the cost is high." Ex. 9, ¶¶15-16; Ex. H.

The court's order restores a recommendation that AAP's membership abandoned in practice, enforced through a VFC mechanism that binds only doctors serving Medicaid children. Dr. Cardenas lost her practice for exercising the clinical judgment that private-practice AAP members exercised without consequence. The order reimposes a two-tier system: informed consent for families who can afford private pediatricians, compelled compliance for Medicaid families who cannot. Ex. 9, ¶¶3-5, 9; Ex. F.

D. The Enforcement Infrastructure Makes Restoration Coercive.

The declarations demonstrate the schedule operates through a coercive infrastructure the court never examined. HEDIS metrics tie physician reimbursement to vaccination rates. Ex. 5, ¶28. Combination vaccines like Pediarix bundle antigens so a parent who declines one component receives all or none. Ex. 5, ¶29.

The Red Book classifies family history of adverse vaccine reactions as a "misperceived contraindication," directing providers to disregard it. Andrea Shaw warned her pediatrician about

a family history of adverse reactions; the pediatrician dismissed the warning consistent with this framework; both twins died eight days later. Ex. 5, ¶30.

Dr. Thomas published the vaccinated-versus-unvaccinated study the IOM had recommended since 2002 and lost his license. The ALJ in Dr. Stoller's case found "the standard of care for medical exemptions, as set forth in the ACIP guidelines adopted by CDPH, requires that exemptions be based on recognized contraindications." AAP attached these disciplinary records to its own opposition. The records confirmed the enforcement infrastructure in the boards' own words. Ex. 13, Exs. A-C.

STANDARD OF REVIEW

Denial of intervention as of right under Rule 24(a)(2) is reviewed de novo on the legal standard and for clear error on factual findings. *Conservation Law Found. v. Mosbacher*, 966 F.2d 39, 41 (1st Cir. 1992). Denial of permissive intervention under Rule 24(b) is reviewed for abuse of discretion. *Daggett v. Comm'n on Governmental Ethics & Election Pracs.*, 172 F.3d 104, 112 (1st Cir. 1999). A failure to exercise discretion is itself an abuse of discretion. *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990).

The court made no legal conclusions for de novo review.

It made no factual findings for clear error review.

It stated no discretionary findings reviewable for abuse.

This Court conducts both inquiries from scratch. The court's PI opinion (Ex. 2), issued 17 days after the denial, supplies the evidence that informs the analysis under these standards.

APPELLANTS ARE ENTITLED TO INTERVENTION AS OF RIGHT

The First Circuit applies a four-factor test: timeliness, interest, impairment, and inadequacy of representation. *Geiger v. Foley Hoag LLP*, 521 F.3d 60, 64-65 (1st Cir. 2008).

A. Neither opposition challenged timeliness.

The motion was filed before the PI ruling, before any party was prejudiced, and contemporaneously with the court's supplemental briefing deadline. *See Pub. Citizen v. Liggett Grp., Inc.*, 858 F.2d 775, 785 (1st Cir. 1988).

B. Interest.

Andrea Shaw's twins died under the schedule Plaintiffs seek to restore. Shanticia Nelson's daughter died under the same schedule. Both mothers are plaintiffs in a pending RICO action whose claims are directly prejudiced by a judicial finding that the schedule was safe.

Drs. Thomas and Stoller lost their medical licenses for deviating from the ACIP schedule; restoration means their individualized clinical approach once again constitutes professional misconduct under the enforcement frameworks that destroyed their practices.

CHD competes with AAP in the market for vaccine-related health information and is a co-plaintiff in the Shaw action. Ex. 4 at 3-5.

AAP argued these interests are "undifferentiated" and "generalized" under *Public Service Co. v. Patch*, 136 F.3d 197, 205 (1st Cir. 1998). Ex. 13 at 8-10. The ratepayers in *Public Service Co.* shared a speculative interest in lower electric rates identical to every consumer in New Hampshire; the benefit was "anybody's guess." 136 F.3d at 205-06.

Andrea Shaw's twins are dead. Sa'Niya Carter is dead. Dr. Thomas's and Dr. Stoller's licenses are gone. None of that is speculative.

The standing asymmetry is telling. The court accepted organizational standing at the pleading stage without requiring individual standing analysis for Plaintiffs' Jane Does, whose claimed injuries include sleeplessness, tooth-grinding, and difficulty accessing pharmacies. It then denied intervention in one sentence to two mothers whose children died and two physicians

whose licenses were revoked, without a word of analysis as to whether those injuries satisfied Rule 24(a)(2)'s interest requirement.[4]

AAP's opposition below devoted seven pages to the argument that Proposed Intervenors lack Article III standing. Ex. 13 at 2-7. The argument misconceives the posture. *Town of Chester, N.Y. v. Laroe Estates, Inc.*, 581 U.S. 433, 439 (2017), holds that "an intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests."

The operative phrase is "additional relief." Appellants sought to intervene as defendants to oppose the preliminary injunction. Defendants do not invoke federal jurisdiction. Plaintiffs did. Resisting the exercise of jurisdiction is not the same as invoking it. Even if the counterclaims require independent standing under *Town of Chester*, the remedy is to sever or defer the counterclaims, not to deny defensive intervention altogether. The court made no distinction between the defensive and affirmative postures.

AAP's reliance on *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), fails for a separate reason. The physicians in *Hippocratic Medicine* never prescribed the drug at issue. Their claimed injury depended on a speculative chain of third-party actions. Here the causal

[4] The court's finding of organizational standing is independently suspect. AAP's claimed resource diversion consisted of publishing the Red Book 2026 with identical recommendations, instructing members to continue vaccinating as before, and spending resources on press releases and webinars opposing the government's policy. Ex. 10 at 11-13; Ex. 11 (App. A, ¶¶73-79). That is issue-advocacy, not operational disruption. Under *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367, 394-95 (2024), organizational standing requires the challenged action to have "directly affected and interfered with" the organization's "core business activities." AAP still recommends the same vaccines. The schedule change created a policy divergence AAP chose to publicize; it did not interfere with AAP's core activity. Appellants request that this Court revisit the lower court's standing determinations and dismiss this case.

chain is direct. The schedule was administered to identified children. Those children died. Plaintiffs ask this Court to restore the same schedule.

C. Impairment.

The PI order (Ex. 2) confirms impairment. The court restored the pre-Kennedy schedule on the basis of AAP's unchallenged representation that it was "rigorously tested." That finding will be cited as judicial endorsement in the Shaw RICO proceeding. Separate litigation cannot vacate a factual finding entered here.

D. Inadequacy of Representation.

Trbovich v. United Mine Workers, 404 U.S. 528, 538 n.10 (1972), requires only that representation "may be" inadequate.

The government lost on every issue it contested and never introduced the evidence that would have mattered: the IOM reports, the unchallenged "rigorously tested" claim. The government's own opposition to intervention (Ex. 12) characterized this as sharing the "same ultimate goal" as Appellants. *PhRMA v. Commissioner*, 201 F.R.D. 12, 14-15 (D. Me. 2001), holds that "only an extreme failure to present obvious arguments constitutes inadequate representation." The government's performance satisfies that standard.

The government cannot argue that the protocol it endorsed for a generation caused harm to identifiable children. And the government is actively litigating against two Appellants in *Thomas v. Bhattacharya* (D.D.C.), where DOJ seeks dismissal of the very claims Appellants seek to protect here.

Appellants' amicus brief (Ex. 10) also presented the argument that Plaintiffs proved 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, without notice-and-comment rulemaking. Every addition for sixty years occurred through the process Plaintiffs now call unlawful. Plaintiffs cannot invoke procedural requirements against revisions that never applied to adoption.

ALTERNATIVELY, THE DISTRICT COURT ABUSED ITS DISCRETION IN DENYING PERMISSIVE INTERVENTION

Permissive intervention under Rule 24(b)(1)(B) requires that the applicant's claim or defense share "a common question of law or fact" with the main action and that intervention will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(1)(B), (b)(3).

Appellants' defenses address schedule safety, a question AAP's own complaint raised through dozens of substantive allegations.

Intervention would cause no delay. Appellants accepted the court's existing schedule and filed opposition papers simultaneously with the intervention motion. Ex. 7. The defensive posture requires no additional discovery and imposes no burden on any party.

AAP argued the Lanham Act counterclaims would cause delay by opening discovery into the Red Book. Ex. 13 at 19. That concern relates only to the counterclaims, not to defensive intervention. The court could have granted intervention on the defense side while deferring the counterclaims to a separate schedule. It denied everything in one sentence without distinguishing between the defensive and affirmative postures. *Cooter & Gell*, 496 U.S. at 405.

The amicus invitation proved inadequate. The court did not cite the amicus brief (Ex. 10) or the Proposed Findings (Ex. 11, App. A). It dismissed the underlying evidence in footnote 75

without adversarial testing. An amicus cannot present witnesses, cross-examine declarants, respond at oral argument or file motions.

IRREPARABLE HARM FROM CONTINUED EXCLUSION

If the stay proceedings go forward without Appellants, this Court inherits the same one-sided record that produced the flawed analysis below.

Party status granted after the stay proceedings have concluded serves no purpose. The moment to participate is now.

THE BALANCE OF EQUITIES AND PUBLIC INTEREST FAVOR RELIEF

No party is prejudiced by intervention.

The court found irreparable harm on a "close call" after weighing AAP's evidence against nothing. Ex. 2 at 40 n.73. Footnote 74 faulted the government for failing to respond to evidence of public health risk. Ex. 2 at 41 n.74. Appellants would have responded.

The 1986 National Childhood Vaccine Injury Act requires biennial reports to Congress on vaccine safety. 42 U.S.C. § 300aa-27(c). HHS has not submitted a single report since 1998. Ex. 5 (Jaffe Decl. ¶25).

During that silence, the schedule expanded from eleven diseases to eighteen.

That schedule was never cumulatively tested, the FDA has rejected it for healthy children with respect to COVID-19, and identified children died under it. Fifteen states examined the same actions and declined preliminary relief. *Arizona v. Kennedy*, No. 3:26-cv-01609-VC (N.D. Cal.). The public interest is not served by restoring a schedule without hearing from the families whose children died under it and the physicians who lost their licenses for questioning it.

APPELLATE JURISDICTION

Appellants have appealed the denial of intervention. That denial is immediately appealable as a collateral order.

Appellants also seek review of the preliminary injunction. The two orders are inextricably intertwined. The PI was entered on a one-sided record that resulted directly from the exclusion of Appellants.

Pendent appellate jurisdiction is appropriate where the resolution of a collateral appeal necessarily implicates a pendent order. *Swint v. Chambers County Comm'n*, 514 U.S. 35, 51 (1995); *Hunt v. Massi*, 773 F.3d 361, 371 (1st Cir. 2014).

The government has not yet appealed the preliminary injunction.

If this Court declines pendent jurisdiction, the PI is unreviewable.

FRAP 8(a)(1)(C) independently authorizes this Court to suspend an injunction while an appeal is pending.

REQUESTED SCHEDULE

This matter may require the attention of the Supreme Court. The October Term 2025 ends in late June 2026. An emergency application to the Circuit Justice requires adequate time for briefing and consideration before the term concludes.

The federal government's vaccine apparatus remains shut down for every day this litigation is pending.

Appellants request the Court to issue an order directing a response to this Motion and a reply such that this Court resolve this motion within twenty-one days of filing to preserve the possibility of further review during the Supreme Court's current term.

CONCLUSION

What Plaintiffs obtained below is a federal court order restoring a recommendation that exceeds what every state requires for school entry. AAP called the revised eleven-vaccine schedule "a very dark day for children" but has never sued Massachusetts or California for requiring ten.

Whether the federal government recommends immunization against 18, 17, or 11 diseases, AAP's 67,000 members will still have to upsell families on these additional vaccines, as they have done in the past.

Most of the industrial world uses the shared decision-making model AAP calls dangerous, and those countries vaccinate at equal or higher rates.

AAP is already conducting its vaccine promotion campaign through the Red Book, 230 endorsing organizations, 24 states, webinars, and press releases.
Preliminary injunctions are not instruments for campaigns the market and the states have rejected.

The families who buried their children under the schedule AAP wants restored were denied a seat at the table in a one-sentence order without a word of analysis.

Appellants respectfully request that this Court:

(a) Reverse the court's February 27, 2026 order (Ex. 1) and remand with instructions to grant intervention under Rule 24(a)(2); or, in the alternative,

(b) Grant provisional party status pending appeal with leave to participate in any stay proceedings;

(c) Set an expedited briefing schedule for this appeal; and

(d) Stay the lower court's preliminary injunction pending the disposition of this appeal; and

(e) Stay proceedings in the district court pending this Court's determination of whether Organizational Plaintiffs maintain Article III standing on the developed evidentiary record, a question the district court acknowledged (Ex. 2 at 11 n.26) but did not analyze.

Dated: April 4, 2026

Respectfully submitted,

/s/ Richard Jaffe
Richard Jaffe
428 J Street, 4th Floor
Sacramento, California 95814
Tel: 916-492-6038
rickjaffeesq@gmail.com

Jed Rubenfeld
1031 Forest Rd.
New Haven CT 06515
203-432-7631
jed.rubenfeld@yale.edu

Robert N. Meltzer,
The Mountain States Law Group
Wheelhouse at the Bradford Mill
33 Bradford Street
Concord, Massachusetts 01742
Tel: (978) 254-6289
inbox@mountainstateslawgroup.com

Counsel for Appellants

CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rules of Appellate Procedure 27(d)(2)(A) and 32(g)(1), counsel certifies that this motion complies with the type-volume limitation because it contains **5,184 words**, excluding the items exempted by Rule 32(f).

This motion complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it was prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman.

Dated: April 4, 2026

/s/ Richard Jaffe
Richard Jaffe
Lead Counsel for Appellants

CERTIFICATE OF SERVICE

I hereby certify that on April 4 , 2026, I caused the foregoing Appellants' Emergency Motion Under FRAP 8 for Relief Pending Appeal, together with the Appendix of Exhibits (Volumes I and II), to be served on the following counsel of record by electronic mail and Federal Express:

James J. Oh
Kathleen Barrett
EPSTEIN BECKER & GREEN, P.C.
227 W. Monroe Street, Suite 4500
Chicago, IL 60606
Tel: (312) 499-1400
joh@ebglaw.com
kbarrett@ebglaw.com

Richard H. Hughes IV
EPSTEIN BECKER & GREEN, P.C., Washington, DC
rhhughes@ebglaw.com (email only)

Elizabeth J. McEvoy
Gianna M. Costello
EPSTEIN BECKER & GREEN, P.C., Boston, MA
emcevoy@ebglaw.com (email only)
gcostello@ebglaw.com (email only)

Counsel for Plaintiffs-Appellees

James W. Harlow
Acting Assistant Director
Isaac C. Belfer
Trial Attorney
Federal Programs Branch, Civil Division
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
Tel: (202) 305-7134
Isaac.C.Belfer@usdoj.gov

Counsel for Defendants

Dated: April 4, 2026

/s/ Richard Jaffe
Richard Jaffe
Lead Counsel for Appellants

EXHIBIT 2

United States Court of Appeals
For the First Circuit

No. 26-1325

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

Plaintiffs - Appellees,

v.

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

Defendants,

ANDREA SHAW; SHANTICIA NELSON; DR. PAUL THOMAS; DR. KENNETH STOLLER; CHILDRENS HEALTH DEFENSE,

Movants - Appellants.

Before

Barron, Chief Judge,
Aframe and Dunlap, Circuit Judges.

ORDER OF COURT

Entered: April 9, 2026

Movants-Appellants have filed an "Emergency Motion Under FRAP 8(a)(2)(A)(ii), For Relief Pending Appeal." Per Federal Rule of Appellate Procedure 8(a)(1)(A), such a motion should

be filed in the district court in the first instance. Accordingly, the motion is denied, without prejudice to movants-appellants' pursuit of relief in the district court in the first instance.

By the Court:

Anastasia Dubrovsky, Clerk

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