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,

and

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

Intervenor-Defendants/Counterclaim Plaintiffs.

AMERICAN ACADEMY OF PEDIATRICS, MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, and INFECTIOUS DISEASES SOCIETY OF AMERICA,

Counterclaim Defendants

INTERVENOR-DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Plaintiffs filed fifty-three declarations in support of their preliminary injunction motion. Not one is from a parent whose child was harmed by the schedule Plaintiffs seek to restore. Not one addresses the Institute of Medicine's finding that the cumulative childhood immunization schedule has never been tested for safety. Not one acknowledges that the catch-up protocol under which children like Sa'Niya Carter received six injections containing twelve antigens in a single visit has no upper limit on simultaneous vaccine loading. These omissions are not accidental.

They are structural. Plaintiffs cannot acknowledge what the IOM found because doing so would undermine the foundational claim on which their entire case rests: that the schedule was "rigorously tested."

It was not. The IOM said so. Twice.

In 2002, the Institute of Medicine found that no study had compared health outcomes between children who received the full schedule and those who did not, and recommended such studies be conducted using the Vaccine Safety Datalink. IOM, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (2002), at 14–15, 107–08. In 2013, the IOM returned to the question and found the studies had not been conducted: "studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." IOM, *The Childhood Immunization Schedule and Safety* (2013), at 6. Neither Plaintiffs nor Defendants have cited these reports in their filings. This Court should have them.

The government's forty-five-page opposition defends the Secretary's authority to revise the schedule. It does not argue that the schedule needed revising. It cannot. The moment the government argues the prior schedule was substantively unsafe, it admits its own agencies endorsed an unsafe protocol for decades. Intervenors fill the gap neither party can fill: the evidence that the childhood immunization schedule Plaintiffs want restored was never cumulatively tested for safety, that AAP's foundational safety claims are unsupported by empirical evidence, and that restoring the prior schedule would cause concrete, irreparable harm to identified families who buried their children under that protocol.

Intervenor Andrea Shaw's fraternal twins Dallas and Tyson died on May 1, 2025, eight days after receiving their 18-month vaccines. She had warned the pediatrician about a family

history of adverse reactions. The pediatrician dismissed the warning consistent with AAP's contraindications framework. Intervenor Shanticia Nelson's daughter Sa'Niya Carter died on March 27, 2025, less than twelve hours after receiving twelve antigens in a single catch-up visit. She was ill at the time. Her mother expressed concern. Clinic staff told her it was safe per AAP guidelines.

Plaintiffs ask this Court to restore the system that produced these outcomes. Intervenors ask the Court to weigh both sides of the equation before it does.

STATEMENT OF INTEREST

Intervenors' Motion to Intervene, filed contemporaneously herewith, sets forth the full basis for intervention under Federal Rule of Civil Procedure 24. This Statement of Interest summarizes the unique perspective Intervenors bring to the preliminary injunction analysis.

Intervenors include two mothers whose children died after receiving vaccines administered pursuant to the schedule Plaintiffs seek to restore; two physicians whose medical licenses were suspended or revoked for questioning the schedule's safety; and a nonprofit organization that competes directly with AAP in the market for vaccine-related health information.

Andrea Shaw and Shanticia Nelson are parties in *Shaw v. American Academy of Pediatrics*, No. 1:26-cv-00171 (D.D.C.), a pending RICO action alleging that AAP made material misrepresentations about the safety of the childhood immunization schedule. Dr. Paul Thomas and Dr. Kenneth Stoller are parties in *Thomas v. Monarez*, No. 1:25-cv-02685 (D.D.C.), challenging CDC's failure to conduct the cumulative safety studies the IOM recommended.

The factual allegations in those proceedings—which are attached to the Declaration of Richard Jaffe as Exhibits A and B—are directly relevant to this Court's preliminary injunction

analysis. They address the safety of the schedule Plaintiffs seek to restore, the enforcement mechanisms through which it was maintained, and the concrete harms it inflicted on the families and physicians who are now before this Court.

The government's opposition confirms the inadequacy of existing party representation. In forty-five pages of briefing, Defendants never argue that the prior schedule needed revising, never cite the IOM reports, never identify a child harmed under the prior protocol, and never challenge AAP's foundational claim in Paragraph 34 of the Fourth Amended Complaint that vaccine safety is "rigorously tested." Defendants defend the Secretary's *right* to act. They do not defend the *reasons* for acting. Intervenors provide the substantive case that no existing party can or will make.

ARGUMENT

I. Plaintiffs Have Not Demonstrated Irreparable Harm

A preliminary injunction requires a "clear showing" of irreparable harm. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). "Irreparable harm must be grounded on something more than conjecture, surmise, or a party's unsubstantiated fears." *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004). Plaintiffs have not carried this burden.

A. Plaintiffs' Harms Are Self-Inflicted

Plaintiffs characterize the January 2026 schedule revision as "dangerous," "a very dark day for children," and predict that it will cause "more disease, more infection, more hospitalizations." PI Mem. 1, 43–44. The revised schedule recommends eleven vaccines for all children. Massachusetts—the state in which this Court sits—requires vaccines for only nine diseases for grades K–6 and ten for grades 7–12. California, with the strictest vaccine mandate in

the nation (having eliminated all personal belief exemptions in 2015), requires only ten. Cal. Health & Safety Code § 120335(b)(1)–(10).

If recommending eleven vaccines is "dangerous" and will cause "more disease, more infection, more hospitalizations," then California's ten-disease mandate and Massachusetts' nine-disease mandate are even more dangerous. Yet AAP has never called California's schedule dangerous. AAP has never sued Massachusetts. AAP has never told Massachusetts parents to "ignore everything" from the Massachusetts Department of Public Health. AAP's alarm is reserved exclusively for the federal government's decision to align its recommendations with the range already in place across multiple states.

Moreover, Plaintiffs' resource diversion claims are the product of their own decision to publish a competing schedule. After the January 5 schedule change, AAP published its own "AAP Harmonized Schedule" directing its 67,000 member pediatricians to follow AAP's version rather than CDC's. AAP cannot simultaneously argue in this Court that only the federal government has authority to set the immunization schedule and then publish a private competing schedule instructing physicians to ignore the government's version. If the schedule is a federal prerogative, AAP has no business publishing a competing one. If private organizations may set their own schedules, the government's decision to change its schedule is an exercise of the same prerogative AAP claims for itself.

The resources AAP claims to have "diverted"—publishing guidance, updating the Red Book, answering member inquiries, issuing press statements—are not diversions from AAP's mission. They *are* AAP's mission. As the government's opposition correctly observes, AAP's mission is to attain "well-being and health for children" through "publication of policies on a broad range of topics." ECF No. 232 at 40. See *FDA v. All. for Hippocratic Med.*, 602 U.S. 367,

394–95 (2024) (an organization "cannot manufacture its own standing" by spending resources on "public advocacy and public education").

B. Fifty-Three Form Letters

Plaintiffs filed fifty-three declarations. They are substantially identical. The final paragraphs of nearly every physician declaration contain the same language—verbatim—about "compounding" harms, the GRADE and EtR frameworks, and clinical practice being pushed "toward a breaking point absent immediate injunctive relief." Several declarations contain the same copy-paste error: "follow established the GRADE" rather than "follow the established GRADE." The declarants practice in different states, treat different populations, and work in different clinical settings. They use the same sentences, down to the same typographical errors. These are not independent accounts of irreparable harm. They are a form letter with a signature line.

Stripped of the boilerplate, the fifty-three declarations reduce to four claims: (1) I have to talk to parents about vaccines and I cannot bill for the time; (2) my combination vaccine inventory is unusable because the products cannot be unbundled; (3) my quality scores dropped because the metrics measure compliance, not care; and (4) I relied on the GRADE framework and now must exercise independent clinical judgment. None of these constitutes irreparable harm. The first three are economic injuries—compensable in damages and therefore not irreparable. *Charlesbank Equity Fund II*, 370 F.3d at 162. The fourth is a confession that the prior system eliminated the need for clinical thinking.

These are economic injuries caused by a shift away from a coercive business model, not irreparable injuries to public health.

C. The Predetermined Outcome

Even the conversations these physicians claim to be having under SCDM are not informed consent. They are scripted advocacy for a predetermined outcome. Dr. Boyce describes his SCDM practice as "briefly discussing the benefits of a vaccine that I recommend the patient receive and risks of not being vaccinated." ECF No. 185-30, ¶ 10. Not risks of the vaccine—risks of declining it. Dr. Andreae states under oath that "there is only one medically reasonable option consistent with the standard of care, and that would be to vaccinate all children." ECF No. 185-32, ¶ 14. Dr. Shaw describes pediatricians as "foot soldiers who can rely on the researched recommendations and findings of the ACIP." ECF No. 185-33, ¶ 8. The answer to every parental question is the same: vaccinate. Every concern is misinformation to be corrected. Every hesitation is an obstacle to the only acceptable outcome.

The physician who told Andrea Shaw to disregard her family history of adverse reactions was following this framework. The clinic staff who told Shanticia Nelson it was safe to vaccinate her sick daughter were following this framework. AAP's contraindications list is so narrow that virtually no child qualifies for an exception—and family history of adverse reactions is expressly classified as a "misperceived contraindication" to be overridden, not respected. These declarations do not describe physicians prepared to exercise individualized clinical judgment. They describe a coordinated network of practitioners dependent on a federal framework that—as the IOM found—never tested the cumulative safety of the schedule they are being paid to enforce.

Not one of the fifty-three declarations is from a parent. Not one identifies a child harmed by the schedule change. Not one addresses the Institute of Medicine's finding that the cumulative schedule was never tested for safety. Not one acknowledges that the catch-up protocol under which Sa'Niya Carter received twelve antigens in a single visit has no upper limit. Plaintiffs ask

this Court to restore a system in which the answer was always vaccinate, the parent never got to say no, and the physician was a foot soldier who did not ask questions. Intervenors ask the Court to recognize that system for what it was—and what it cost their families.

II. The Balance of Equities Favors Intervenors

A. Dead Children Versus Diverted Resources

The balance of equities requires the Court to weigh competing harms. Plaintiffs' declarations describe institutional disruption: diverted resources, confused providers, supply chain headaches, reduced quality scores. The three individual plaintiffs—Jane Does 1, 2, and 3—describe losing sleep, stress-induced tooth-grinding, and gasoline expenses from driving to pharmacies. ECF Nos. 185-49, 185-50, 185-53.

Intervenors describe dead children.

Andrea Shaw's fraternal twins Dallas and Tyson both died on May 1, 2025, eight days after receiving their 18-month vaccines, including Hepatitis A, influenza, and DTaP. Mrs. Shaw and her mother-in-law had warned the pediatrician about a family history of adverse reactions to the flu vaccine. The pediatrician dismissed these concerns consistent with AAP's Red Book, which classifies family history of adverse vaccine reactions as a "misperceived contraindication"—meaning a factor that providers and parents may believe warrants caution but that AAP's framework directs them to disregard. The emergency room physician diagnosed a post-immunization reaction (ICD-10 code T88.1XXA) the following morning. Both twins continued to deteriorate and died. Rather than investigating the documented post-immunization reaction, prosecutors opened a homicide investigation against the mother. *Shaw* Compl. ¶¶ 16–21.

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 of the appointment. Ms. Nelson expressed concern about vaccinating her daughter while she was unwell. Clinic staff told her it was safe per AAP guidelines. Sa'Niya experienced seizures and cardiac arrest. The coroner found a swollen brain consistent with encephalitis—a recognized DTaP Table Injury under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-14. The death certificate listed the cause as Sudden Unexplained Death in Childhood. *Shaw* Compl. ¶¶ 22–27.

The Court must weigh both sides of this equation. Three individuals who had difficulty finding a pharmacy against families who buried their children. Sleeplessness against death. Tooth-grinding against a coroner's report. Gasoline expenses against three funerals. The balance is not close.

B. The Schedule Plaintiffs Seek to Restore Was Never Tested for Safety

Plaintiffs' entire case rests on Paragraph 34 of the Fourth Amended Complaint, which states: "The safety of a vaccine is rigorously tested before receiving FDA authorization. Work Groups of the ACIP thoroughly examine the safety data before the ACIP votes on a vaccine's recommended use. The safety of a vaccine is continually monitored after listed on a CDC schedule."

This paragraph conflates two fundamentally different propositions: (a) that individual vaccines undergo pre-licensure testing, and (b) that the cumulative childhood immunization schedule—the protocol as actually administered to American children, involving dozens of simultaneous and sequential vaccinations—has been tested for safety. Proposition (a) is generally true, though many individual vaccines were licensed without true saline placebo controls.

Proposition (b) is false. The IOM said so twice, and neither party in this case has cited the IOM reports.

This distinction matters for the preliminary injunction analysis because Plaintiffs ask the Court to restore a specific protocol—not merely individual vaccine approvals, but the schedule as administered. A child receiving the full schedule by age two receives vaccines targeting up to fourteen diseases, involving multiple simultaneous injections at single well-child visits. No clinical trial has ever tested this cumulative protocol. The 2013 IOM report specifically found that "key elements of the entire schedule—the number, frequency, timing, order, and age at administration of vaccines—have not been systematically examined in research studies." IOM, *The Childhood Immunization Schedule and Safety* (2013), at 5–6.

AAP's leading vaccine expert, Dr. Paul A. Offit, published the foundational justification for unlimited vaccine loading: a theoretical calculation that infants could respond to 10,000 vaccines at once. Offit PA, et al., "Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?" *Pediatrics* 2002;109(1):124–129. This was an immunological abstraction about B-cell epitope capacity—not a clinical safety study. It said nothing about cumulative aluminum dose, mercury toxicokinetics, synergistic adjuvant effects, neuroinflammation, or autoimmune activation. It has never been empirically validated. And it was published in AAP's own journal.

When the IOM recommended in 2002 that CDC study cumulative schedule safety using the Vaccine Safety Datalink, Dr. Offit argued it would be "unethical" to conduct such studies because they would require withholding vaccines from children. The IOM never recommended withholding vaccines. It recommended database analysis of existing health records—a methodology that requires no change in clinical practice. By conflating database analysis with

randomized trials, AAP's expert made an easy study sound impossible and an ethical study sound unethical. Twenty-four years later, the study has not been conducted.

A court of equity should not restore a protocol promoted through this kind of misdirection without examining whether the protocol was ever proven safe. It was not.

C. The Catch-Up Schedule: No Upper Limit

Neither the CDC's catch-up immunization schedule nor AAP's Red Book imposes any upper limit on the number of vaccines that may be administered simultaneously. The CDC's General Best Practice Guidelines state: "As a general rule, almost all vaccines can be administered at the same visit." The Red Book confirms that "[i]nfants and children have sufficient immunologic capacity to respond to multiple vaccine antigens administered at the same time." AAP Committee on Infectious Diseases, *Red Book: 2024–2027 Report of the Committee on Infectious Diseases* at 63 (33d ed. 2024).

Sa'Niya Carter received six injections containing at least twelve antigens in a single catch-up visit. She died twelve hours later. The catch-up protocol that killed her is part of the schedule Plaintiffs seek to restore.

By contrast, the Department of Defense limits healthy adults to five vaccines in one sitting. The U.S. Marine Corps Officer Candidates School Pre-Ship Preparation Letter for Class 251 states: "Medical restrictions prevent officer candidates from receiving more than five immunizations over a short period of time." U.S. Marine Corps, Officer Candidates Class 251 Pre-Ship Preparation Letter § 13(a)(2) (Nov. 12, 2025).

Adults healthy enough to become Marine officers are subject to protections that AAP deems unnecessary for newborns. The military studied cumulative vaccine effects after the Gulf War and found a five-fold increase in chronic illness among soldiers who received multiple

vaccinations during deployment. Hotopf M, et al., *BMJ* 2000;320:1363–67. The military implemented restrictions in response. Infants with immature immune systems face no limit whatsoever—because AAP's theoretical calculation declared their immune systems could handle 10,000.

This is not a policy disagreement. This is the absence of a basic safety parameter in the protocol Plaintiffs ask this Court to restore by judicial order.

III. The Public Interest Favors Hearing From Affected Families

Plaintiffs devote substantial briefing to the public interest in maintaining vaccination rates. PI Mem. 46–51. Intervenors do not dispute that vaccination serves public health. They dispute the premise that restoring the prior schedule—without examining whether it was safe as administered—serves the public interest.

Shared clinical decision-making is not a radical experiment. It is the international norm. Seventeen European Union nations, the United Kingdom, and Japan have no mandatory childhood vaccination requirements. They use voluntary recommendation programs—the functional equivalent of SCDM—and achieve coverage rates that equal or exceed those of the United States: Sweden 97%, Denmark 95%, Japan 98%. *Thomas* Compl. ¶¶ 54–59. SCDM does not mean no vaccination. It means what most of the developed world already does: recommend rather than require.

The 1986 National Childhood Vaccine Injury Act requires the Secretary of Health and Human Services to submit biennial reports to Congress on efforts to improve vaccine safety, including adverse event data and research progress. 42 U.S.C. § 300aa-27(c). HHS disbanded the task force responsible for these reports in 1998 and has not submitted a single report in twenty-seven years. During that twenty-seven-year silence, the childhood immunization schedule grew

from eleven recommended diseases to eighteen. Plaintiffs ask this Court to restore a schedule that expanded without the congressional safety oversight that the 1986 Act required.

The public interest is not served by restoring a schedule that was never cumulatively tested for safety, that expanded without congressionally mandated oversight, and that produces outcomes like those experienced by the Shaw and Nelson families—over the objection of the families who lived under it.

IV. Plaintiffs' Proposed Injunction Is Overbroad

Intervenors adopt Defendants' overbreadth arguments. ECF No. 232 at 43–45. Intervenors add one further point: Paragraph 3 of the Proposed Order would block all future ACIP meetings. This is an unprecedented prior restraint on government deliberation. FACA requires that advisory committee meetings be open to the public. 5 U.S.C. § 1009(a). An order prohibiting ACIP from meeting would prevent the government from receiving advice on vaccine policy, prevent the public from observing and participating in those deliberations, and violate the very transparency that FACA was enacted to ensure.

Plaintiffs cannot have it both ways. They cannot argue that FACA requires transparent, public advisory committee proceedings and simultaneously ask this Court to prohibit all such proceedings from occurring. If ACIP's composition is the problem, the remedy is to correct the composition—not to shut down the committee entirely.

Moreover, if this Court is being asked to restore a vaccination schedule that affects millions of American children, the families on the receiving end of that schedule are indispensable parties under Federal Rule of Civil Procedure 19. Before this intervention, the Court was being asked to adjudicate the propriety of the childhood immunization schedule without hearing from a single family affected by it.

CONCLUSION

The Court is being asked to reimpose a vaccination schedule that neither party has examined on the merits. Plaintiffs assert that the prior schedule was "rigorously tested" without acknowledging the two IOM reports that found the opposite. Defendants defend the authority to revise the schedule without explaining why revision was warranted. Neither party has cited the IOM findings. Neither party has identified a single child harmed by the schedule Plaintiffs seek to restore.

Andrea Shaw lost twin sons eight days after vaccination. Shanticia Nelson lost a daughter twelve hours after receiving twelve antigens in a single catch-up visit. Dr. Thomas and Dr. Stoller lost their medical licenses for questioning the schedule's safety. Children's Health Defense has spent two decades advocating for the studies the IOM recommended and that were never conducted.

If this Court grants the preliminary injunction and restores the prior schedule without hearing from these Intervenors, it will reimpose on American children a vaccination protocol that the Institute of Medicine found has never been tested for safety—over the objection of the families who buried their children under that protocol.

For these reasons, the Court should deny Plaintiffs' Motion for Preliminary Injunction.

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Dated: February 18, 2026

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[PROPOSED] ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

Upon consideration of Plaintiffs' Motion for a Preliminary Injunction, Defendants' Opposition thereto, Intervenor-Defendants' Opposition thereto, the Declaration of Richard Jaffe with Exhibits A through E, all supporting and opposing papers, and the arguments of counsel, the Court finds as follows:

1. Plaintiffs have not demonstrated a likelihood of success on the merits.

2. Plaintiffs have not demonstrated that they will suffer irreparable harm absent injunctive relief.

3. The balance of equities does not tip in Plaintiffs' favor.

4. The public interest does not favor the issuance of a preliminary injunction.

Accordingly, it is hereby **ORDERED** that Plaintiffs' Motion for a Preliminary Injunction is DENIED.

SO ORDERED.

Dated: _____

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HONORABLE BRIAN E. MURPHY

United States District Judge