UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, et al.,
Plaintiffs,
v.
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.
v.
AMERICAN ACADEMY OF PEDIATRICS, MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, and INFECTIOUS DISEASES SOCIETY OF AMERICA,
Counterclaim Defendants

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

EMERGENCY MOTION OF CHILDREN'S HEALTH DEFENSE, ANDREA SHAW, SHANTICIA NELSON, DR. PAUL THOMAS, AND DR. KENNETH STOLLER TO INTERVENE AS DEFENDANTS AND COUNTERCLAIM PLAINTIFFS

Proposed Intervenor-Defendants Children's Health Defense ("CHD"), Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (collectively, "Proposed Intervenors") respectfully and on an emergency basis move this Court for leave to intervene as defendants/counterclaim plaintiffs in this action pursuant to Fed. R. Civ. P. 24(a)(2), or in the alternative, Fed. R. Civ. P. 24(b)(1)(B), and to file the accompanying Proposed Answer to the Fourth Amended Complaint with Affirmative Defenses and Counterclaims, and their Opposition to Plaintiffs' Motion for a Preliminary Injunction.

In support of this Motion, Proposed Intervenors submit the following documents filed simultaneously herewith: (1) Memorandum of Law in Support of Emergency Motion to Intervene, (2) Declaration of Richard Jaffe, Esq. (with Exhibits A through E), (3) Proposed

Answer to the Fourth Amended Complaint with Affirmative Defenses and Counterclaims, (4) Proposed Order Granting Intervention, (5) Intervenors' Opposition to the Preliminary Injunction Motion, (6) Proposed Order Denying Preliminary Injunction.

CERTIFICATION OF EMERGENCY

Proposed Intervenors certify that this motion requires emergency consideration for the following reasons:

1. At its February 13, 2026, hearing, the Court granted Plaintiffs' Motion to File a Fourth Amended Complaint. At the same hearing, the Court heard argument on the first part of Plaintiffs' Preliminary Injunction Motion and took the motion under advisement. Per the clerk's notation, the Court ordered the defendants to file a supplemental opposition to Plaintiffs' supplemental declarations by 5:00 p.m. on February 18, 2026, and ordered counsel to file additional briefing regarding the legal consequence of the January guidance no later than the same date. The Court's ruling on the Preliminary Injunction motion appears to be imminent after it reviews the additional filings.

2. The ACIP meeting that Plaintiffs seek to enjoin is scheduled for February 25–26, 2026. Plaintiffs seek to restore the prior vaccination schedule before that meeting occurs. If the Court rules without hearing from Proposed Intervenors, it will do so on a record in which no party has presented: the Institute of Medicine's findings that the cumulative childhood immunization schedule has never been tested for safety; the families whose children died under the schedule Plaintiffs seek to restore; or the physicians who lost their licenses for questioning it.

3. This motion is filed contemporaneously with the deadline the Court set for the parties' supplemental submission. Proposed Intervenors have made every effort to file at the earliest

opportunity after learning the scope and posture of the Court's inquiry from the February 13 hearing. No party will be prejudiced by considering this motion now; all parties and the public will be prejudiced if the Court rules on an incomplete record.

4. Absent emergency consideration, the Court may restore a vaccination schedule under which the Shaw twins and Sa'Niya Carter died, that the IOM found has never been tested, and that two physicians lost their licenses for questioning—all without hearing from a single affected family or any physician who can speak to what the schedule does to children. A family whose child is injured under a judicially restored schedule cannot be unvaccinated. The harm is irreversible.

GROUNDS FOR INTERVENTION

5. Proposed Intervenors are entitled to intervene as of right under Fed. R. Civ. P. 24(a)(2). The motion is timely—it is filed before the Court has ruled on the preliminary injunction and before any existing party is prejudiced. Proposed Intervenors have direct, concrete interests in this action: their children died under the schedule Plaintiffs seek to restore; their medical licenses were revoked for practicing the individualized medicine the government's new SCDM policy now permits; and they are parties to a pending RICO action against AAP whose outcome will be directly affected by this Court's PI ruling. These interests will be impaired if the Court rules without their evidence. And no existing party adequately represents these interests.

6. The government's defense is procedural. In forty-five pages of opposition briefing, the government argues that the Secretary had the authority to revise the schedule. It does not argue the schedule needed revising. It does not present the IOM's findings. It does not challenge AAP's claim that the schedule was "rigorously tested." It does not identify a single child harmed. The government defends its right to act. It does not—and institutionally cannot—defend the

reasons for acting. The moment the government argues the prior schedule was substantively unsafe, it admits its own agencies endorsed an unsafe protocol for decades.

7. This case is readily distinguishable from the Court's denial of Jose Perez's motion to intervene. Mr. Perez was pro se, did not confer with opposing counsel, filed procedurally deficient papers, and asserted only diffuse constitutional interests indistinguishable from those of any citizen. Proposed Intervenors are represented by experienced federal litigation counsel who serves as counsel of record in three related federal proceedings. They assert concrete interests—dead children, revoked licenses, pending RICO litigation—that no existing party represents. They offer evidence the government has not and cannot present: the IOM reports, the state-by-state comparison, the enforcement architecture that Plaintiffs' own declarations unwittingly expose. Their Proposed Answer with Affirmative Defenses and Counterclaims is filed simultaneously with this Motion.

8. In the alternative, intervention is appropriate under Fed. R. Civ. P. 24(b)(1)(B). Proposed Intervenors' defenses and counterclaims share common questions of law and fact with the main action—principally, whether the childhood immunization schedule is evidence-based and safe. Intervention will not delay proceedings. Proposed Intervenors accept the Court's existing schedule and will not seek continuances.

EVIDENCE BEFORE THE COURT

9. Proposed Intervenors present evidence that transforms the factual landscape of this case and that bears directly on three of the four preliminary injunction factors:

The schedule has never been tested. The Institute of Medicine found in 2002 and again in 2013 that the cumulative childhood immunization schedule—the protocol as actually administered to American children, involving dozens of simultaneous and sequential

vaccinations—has never been tested for safety. Paragraph 34 of the Fourth Amended Complaint states that vaccine safety is "rigorously tested." The IOM said otherwise, twice. Neither Plaintiffs nor Defendants have cited these reports. They are attached to the Jaffe Declaration as Exhibits C and D.

Plaintiffs' alarm is pretextual. AAP calls the new schedule of 11 recommended vaccines "a very dark day for children." Massachusetts—where Plaintiffs chose to file—requires only 9 vaccines for grades K–6 and 10 for grades 7–12. California requires 10. AAP has never sued Massachusetts. AAP has never sued California. AAP has never called either state's schedule dangerous. If 11 is a "very dark day," then California's 10 and Massachusetts' 9 are darker still. Yet children in both states are healthy and vaccination rates exceed 95%.

Plaintiffs' own declarations are confessions. Every physician declaration filed in support of the preliminary injunction describes an enforcement infrastructure—HEDIS metrics tying reimbursement to compliance rates, combination vaccines that cannot be unbundled, "unbillable time" for informed consent counseling—that reveals a coercive system, not a public health program. What Plaintiffs characterize as harms from SCDM are the withdrawal symptoms of a system that never required the informed consent conversation in the first place.

The balance of irreparable harms weighs against restoration. Plaintiffs' Jane Does lost sleep, ground their teeth, and spent gasoline driving to pharmacies. Proposed Intervenors' families buried their children. The balance of irreparable harms weighs against restoration, not for it.

RELIEF REQUESTED

10. Proposed Intervenors respectfully request that this Court:

(a) Grant this Motion to Intervene and accept the accompanying Proposed Answer to the Fourth Amended Complaint with Affirmative Defenses and Counterclaims.

(b). Accept and consider Intervenors' Opposition paper to the Preliminary Injunction Motion.

(c) Consider the evidence presented in the Declaration of Richard Jaffe and its Exhibits before ruling on Plaintiffs' motion for a preliminary injunction; and

(d) Set an expedited briefing schedule for any opposition to this Motion, given the Court's stated need to decide the preliminary injunction on a tight timeline.

CERTIFICATION OF CONFERRAL

Pursuant to L.R., D. Mass. 7.1(a)(2), undersigned counsel certifies that he had a lengthy zoom call with Plaintiffs' counsel James Ho and his partner. Plaintiffs oppose this motion, and request to respond to the motion within the 14-day time set out in the local rules. Plaintiffs will file a notice of intent to respond. Movants have no objection, except if it forecloses the Court's consideration of the facts and arguments related herein in its decision on the first Part of the pending preliminary injunction motion. In that case, Movant request the Court order a preliminary response to allow for the Court to consider the facts and arguments set forth herein on the pending motion or grant oral argument at the Court's earliest convenience. I contacted the government's lead counsel yesterday afternoon, left a detailed voicemail but haven't heard back as of the time of filing.

ORAL ARGUMENT

Intervenors' counsel can appear for oral argument on this motion at the Court's earliest convenience, with five hours advance notice. However, given the obvious tight schedule for the

first part of this Preliminary Injunction hearing, we waive oral argument, unless the Court's schedule permits, it is determined that oral argument will assist in its deliberations, or as stated above, to serve as Plaintiffs' response to this motion within the time frame of the Court's impending decision.

Dated: February 18, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the date indicated above, I caused the foregoing Emergency Motion to Intervene, Memorandum of Law in Support of Emergency Motion to Intervene, Intervenor-Defendants' Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction, Proposed Answer to the Fourth Amended Complaint with Affirmative Defenses and Counterclaims, Declaration of Richard Jaffe with Exhibits A through E, Proposed Order

Granting Intervention, Proposed Order Denying Preliminary Injunction to be filed electronically through the Court's CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Robert N. Meltzer

Robert N. Meltzer

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Counterclaim Defendants

PROPOSED ANSWER TO FOURTH AMENDED COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS OF INTERVENOR-DEFENDANTS/COUNTERCLAIM PLAINTIFFS

Intervenor-Defendants/Counterclaim Plaintiffs Children's Health Defense ("CHD"), Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (collectively, "Intervenors"), by and through undersigned counsel, respectfully submit this Answer to the Fourth Amended Complaint ("4AC") filed by Plaintiffs American Academy of Pediatrics, et al.

("Plaintiffs" or "AAP"), together with Affirmative Defenses and Counterclaims, and state as follows:

PRELIMINARY STATEMENT

1. None of the original parties to this case (or amici) speak for the children who have been injured or who have died from the vaccines which the Plaintiff trade and other public health organizations promote. The intervenors/counterclaim plaintiffs include two mothers who allowed their children to receive multiple vaccinations based on plaintiff American Academy of Pediatrics combination vaccine guidelines. Their decision and those guidelines resulted in the deaths of three children.

2. Plaintiffs are seven trade organizations representing physicians who administer and profit from vaccinating children, public health organizations, a trade group representing infectious disease specialists, and three unnamed pregnant women who wish to take the COVID-19 vaccine three years after the end of the pandemic and who are alleged to have experienced difficulty accessing this vaccine.

3. Defendants are government officials defending executive prerogative. In forty-five pages of opposition briefing, Defendants never argue that restoring the prior schedule would harm anyone. Defendants defend the Secretary's right to change the schedule. They do not argue the schedule should be changed, because doing so would constitute an admission against the government's own prior conduct in endorsing the schedule for decades.

4. Intervenors fill the gap that neither side can fill. Children's Health Defense is a nonprofit organization that publishes books on vaccine safety and children's health, produces daily news content through The Defender, operates a streaming platform (CHD.TV), and

conducts educational seminars and events—all addressing vaccine safety and informed consent. CHD's mission is directly impeded by the relief Plaintiffs seek. Perhaps most importantly, CHD's media give a voice to families like Intervenor Andrea Shaw who lost her fraternal twins eight days after their 18-month vaccinations, and Intervenor Shanticia Nelson who lost her daughter twelve hours after a single catch-up vaccination visit during which twelve antigens were administered. As described below, according to Plaintiff AAP's vaccine guidelines, it was perfectly appropriate to give Intervenor Nelson's infant daughter six shots and 12 antigens in a single visit shortly after her first birthday. A healthy adult Marine officer candidate would never have been given more than five immunizations at one time.

5. Dr. Paul Thomas and Dr. Kenneth Stoller lost their medical licenses for questioning the schedule's safety. If the prior schedule is restored, the clinical approach of prioritizing their patients' health and right to informed consent—the approach for which both physicians lost their licenses—will once again constitute professional misconduct.

6. What Intervenors bring to this case is what no existing party will provide: the evidence that the childhood immunization schedule Plaintiffs want restored was never cumulatively tested for safety, despite the Institute of Medicine's repeated requests for such studies; that Plaintiffs' own foundational safety claims are unsupported by empirical evidence; and that restoring the prior schedule would cause concrete, irreparable harm to Intervenors and the families they represent.

7. The factual allegations in this Answer are drawn from the Complaint filed in *Shaw v. American Academy of Pediatrics*, No. 1:26-cv-00171 (D.D.C.), in which CHD and individual plaintiffs have brought claims under the Racketeer Influenced and Corrupt

Organizations Act against AAP for the same pattern of conduct described herein, and *Thomas v. Monarez*, No. 1:25-cv-02685 (D.D.C.), wherein the relief requested is that all childhood vaccines be moved from Category A, "Recommended" to Category B, "shared clinical decision-making," primarily on the grounds that it is arbitrary and capricious for the CDC to recommend a combination vaccine schedule where the incontrovertible fact is that the schedule itself has never been safety tested or shown to provide more benefit than harm.

ANSWER TO FOURTH AMENDED COMPLAINT

Introduction (¶¶ 1–23)

8. Intervenors admit that this action challenges certain actions taken by the Department of Health and Human Services and the Centers for Disease Control and Prevention regarding the Advisory Committee on Immunization Practices and the childhood immunization schedule. Intervenors deny that such actions are unlawful.

9. Intervenors admit the procedural history described in ¶¶ 2–7 to the extent it is consistent with the Court's docket. To the extent these paragraphs characterize the challenged actions as unlawful, arbitrary, or capricious, Intervenors deny those characterizations.

10. Intervenors admit that the Court has entered certain orders as described in ¶ 8. Intervenors deny that these orders establish the merits of Plaintiffs' claims.

11. Intervenors admit that AAP describes itself as "the nation's premier professional organization for pediatric medicine" with approximately 67,000 members. Intervenors further state that AAP generates $115–125 million in annual revenue; that AAP's commercial publications include the Red Book, sold for $175, which AAP markets as "the authoritative guide" to pediatric infectious disease; and that AAP's financial

interests are directly tied to the vaccination schedule through administration fees, quality bonuses, and pay-for-performance metrics tied to schedule compliance. AAP's characterization of itself as a purely scientific organization omits these material financial interests.

12. Intervenors admit that ACP is a professional organization as described in ¶ 10. Intervenors deny that ACP's organizational interests in this litigation are representative of the public interest.

13. Intervenors admit the general descriptions of APHA, IDSA, SMFM, MPHA, and MCAAP in ¶¶ 11–15. Intervenors note that these are trade and professional organizations representing the interests of their physician and public health professional members—not the interests of the families and children who receive vaccines, families of children who have been injured or who have died from these vaccines.

14. Intervenors do not have the knowledge or information to admit or deny the allegations concerning Plaintiffs Jane Does 1, 2, and 3, but deny that these Plaintiffs' alleged difficulties obtaining the vaccine constitute irreparable harm sufficient to justify the extraordinary remedy of a preliminary injunction. Intervenors further state that Intervenor Andrea Shaw's fraternal twins died eight days after receiving their 18-month vaccines, and Intervenor Shanticia Nelson's daughter died twelve hours after a catch-up visit in which twelve antigens were administered. The Court must weigh both sides of this equation: three individuals who allegedly had difficulty finding a pharmacy against families who buried their children who received multiple doses of vaccines per the schedule promoted by AAP and endorsed by the other Plaintiff organizations.

15. Intervenors admit the general descriptions of the Defendants as government officials and agencies in ¶¶ 19–23. For the reasons set forth in this pleading, Intervenors deny that the Defendants can adequately represent the interests of Intervenors and the families similarly situated to the individual Intervenors. Defendants' institutional interests in defending executive authority are distinct from Intervenors' interests in protecting the health and safety of their children.

Factual Allegations: The ACIP Process (¶¶ 24–36)

16. Intervenors admit the general historical description of ACIP's creation and procedural framework in ¶¶ 24–33. Intervenors note that nothing in this history addresses whether the cumulative childhood immunization schedule—the protocol as actually administered to American children—has ever been tested for safety. The GRADE framework, the EtR framework, and the Work Group process described in these paragraphs all evaluate individual vaccines in isolation. None evaluates the cumulative effect of administering multiple vaccines simultaneously or in rapid sequence to infants and children, which is the protocol Plaintiffs seek to restore.

17. Response to ¶ 34: Denied as materially misleading. Paragraph 34 is the load-bearing factual allegation of Plaintiffs' entire case. It 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."

18. 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.

19. In 2002, the Institute of Medicine found that no study had ever compared health outcomes between children who received the full schedule and those who did not, and recommended such studies be conducted using existing data in the Vaccine Safety Datalink ("VSD"). IOM, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (2002), at 14–15, 107–08. The IOM specifically identified the VSD—a database containing health records for millions of children—as the tool for conducting these studies without withholding vaccines from anyone.

20. In 2013, the IOM returned to this issue and found that the recommended studies had not been conducted. The IOM concluded that "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: Stakeholder Concerns, Scientific Evidence, and Future Studies* (2013), at 6.

21. As of this filing, twenty-four years after the IOM's first recommendation, no cumulative schedule safety study has been conducted. The VSD data exists. The filing cabinet remains unopened.

22. Plaintiff AAP's foremost vaccine expert, Dr. Paul A. Offit, was lead author of the foundational article published in AAP's journal *Pediatrics* claiming that infants could "theoretically" 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 a theoretical calculation about B-cell epitope

capacity that answered an immunological question no parent was asking, while ignoring the toxicological and clinical safety questions parents were asking—including cumulative aluminum dose, mercury toxicokinetics, synergistic adjuvant effects, neuroinflammation, and autoimmune activation. The 10,000 vaccines claim has never been empirically validated. It substituted theory for testing and has been deployed for twenty-four years to block the studies the IOM recommended, and the theoretical basis for why children like Intervenors Shaw and Nelson receive so many vaccines at one time.

23. Paragraph 34's claim that vaccine safety is "rigorously tested" is the equivalent of claiming that because each ingredient in a recipe has been individually tasted, the finished dish has been tested. It has not. The IOM said so twice. AAP knows this because its own committee members participated in the IOM reviews.

24. Intervenors admit the general description of the CDC Director's role in approving ACIP recommendations in ¶ 35. Intervenors deny any implication that this process has resulted in a cumulatively tested immunization schedule.

25. Intervenors admit that individual vaccines undergo clinical trials before licensure as described in ¶ 36, but deny that all such trials span years. Intervenors deny that this testing establishes the safety of the cumulative schedule as administered, or that it is safe to receive the dozen antigens which Intervenor Nelson's daughter received in one "well-child" visit. A child receiving the full schedule by age two receives vaccines targeting up to 14 diseases, involving multiple simultaneous injections at single well-child visits. No clinical trial has ever tested this cumulative protocol.

The Challenged Actions (¶¶ 37–70)

26. Intervenors admit that on January 5, 2026, Acting CDC Director Jim O'Neill signed a decision memorandum revising the childhood immunization schedule as described in ¶¶ 37–46. Intervenors deny that this action was arbitrary, capricious, or unsupported by evidence. The HHS scientific assessment found that the United States was "a global outlier" in recommended vaccine doses, yet "does not have higher vaccination rates" than peer nations relying on recommendation-only models. Seventeen EU member states, the United Kingdom, and Japan use such models while maintaining vaccination rates exceeding 90%.

27. Intervenors admit that the Secretary issued directives regarding COVID-19 vaccine recommendations as described in ¶¶ 47–53. Intervenors deny that these directives were arbitrary or unsupported. Intervenors further state that the COVID-19 vaccine was recommended for pregnant women despite pregnant women being excluded from the Pfizer and Moderna pivotal trials. The recommendation was made based on theoretical benefit and observational data, not randomized controlled trials in the target population.

28. Intervenors lack knowledge or information sufficient to form a belief about whether specific ACIP appointments comply with the ACIP Charter's requirements as alleged in ¶¶ 54–61 and therefore deny the same. Intervenors note, however, that Plaintiffs' characterization of new ACIP members as "anti-vaccine" (¶ 78) is belied by the members' actual voting records. At the September 2025 meeting, ACIP members voted in favor of COVID-19 SCDM, thimerosal-free flu vaccines, and Hepatitis B SCDM—all votes that accepted the vaccines while introducing individualized clinical judgment. Voting for informed consent is not "anti-vaccine."

29. Response to ¶¶ 62–70 (The Assessment): Intervenors deny that the HHS Assessment was scientifically unsound. Plaintiffs' primary criticism is the Denmark comparison (¶¶ 62–69). Plaintiffs themselves cite Martin Kulldorff's contribution to the IOM 2013 report to argue that country comparisons are "very difficult to do well" (¶ 69 n.34). But this citation opens a door Plaintiffs cannot close: the very IOM report Plaintiffs cite concluded that "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 2013 at 6. Plaintiffs invoke the IOM's methodological caution about country comparisons while ignoring the IOM's central finding that the schedule they want restored has never been tested.

30. Moreover, Plaintiffs' characterization of the new schedule as "dangerous" is contradicted by their own silence about state schedules that are less comprehensive. California law requires vaccines for only 10 diseases for school entry. Cal. Health & Safety Code § 120335(b)(1)–(10). California eliminated all personal belief exemptions in 2015, creating the strictest vaccine mandate in the nation. The new CDC schedule recommends 11 vaccines—one more than California mandates. Massachusetts, where Plaintiffs chose to file this action, requires vaccines for only 9 diseases for grades K–6 and 10 for grades 7–12.

31. If recommending 11 vaccines is "dangerous," "a very dark day for children," and will cause "more disease, more infection, more hospitalizations," then California's 10-disease mandate and Massachusetts' 9-disease mandate are even more dangerous. Yet AAP has never called California's schedule dangerous, never sued Massachusetts, never told Massachusetts parents to "ignore everything" from the Massachusetts Department of

Public Health. The only variable that changes between a "safe" 10-disease state mandate and a "dangerous" 11-disease federal recommendation is revenue: under SCDM, physicians must discuss rather than simply administer, the bundled well-child visit becomes less efficient, and pay-for-performance metrics become harder to achieve.

ACIP Member Allegations (¶¶ 71–83)

32. Intervenors deny the characterization of ACIP members as unqualified or "anti-vaxxer" in ¶¶ 71–78. Plaintiffs' standard for "qualification" appears to be agreement with AAP's position that the cumulative schedule has been rigorously tested—a standard that excludes anyone who has read the IOM reports.

33. Intervenors lack knowledge or information sufficient to form a belief about the specific procedural requirements for ACIP member appointments as alleged in ¶¶ 79–83 and therefore deny the same. Intervenors note that Plaintiffs' characterization of the Secretary's statement—"we need to stop trusting the experts"—omits the broader point that scientific questions should be resolved by evidence, not authority. This is the position the IOM took when it recommended that the cumulative schedule be studied rather than assumed safe.

Three ACIP Meetings (¶¶ 84–100)

34. Intervenors admit that ACIP held three meetings in 2025 at which members and presenters made various statements about vaccine safety. Intervenors deny that all such statements were "false or misleading." Plaintiffs' "correction" regarding Hepatitis B trials (¶ 85) states that "there have been more than 15 studies of Hep B vaccines, including randomized control studies." This is partially responsive to the individual vaccine

question (ignoring fundamental flaws with a number of HepB vaccine studies) but completely ignores the cumulative schedule question. No study has ever tested the safety of administering the Hepatitis B birth dose in combination with the other vaccines an infant receives in the first months of life.

35. The United Kingdom, Canada, and seventeen EU member states delay the Hepatitis B birth dose without infection surges or increased liver cancers, directly contradicting AAP President Susan Kressly's claim that the ACIP Hepatitis B decision would cause "99,000 preventable hepatitis B infections" and "devastating results." Kressly's projections derive from unpublished models, not observed outcomes from the many industrialized nations that have implemented exactly the policy ACIP adopted.

Counts I–IV (¶¶ 101–183)

36. Intervenors deny that the January 5 Action alleged in Count I (¶¶ 101–115) was arbitrary, capricious, or contrary to law. The Action moved six vaccines from universal recommendation to shared clinical decision-making—a framework that preserves access to all vaccines, as well as insurance coverage, while introducing individualized physician-patient discussion. This is not the elimination of vaccines. It is the introduction of informed consent.

37. Intervenors lack knowledge or information sufficient to form a belief about the FACA compliance of ACIP appointments alleged in Count II (¶¶ 116–133) and therefore deny the same. Intervenors deny, however, that seeking candidates outside the traditional AAP-industry nomination pipeline constitutes "inappropriate influence." (Supp. Ex. A, Zuckerman Decl.) To the contrary, FACA's "fair balance" requirement, 5 U.S.C. App. § 5(b)(2), exists precisely to prevent the kind of single-viewpoint advisory committee that

AAP maintained for decades — a committee whose members were drawn from AAP's own liaison network, shared AAP's foundational assumption that the schedule was "rigorously tested," and never recommended the studies the IOM identified as necessary. The Zuckerman declaration does not describe corruption of the appointment process. It describes the end of a captured appointment process.

38. Intervenors deny that the three challenged ACIP votes alleged in Count III (¶¶ 134–154) were arbitrary, capricious, or contrary to law. The Hepatitis B vote aligned with practices in the UK and Canada. The COVID-19 SCDM vote recognized limitations in the evidence base. The thimerosal vote reflected decades of concern about mercury exposure in infant vaccines.

39. Intervenors deny that the Secretarial Directive alleged in Count IV (¶¶ 155–183) was arbitrary, capricious, or contrary to law. The Directive removed the routine COVID-19 recommendation for children—a population which faced minimal COVID-19 mortality risk.

Standing and Harm Allegations

40. Intervenors deny that ACIP deliberations constitute "misinformation" as alleged in ¶ 119. AAP's own foundational safety claim—that the cumulative schedule has been rigorously tested—is contradicted by the IOM's findings. AAP cannot credibly accuse others of spreading misinformation when its own published claims misrepresent the state of scientific evidence.

41. Intervenors do not have knowledge or information to admit or deny whether Jane Does 1, 2, and 3 experienced the difficulties described in ¶¶ 121–123. Jane Doe 1's claimed injuries include losing sleep and headaches from difficulty finding a COVID-19 vaccine.

Jane Doe 2's claimed injuries include stress-induced tooth-grinding and gasoline expenses from driving to pharmacies. Jane Doe 3's son had an anxiety attack about a rescheduled appointment. These claimed injuries, even if true, must be weighed against the injuries of Intervenors: Andrea Shaw buried twin sons. Shanticia Nelson buried a daughter. Sleeplessness against death. Tooth-grinding against a coroner's report. Gasoline expenses against three funerals.

The Physician Declarations: Confessions Dressed as Complaints

42. Every declaration Plaintiffs filed in support of their motion is a confession dressed as a complaint. The physician who cannot bill for a counseling session is admitting she never had the conversation before. The practice that must discard $847 combination vaccines is admitting it stocked products designed to make the full schedule administratively mandatory. The specialist who cannot meet quality benchmarks under SCDM is admitting her compensation was tied to administering vaccines without individualized clinical discussion. The infectious disease expert who protests the abandonment of the GRADE framework is admitting that the framework was designed to evaluate individual vaccines in isolation — making it structurally incapable of asking the cumulative safety question the IOM told everyone to ask twenty-four years ago. These declarants are not describing injuries inflicted by the government; they are describing dependencies created by the prior system — and their disruption is the strongest evidence that the system operated exactly as Intervenors' Counterclaims allege.

43. Fifty-Three Form Letters. Before examining the substance of these confessions, the Court should know how they were assembled. Plaintiffs filed fifty-three declarations in support

of their preliminary injunction motion. 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 the confessions described below.

44. The "Unbillable Time" Confession. Several physician declarants complain that SCDM requires 10–20 minutes of counseling per vaccine conversation, time that current reimbursement codes do not cover. (Ex. 46, Srinivas Decl.; Ex. 38, Wheeler Decl.) This is an admission that under the prior schedule, these conversations were not happening. The prior framework treated vaccination as a ministerial act — check the box, administer the dose, bill the visit — not as a medical decision requiring physician judgment and true informed patient consent. The "unbillable time" these physicians now face is the time required for informed consent. If informed consent is too expensive to provide, the problem is not SCDM. The problem is a reimbursement structure built on the assumption that consent was unnecessary. Plaintiffs ask this Court to restore that assumption. Intervenors ask the Court to recognize it for what it is: compelled speech enforced through economic architecture.

45. The Combination Vaccine Confession. Plaintiffs' declarants report that the schedule change renders existing combination vaccine inventory — products like VAXELIS and PEDIARIX, valued at up to $847 per dose — unusable, because these products bundle multiple antigens that cannot be administered separately. (Ex. 43, Bornstein Decl.; Ex. 31, Berman Decl.) This is not a harm caused by the challenged actions. It is a harm caused by product architecture that was designed to make the full schedule administratively mandatory. A hexavalent vaccine cannot be unbundled. A physician who stocks VAXELIS must administer all six antigens or none. The product does not permit clinical judgment about individual components. When Plaintiffs complain about "wasted" inventory, they are describing a supply chain engineered to prevent exactly the kind of individualized assessment SCDM introduces. The waste is a feature of an assembly line approach to vaccines which abnegates the rule of individual clinical judgment and informed consent.

46. The Quality Metric Confession. Physician declarants report that SCDM makes it impossible to meet HEDIS vaccination quality measures and pay-for-performance targets tied to schedule compliance rates. (Ex. 46, Srinivas Decl.) This admission maps the compensation-side enforcement mechanism that complements the medical-board-side enforcement alleged in Intervenors' Counterclaims. Under the prior system, physicians were financially rewarded for achieving target vaccination rates — rates defined by AAP's schedule, adopted by insurers, and measured by metrics that treated any deviation as a quality failure. A physician who spent twenty minutes discussing vaccine risks with a concerned parent and ultimately respected the parent's decision to defer one vaccine was penalized twice: once in unbillable time, once in a missed quality target. The

performance metric did not measure quality of care. It measured compliance with AAP's protocol. When these physicians complain that SCDM disrupts their quality scores, they are admitting that the scores measured obedience, not medicine focused on the individual patient.

47. The VFC and Pharmacy Access Confession. Plaintiffs and their amici argue that moving vaccines to SCDM will disconnect them from the Vaccines for Children program and from pharmacy administration, because pharmacies stock only "routine" vaccines and VFC funds only CDC-recommended vaccines. (Ex. 31, Berman Decl.; Ex. 27, Kressly Decl.) This argument maps the supply-chain enforcement mechanism. VFC conditions federal funding on following the CDC schedule. Pharmacies stock what VFC covers. Practices order what pharmacies stock. Parents receive what practices order. No actor in this chain exercises independent clinical judgment — each follows the signal from the level above, and the signal originates with AAP's recommendations, laundered through CDC adoption, and funded by federal appropriation. When Plaintiffs complain that SCDM disrupts this pipeline, they are not describing a public health harm. They are describing a vertically integrated distribution system in which every participant's financial incentive points in the same direction: administer the full schedule, do not ask questions, do not deviate.

48. The GRADE Framework Confession. Plaintiffs' physician declarants — including specialists in infectious disease and pediatric medicine — protest that the reconstituted ACIP abandoned the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) and EtR (Evidence-to-Recommendations) frameworks that governed prior ACIP deliberations. (Ex. 36, Pavia Decl.; Ex. 30, Boyce Decl.; Ex. 35, Goldman

Decl.) GRADE is a systematic methodology for evaluating individual interventions against individual clinical endpoints using randomized controlled trial data. It is a rigorous tool — for the question it was designed to answer. But the IOM did not ask ACIP to evaluate individual vaccines. The IOM asked ACIP to evaluate the cumulative schedule — the protocol as actually administered. GRADE has no methodology for this question. It cannot evaluate a protocol that was never tested as a protocol. It evaluates components, not systems. When these declarants insist that GRADE must govern ACIP deliberations, they are insisting on a framework that is structurally incapable of asking the question the IOM identified as the central unresolved safety issue in American pediatric medicine. GRADE suppresses the cumulative safety question by design — because the question falls outside its analytical architecture. The declarants' protest that GRADE was abandoned is an admission that the tool used to foreclose the IOM's recommendation was finally set aside.

49. The Predetermined Outcome Confession. 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 framework that never tested the cumulative safety of the schedule they were paid to enforce.

50. Intervenors are grateful for the candor of Plaintiffs' declarants. Their declarations, intended to demonstrate irreparable harm, instead constitute the most detailed evidentiary record ever assembled of the enforcement mechanisms through which AAP's untested schedule was maintained for two decades. No discovery could have produced what Plaintiffs volunteered.

51. Intervenors admit that several Northeastern states formed a cooperative to issue joint vaccine recommendations as described in ¶ 124. Intervenors note that this cooperative's adoption of AAP's schedule, under the Brentwood delegation mechanism documented by the Association of State and Territorial Health Officials, transforms AAP's private recommendations into state-enforceable standards—the very state action that gives rise to the compelled speech and listener's rights injuries alleged in Intervenors' Counterclaims.

52. Intervenors deny that the challenged actions "injected mistrust" into the physician-patient relationship as alleged in ¶ 125. The SCDM framework enhances that relationship by

requiring physicians to engage in genuine informed consent. The prior schedule—which Plaintiffs seek to restore—is what injected mistrust: physicians were compelled to deliver safety assurances that the IOM had found to be unsupported, and families who questioned those assurances were dismissed, ostracized, or expelled from practices.

Proposed Remedy

53. Intervenors oppose the Proposed Order's request to restore the prior schedule. Restoring the prior schedule would reimpose on American children a cumulative vaccination protocol that the IOM found has never been tested for safety. It would subject Intervenor Shaw's and Intervenor Nelson's surviving family members to the same protocol under which their children died. It would compel physicians who have adopted SCDM conversations to return to AAP's compelled script.

54. Intervenors oppose the Proposed Order's request to block all ACIP meetings as unconstitutional. The First Amendment protects the government's right to seek and receive information. FACA requires that advisory committees meet publicly. An order blocking all ACIP meetings would prevent HHS from deliberating on vaccine policy entirely.

55. Intervenors further note that AAP's request for judicial restoration of the prior schedule is belied by AAP's own conduct. After the January 5 schedule change, AAP did not merely file this lawsuit. AAP published its own competing immunization schedule — the "AAP Harmonized Schedule" — directing its 67,000 member pediatricians to follow AAP's version rather than the 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. AAP's Harmonized Schedule is not a scientific document. It is a commercial product distributed through the same channels — the Red Book, HealthyChildren.org, state chapter networks — that Intervenors' Counterclaims identify as the distribution infrastructure of the enterprise.

AFFIRMATIVE DEFENSES

First Affirmative Defense: Unclean Hands

56. Plaintiffs seek equitable relief to restore a schedule they promoted through material misrepresentations. AAP represented the cumulative childhood immunization schedule as "rigorously tested" and safe when no cumulative safety study exists. AAP's foundational expert published the 10,000 vaccines claim as a substitute for empirical testing. AAP blocked the studies the IOM recommended. AAP's Committee on Infectious Diseases published a clinical report claiming the IOM "strongly affirmed" the schedule's safety while omitting the IOM's central finding that the cumulative schedule had never been studied. A court of equity should not restore a protocol promoted through misrepresentation.

Second Affirmative Defense: No Irreparable Harm / Self-Inflicted Harm

57. Plaintiffs' claimed harms are self-inflicted consequences of their own decision to maintain recommendations inconsistent with the evolving scientific evidence. AAP has never sued California (10 diseases), Massachusetts (9–10 diseases), or any state whose

schedule is less comprehensive than the new CDC schedule (11 diseases). Plaintiffs' resource diversion is the result of their own decision to publish a competing schedule and oppose federal health policy, not of any unlawful government action.

Third Affirmative Defense: Overbreadth of Requested Relief

58. The relief Plaintiffs seek is grossly overbroad. Paragraph 3 of the Proposed Order would block all future ACIP meetings—an unprecedented prior restraint on government deliberation that violates the First Amendment and FACA's public meeting requirements. Paragraph 1 would restore a schedule that no court has ever been asked to mandate by judicial decree.

Fourth Affirmative Defense: Failure to Join Indispensable Parties

59. If the 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. Prior to 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.

COUNTERCLAIMS

Intervenor-Defendants/Counterclaim Plaintiffs Children's Health Defense, Andrea Shaw, Shanticia Nelson, Dr. Paul Thomas, and Dr. Kenneth Stoller (collectively, "Counterclaim Plaintiffs"), assert the following Counterclaims against Counterclaim Defendants American Academy of Pediatrics, Massachusetts Chapter of the American Academy of Pediatrics, and Infectious Diseases Society of America (collectively, "Counterclaim Defendants"):

PARTIES TO THE COUNTERCLAIMS

Counterclaim Plaintiffs

60. Counterclaim Plaintiff Children's Health Defense ("CHD") is a nonprofit organization headquartered in Franklin Lakes, New Jersey. CHD publishes books on vaccine safety and children's health, produces daily news content through The Defender, operates a streaming platform (CHD.TV), and conducts educational seminars and live events. CHD competes directly with AAP in the market for vaccine-related health information directed at healthcare providers and families. CHD sues on its own behalf and in its associational capacity on behalf of its members whose children are subject to the childhood immunization schedule.

61. Counterclaim Plaintiff Andrea Shaw is the mother of fraternal twins Dallas and Tyson Shaw, who both 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 consistent with AAP's contraindications framework, which classifies family history as a "misperceived contraindication." Shaw Compl. ¶¶ 16–21.

62. Counterclaim Plaintiff Shanticia Nelson is the mother of Sa'Niya Carter, who 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. Ms. Nelson expressed concern. Clinic staff told her it was safe per AAP guidelines. The coroner found a swollen brain consistent with encephalitis—a recognized DTaP Table Injury—but listed the cause of death as Sudden Unexplained Death in Childhood. Shaw Compl. ¶¶ 22–27.

63. Counterclaim Plaintiff Dr. Paul Thomas is a board-certified pediatrician in Oregon. Dr. Thomas published a peer-reviewed vaccinated-versus-unvaccinated study—the type of

comparative analysis the IOM recommended in 2002. His medical license was suspended shortly after publication. Thomas Compl. ¶¶ 12–13.

64. Counterclaim Plaintiff Dr. Kenneth Stoller is a physician who used genetic testing to identify children at heightened risk of adverse vaccine reactions and adjusted their vaccination protocols accordingly. His license was revoked for deviating from ACIP guidelines. Thomas Compl. ¶¶ 21–30. If the prior schedule is restored, the clinical approach for which both Dr. Thomas and Dr. Stoller lost their licenses will once again constitute professional misconduct.

Counterclaim Defendants

65. Counterclaim Defendant American Academy of Pediatrics ("AAP") is a nonprofit corporation headquartered in Itasca, Illinois, with an office in the District of Columbia. AAP generates $115–125 million in annual revenue and represents approximately 67,000 pediatricians. AAP publishes the Red Book ($175/copy), which it markets as "the authoritative guide" to pediatric infectious diseases. AAP operates HealthyChildren.org, a consumer-facing health information portal.

66. Counterclaim Defendant Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP") represents over 1,600 pediatricians in Massachusetts and is the conduit through which AAP's national guidelines become the operative standard of care in this judicial district.

67. Counterclaim Defendant Infectious Diseases Society of America ("IDSA") represents over 13,000 infectious disease specialists. IDSA members serve on ACIP and its Work Groups and co-develop the recommendations that form the basis of the childhood immunization schedule.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTERCLAIMS

A. The Foundational Fraud: Theory Substituted for Testing

68. The childhood vaccine schedule expanded from 11 doses targeting four diseases in 1983 to over 72 doses targeting 18 diseases. This expansion dramatically accelerated after the National Childhood Vaccine Injury Act of 1986 granted manufacturers immunity from liability.

69. In January 2002, AAP published in its journal *Pediatrics* an article by Paul A. Offit, M.D., FAAP, a member of AAP's Committee on Infectious Diseases, claiming that infants could "theoretically" 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.

70. Parents were asking a toxicological question: Is it safe to inject my infant with multiple vaccines containing aluminum adjuvants, thimerosal, formaldehyde, polysorbate 80, residual DNA fragments, and other components? Offit answered a different question—an immunological one about whether the immune system could theoretically generate antibody responses. His calculation said nothing about cumulative aluminum dose, mercury toxicokinetics, synergistic adjuvant effects, neuroinflammation, autoimmune activation, or any clinical safety endpoint.

71. The misdirection created a framework that foreclosed the safety question. Under Offit's paradigm, concerns about cumulative vaccine load became anti-science. Questioning the schedule was no longer a scientific inquiry to be resolved by evidence—it was a failure to understand basic immunology. The contraindication framework, already narrow before 2002, became locked in for 72+ doses.

72. AAP distributed this paradigm through its 67,000-member network. Pediatricians learned to cite the 10,000 vaccines figure when parents expressed concern. The Red Book incorporated it. HealthyChildren.org repeated it. Board certification and continuing medical education reinforced it.

B. The IOM Recommendations: Open the Filing Cabinet

73. One month after Offit's article, the IOM found that no study had compared health outcomes between vaccinated and unvaccinated children and recommended such studies. IOM, *Immunization Safety Review: Multiple Immunizations and Immune Dysfunction* (2002), at 14–15, 107–08. The IOM specifically told CDC to use the VSD—a database containing health records for millions of children—to conduct these studies without withholding vaccines from anyone.

74. In 2013, the IOM returned and found the filing cabinet remained unopened: "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.

75. When pressed to explain why, Offit argued it would be "unethical" to conduct placebo-controlled trials withholding vaccines from children—an objection to a recommendation the IOM never made. By conflating database analysis with randomized trials, Offit made an easy study sound impossible and an ethical study sound unethical. Twenty-four years later, the filing cabinet remains unopened.

C. The Suppressed Studies Show the Harm

76. Independent researchers worldwide have conducted comparative analyses consistently finding concerning health outcomes associated with the cumulative vaccine schedule.

These include Jablonowski & Hooker (2025), analyzing Louisiana infant deaths, finding 68% higher mortality for infants vaccinated at two months and 112% higher mortality for female infants.

77. Military medicine has recognized what AAP denies. The U.S. Marine Corps limits healthy adults selected for physical resilience to five vaccines in one sitting. Infants face no limit whatsoever—because the Offit paradigm declares their immune systems can theoretically handle 10,000.

D. The Financial Architecture

78. Vaccine manufacturers have systematically acquired companies developing treatments for conditions listed as adverse events in their own vaccine package inserts (or developed drugs through their R&D processes). Pfizer acquired Anacor (pediatric eczema, $5.2B). Sanofi acquired Principia Biopharma (immune thrombocytopenia, $3.7B). GSK acquired Human Genome Sciences (lupus, $3.6B). Merck acquired Pandion Therapeutics (IBD, $1.85B). These acquisitions create a closed-loop revenue system.

79. AAP ensures this revenue continues. Vaccine administration is essential revenue for pediatric practices: administration fees, performance bonuses, bundled well-child visits. Major insurers enforce the schedule through incentive programs. AAP acknowledges these financial dependencies while publicly denying that pediatricians profit from vaccines.

E. The Enforcement Mechanisms: How the Schedule Was Maintained

80. The childhood immunization schedule was not maintained by scientific consensus. It was maintained by an interlocking set of enforcement mechanisms — intellectual, financial,

logistical, and professional — each of which Plaintiffs' own declarants have now described under oath.

81. The intellectual enforcement mechanism was the GRADE framework. GRADE evaluates individual interventions against individual endpoints using randomized controlled trial data. It has no methodology for evaluating a cumulative protocol. Because GRADE governed all ACIP deliberations for two decades (Ex. 36, Pavia Decl.; Ex. 30, Boyce Decl.; Ex. 35, Goldman Decl.), the IOM's recommendation to study the cumulative schedule could never enter the analytical framework. The question was not suppressed by fiat. It was suppressed by architecture: GRADE made the question unaskable within the only institution authorized to ask it.

82. The financial enforcement mechanism was the quality metric system. HEDIS vaccination measures and pay-for-performance targets rewarded physicians for achieving schedule compliance rates and penalized deviation. (Ex. 46, Srinivas Decl.) A physician who engaged in genuine informed consent — spending twenty minutes discussing risks and ultimately respecting a parent's decision to defer — was penalized twice: unbillable time and a missed quality target. The metrics measured compliance, not care.

83. The logistical enforcement mechanism was the VFC/pharmacy supply chain. VFC conditioned federal funding on following the CDC schedule. Pharmacies stocked what VFC covered. Practices ordered what pharmacies stocked. Parents received what practices ordered. (Ex. 31, Berman Decl.; Ex. 27, Kressly Decl.) No actor exercised independent clinical judgment. Each followed the signal from the level above, and the signal originated with AAP's recommendations.

84. The product enforcement mechanism was the combination vaccine. Products like VAXELIS and PEDIARIX bundle multiple antigens into a single injection that cannot be unbundled. (Ex. 43, Bornstein Decl.) A physician who stocks a hexavalent vaccine must administer all six antigens or none. The product architecture eliminated clinical discretion at the point of care. When the schedule changed and the bundles could no longer be administered as designed, the "waste" was not caused by the government. It was caused by products designed to prevent the very flexibility the new schedule introduced.

85. The professional enforcement mechanism was the medical board disciplinary system. Physicians who deviated from the schedule — whether by recommending alternative schedules, expressing concerns about cumulative safety, or supporting parental choice — faced investigation, suspension, or license revocation. Dr. Paul Thomas, a board-certified pediatrician in Oregon and a Counterclaim Plaintiff herein, had his medical license suspended by the Oregon Medical Board after publishing a peer-reviewed study comparing health outcomes between vaccinated and unvaccinated children in his practice — a study that attempted to answer the very question the IOM recommended. Dr. Kenneth Stoller, also a Counterclaim Plaintiff herein, faced medical board discipline for exercising the individualized clinical judgment that SCDM now requires. These are not hypothetical risks. They are documented consequences, inflicted on physicians who tried to do what the IOM said needed doing, by a system that punished the question rather than answer it.

86. These mechanisms operated in concert. GRADE prevented the question from being asked. Quality metrics prevented the answer from being sought. VFC prevented the supply chain from accommodating alternatives. Combination products prevented clinical

discretion at the point of care. Medical boards punished anyone who tried to exercise it anyway. The result was a system that appeared to reflect scientific consensus but in fact reflected structural coercion — a distinction that Plaintiffs' own declarations have now made visible.

F. AAP as Distribution Network: The Red Book as Rulebook

87. AAP controls pediatric medicine. Its Red Book defines the standard of care. Through the *Brentwood* delegation mechanism, AAP's recommendations have been adopted by at least 28 states as regulatory standards. The Association of State and Territorial Health Officials documented approximately 600 statutes across 49 states that automatically incorporate ACIP recommendations—recommendations that AAP historically co-developed. This transforms AAP's private guidelines into state action under *Brentwood Academy v. Tennessee Secondary School Athletic Ass'n*, 531 U.S. 288 (2001).

88. Physicians who deviate face medical board discipline, loss of hospital privileges, exclusion from insurance networks, and professional destruction. The message is clear: follow AAP's script or lose your livelihood.

G. The Families

89. 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." The emergency room diagnosis was "post-

immunization reaction." A homicide investigation was opened targeting the mother. Shaw Compl. ¶¶ 16–21.

90. 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. Ms. Nelson expressed concern. 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. The death certificate listed the cause as Sudden Unexplained Death in Childhood. Shaw Compl. ¶¶ 22–27.

91. These families trusted the protocol. They followed the recommendations. They did everything AAP told them to do. Their children died under the schedule Plaintiffs seek to restore.

H. The California/Massachusetts Comparison

92. AAP filed this action in the District of Massachusetts, asking the Court to restore a schedule recommending vaccines for 18 diseases. Massachusetts requires only 9 diseases for grades K–6. California requires only 10, with the strictest mandate in the nation. The new CDC schedule recommends 11.

93. AAP has never sued California. AAP has never called Massachusetts' schedule dangerous. If recommending fewer vaccines than 18 were dangerous, California and Massachusetts would be in crisis. They are not. Vaccination rates exceed 95% in both states. AAP's alarm is pretextual. The concern is not public health—it is revenue.

COUNTERCLAIM I

DECLARATORY JUDGMENT — CUMULATIVE CHILDHOOD SCHEDULE SAFETY
(Against AAP, MCAAP, IDSA)

94. Counterclaim Plaintiffs reallege and incorporate by reference the preceding paragraphs.

95. An actual controversy exists between the parties within the meaning of 28 U.S.C. §§ 2201–2202. AAP alleges in Paragraph 34 of its Fourth Amended Complaint that vaccine safety is "rigorously tested." Counterclaim Plaintiffs contend this representation is materially misleading because the cumulative childhood immunization schedule has never been tested for safety.

96. The IOM found in 2002 that no study had compared health outcomes between children receiving the full schedule and those who did not, and recommended such studies. In 2013, the IOM found these studies had not been conducted. As of this filing, no such study has been produced.

97. Counterclaim Plaintiffs seek a declaration that: (a) no study has established the cumulative safety of the childhood immunization schedule as administered; (b) the IOM recommended such studies in 2002 and 2013; and (c) those studies have not been conducted.

COUNTERCLAIM II

FALSE ADVERTISING UNDER THE LANHAM ACT, 15 U.S.C. § 1125(a)
(Against AAP)

98. Counterclaim Plaintiffs reallege and incorporate by reference the preceding paragraphs.

99. AAP has made and continues to make false or misleading representations of fact in commercial advertising and promotion, in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). These include: (a) that the childhood immunization schedule is

"fully tested and proven safe"; (b) that infants can "theoretically respond to 10,000 vaccines at once"; and (c) that "Vaccines are not associated with autism or developmental delay," when the IOM found evidence "inadequate to accept or reject a causal relationship."

100. These representations appear in commercial products: the Red Book ($175), HealthyChildren.org, CME programs, and annual conferences generating pharmaceutical exhibitor revenue. They constitute commercial advertising and promotion.

101. CHD is a direct market competitor, publishing books on vaccine safety, producing The Defender, operating CHD.TV, and conducting educational seminars—all in the same market for vaccine-related health information. AAP's false representations suppress demand for CHD's competing content and damage CHD's credibility. CHD has standing under *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014).

102. Most recently, following the January 5, 2026 schedule change, AAP published the "AAP Harmonized Schedule" as a commercial alternative to the new CDC schedule, directing its 67,000 members to follow AAP's version and distributing it through the Red Book, HealthyChildren.org, and state chapter networks. The Harmonized Schedule repeats the same unqualified safety representations that underlie the prior schedule — representations the IOM found unsupported — and constitutes the most recent act of false advertising in the pattern of commercial misrepresentation alleged herein.

103. Counterclaim Plaintiffs seek injunctive relief under 15 U.S.C. § 1116: AAP must either produce the cumulative safety study or cease making unqualified safety claims in its commercial publications, and provide corrective disclosure in the Red Book and on HealthyChildren.org.

COUNTERCLAIM III

42 U.S.C. § 1983 — COMPELLED SPEECH (FIRST AMENDMENT)
(Against AAP, MCAAP)

104. Counterclaim Plaintiffs reallege and incorporate by reference the preceding paragraphs.

105. Through the *Brentwood* delegation mechanism, AAP's recommendations have been adopted by at least 28 states as the operative standard of care. This transforms AAP's private guidelines into state action under *Brentwood Academy v. Tennessee Secondary School Athletic Ass'n*, 531 U.S. 288 (2001).

106. Physicians who deviate face state-imposed consequences: medical board investigation, suspension, or revocation; loss of hospital privileges; exclusion from insurance networks; and professional destruction.

107. Under *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018), the government cannot compel professionals to deliver a misleading state-scripted message. Counterclaim Plaintiffs Dr. Thomas and Dr. Stoller were compelled to deliver AAP's safety assurances—that the schedule is "rigorously tested," that infants can handle 10,000 vaccines—or face professional consequences. These assurances are unsupported. Both lost their licenses for refusing to deliver them.

108. Counterclaim Plaintiffs seek a declaration that AAP's guidelines, as enforced through state action, compel physician speech in violation of the First Amendment, and an injunction prohibiting such enforcement.

COUNTERCLAIM IV

42 U.S.C. § 1983 — LISTENER'S RIGHTS (FIRST AMENDMENT)
(Against AAP, MCAAP)

109. Counterclaim Plaintiffs reallege and incorporate by reference the preceding paragraphs.

110. Under *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council*, 425 U.S. 748 (1976), the First Amendment protects the right to receive information. Counterclaim Plaintiffs Andrea Shaw, Shanticia Nelson, and CHD's community members have a constitutional right to receive truthful medical information about the vaccines administered to their children.

111. AAP's monopoly on the pediatric information channel—67,000 members who deliver AAP's message or face professional destruction—deprives families of the honest disclosure required for informed consent. Andrea Shaw's and Shanticia Nelson's children were vaccinated based on safety assurances that omitted material facts: that the cumulative schedule had never been tested, that the IOM recommended studies were never conducted, and that AAP's expert substituted theory for evidence.

112. Counterclaim Plaintiffs seek a declaration that AAP's control of medical communication, as enforced through state action, violates the First Amendment rights of families to receive truthful information, and an injunction requiring that physicians be permitted to disclose the IOM findings and the limitations of the evidence without professional penalty.

PRAYER FOR RELIEF

WHEREFORE, Intervenors/Counterclaim Plaintiffs respectfully request that the Court:

A. Deny the Plaintiffs' claims for relief in their entirety.

B. Declare that no study has established the cumulative safety of the childhood immunization schedule as administered to American children, and that the Institute of

Medicine recommended such studies in 2002 and 2013 and they have not been conducted;

C. Enjoin AAP from representing in commercial publications that the cumulative childhood immunization schedule has been "rigorously tested" or "proven safe" unless and until such testing has been conducted, or require corrective disclosure;

D. Enjoin the enforcement of AAP guidelines through state action insofar as such enforcement compels physicians to deliver unqualified safety assurances about a schedule that has never been cumulatively tested;

E. Declare that families have a First Amendment right to receive truthful information about the limitations of the cumulative safety evidence and that AAP's control of the medical information channel violates that right;

F. Award Counterclaim Plaintiffs their reasonable attorneys' fees and costs pursuant to 15 U.S.C. § 1117 and 42 U.S.C. § 1988; and

G. Grant such other and further relief as the Court deems just and proper.

Dated February 18, 2026

Respectfully submitted,

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